AMA
AMERICAN MEDICAL ASSOCIATION

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

Re: Center for Program Integrity Request for Information on the Future of Program Integrity

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity's Request for Information on the Future of 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. 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.

Questions on Program Integrity for Value Based Payment Programs

- *What does program integrity look like in a value-based world?*

Value-based care can provide significant opportunities for physicians to improve the quality and outcomes of their patients' care in ways that also lower growth in Medicare and Medicaid spending. Many patients develop health problems that could have been prevented, receive duplicate tests and procedures due to lack of care coordination, are hospitalized because their health problems were not effectively managed, or experience complications and infections that could have been avoided. Other patients could receive different types of treatment than they do today, or be treated in different sites of service, that would be equally effective but cost less. If these avoidable health problems, services, and costs could be eliminated, billions of dollars could be saved and patients' quality of life improved. It is critical that physicians be involved in designing value-based arrangements because only physicians can ensure that alternative ways of delivering services will safely and appropriately address patient needs and not produce savings by delivering lower quality care.

CMS needs to recognize and become comfortable with value-based payments being fundamentally different than fee-for-service (FFS). Rather than having a ledger system where each fee has a corresponding service, value-based care may have a single payment that covers multiple services. Moreover, program integrity requirements in a value-based world should: (1) not cause unnecessary, additional administrative burden just because the program is new or unknown and (2) not create a program integrity regime that repeats the administrative burdens caused by program integrity requirements of FFS. Prior authorization, certification, documentation and reporting requirements, and electronic health record systems that do more to hinder than support patient care are enormously burdensome. For example, certification requirements create an unnecessary barrier for diabetic patients attempting to obtain the shoes prescribed by their endocrinologists.

Accordingly, CMS should not include new program integrity requirements in value-based care unless it can be shown that they are essential and supported by data analytics. Before any program integrity requirement is imposed, current and potential participants in a value-based arrangement should be given the opportunity to suggest less burdensome approaches to achieving the same goal, and then the value-based arrangement should provide participants with adequate resources to cover the costs of implementing any requirements. At a minimum, CMS should provide additional resources and technical assistance to ensure practices of all sizes and specialties are able to participate in value-based arrangements.

The AMA understands that program integrity for value-based arrangements may open questions about what type of data CMS or other payers need. That said, the AMA urges that proper protections may need to be put in place to prevent payers from unnecessarily requesting bulk data. Specialty societies should be able to provide input on data elements needed for quality measures and to ensure appropriate care. We are concerned that program integrity in value-based care could lead to massive and unnecessary data requests.

With value-based arrangements, CMS also could use claims data to identify aberrant claims, cross reference such claims with other data sets to recognize potentially fraudulent or abusive activity by physicians, and work with the Office of Inspector General to develop fraud risk scores. These types of comparisons need to take subspecialization and patient mix into account. When a physician is identified based on aberrant behavior or if an audit identifies potential errors, CMS should work with the provider to understand the reasons why the provider was identified, and if there are problems, CMS should educate the provider or take other appropriate, corrective actions. The goal should not be to punish physicians for billing errors or technical flaws.

Operating under a Model

CMS does not need to layer any additional program integrity requirements upon models. The participation agreements already have many program integrity safeguards, including transparency of data and monitoring for indicators of abuse or gaming. The very design of the waivers is premised on the expectation that the requirements of the Participation Agreement promote program integrity and mitigate risks of fraud and abuse. For example, Participation Agreements generally require participant screening by CMS for program integrity issues prior to and during program participation; certification of completeness, truthfulness, and accuracy of virtually all data generated and submitted to CMS; patient protections including notice and freedom of choice; a compliance program with reporting of any probable violation of fraud; and enhanced CMS monitoring through identification of all participants, site visits, and multi-year maintenance of record provisions. Thus, program integrity is already layered on top of every

model and provides greater assurance of program compliance and monitoring capabilities than providers operating outside of the models.

Testing a Program Integrity Model

CMS may also want to consider creating a new program integrity model based on provider screening to identify physicians and providers who are already in compliance with all program requirements. Once the providers have passed this check and agreed to certain program integrity measures in a participation agreement, the providers operating under the model could be allowed to provide innovative and cost-saving care for specified services with certain fraud and abuse waivers. Similar to the Transportation Security Administration Pre-check program for air transportation, physicians in this model would have more flexibility in their use of waivers than those who have not gone through the pre-screening process. This screening should be focused on how providers are already preventing and monitoring for fraud, waste, and abuse, and corrective actions could include an appropriate compliance program based on the provider's resources and size.

Provide Data to Physicians

CMS needs to provide data to physicians to help promote the economy, efficiency, and effectiveness of value-based care. CMS needs to create more effective and user-friendly mechanisms through which physicians can access and analyze CMS claims data and provide financial support to physicians to help them gather and analyze relevant clinical data that is not contained within claims data.

One of the greatest barriers physicians face in designing and implementing new approaches to care delivery and payment that will reduce Medicare spending is their inability to obtain data on the full range of services their patients are receiving today. Most of the savings from improved care delivery come from lower spending on services such as hospital admissions and post-acute care that are not delivered directly by physicians, and some of the biggest opportunities for improved care coordination come from avoiding duplication and conflicts with services delivered by other providers. Too often, physicians do not have access to information about the other services their patients are receiving that would enable them to identify and quantify opportunities for savings or take action to achieve these savings.

Alternative Payment Model (APM) developers also need assistance with technical issues such as risk stratifying patients and risk adjusting payments. The risk adjustment methodologies used in the Medicare and Medicaid programs to date are designed to address differences in patient needs among large populations associated with a health plan or hospital. These methods cannot be appropriately transferred for use in risk adjusting payments associated with medical practices or with a particular condition. Current risk adjustment methods, for example, do not take into account patients' stage of disease, functional status, whether they have a caregiver at home, and social factors. Factors like these can have a significant effect on treatment plans, adherence, patient outcomes, and health care costs, but it is expensive and time-consuming for physician practices to collect these data, particularly given the limitations of current electronic health record (EHR) systems.

We recommend that CMS seek information from specialty societies about the specific types of services where appropriately-designed APMs could achieve savings. CMS should then create mechanisms for providing Medicare claims data and analyses regarding those services to physicians in that specialty who

are developing APMs. CMS should also compensate physician practices that are willing to collect the types of data that would help in the design of better risk adjustment methods that can be used for APMs.

Quality Payment Program (QPP)

CMS should consider its program integrity approach to value-based arrangements in context of the QPP, including both the Merit-based Incentive Payment System (MIPS) and APMs. While we are beginning to see some progress toward creating more harmony between MIPS and APMs in the MIPS Value Pathways (MVP), most physicians have limited opportunities to pilot test or gain experience with value-based payment arrangements before taking on investment, operational, and financial risk in an Advanced APM. One barrier is the fraud and abuse regulations that were implemented prior to the QPP. CMS should consider modifying its program integrity approach to reflect the entire spectrum of value-based care, from MIPS to an MVP to an APM to an Advanced APM, to allow physicians flexibility to improve care and increase efficiencies while participating in the QPP.

MIPS Value Pathways (MVPs)

Although CMS has only proposed a high-level framework for this new approach in MIPS and the AMA has expressed several concerns about its design including opposition to it being mandatory, we see potential for MVPs to resolve barriers in the QPP that prevent clinicians from participation. If properly implemented, MVPs have the potential to hold clinicians responsible for those aspects of utilization/spending and quality that they control for a specific condition, procedure, or public health priority. The ultimate goal of MVPs should be to make MIPS more cohesive, more clinically relevant and reduce the program integrity-based reporting requirements by tying the program's metrics and MIPS payment adjustments to episodes of care that clinicians manage.

MVPs should strike a middle ground between MIPS and APMs and give physicians an opportunity to take on accountability for cost and quality of a specific condition or procedure. However, to be successful, CMS will need to consider MVP proposals from specialty societies and other stakeholders that include more flexibility to improve value for the patient population. For example, the specialty society or other stakeholder group proposing that management of a condition be eligible for the MVP track of MIPS could propose certain payment changes to support improvements needed to care for this condition, such as being able to bill for Chronic Care Management for patients with the condition even if they do not have two or more chronic conditions, or paying for Collaborative Care to help support team-based approaches to managing patient care. Although MVP clinicians would not be subject to the two-sided risk requirements of Advanced APMs, the MIPS measures of cost and quality for the episode and MIPS payment adjustments will serve to hold them accountable in a similar manner to APM participants.

Virtual Groups

The AMA has consistently supported the ability for small groups and solo practitioners to form virtual groups, and has encouraged CMS to maintain maximum flexibility in the formation of virtual groups. Despite CMS' previous proposals that have allowed for flexibility in the formation of virtual groups, the AMA remains concerned that a greater number of physicians are not choosing this reporting option. Given the small number of virtual groups that we believe chose to participate in the MIPS program, the AMA believes CMS must continue to make changes to make this a viable option for physicians in small practices including making changes from a program integrity perspective.

One key change to promote participation in virtual groups is to provide protection from Stark and Anti-Kickback Violations. Many solo practitioners and groups of 10 or fewer MIPS eligible clinicians have limited resources and technical capabilities. Virtual groups will involve preparation of health IT systems and training staff to be ready for implementation, sharing and aggregating data, and coordinating workflows. While these are necessary steps to ensure the success of virtual groups, these steps could raise concerns involving fraud and abuse. For example, the Stark law (physician self-referral statute) does not allow a physician to refer patients to an entity that the physician has a financial relationship with and the anti-kickback statute prohibits the exchange of anything of value in an effort to induce the referral of Medicare patients. By pooling resources together to participate in MIPS, individual physicians may receive an ownership interest in the virtual group or other compensation arrangement from the virtual group (e.g., disbursement of any incentive payments). Moreover, physicians may prefer to refer patients within their own virtual group to control unnecessary costs and provide higher quality care because both physicians' performance is tied to the same virtual group's MIPS score. Any of these referrals within the virtual group between physicians could violate Stark and potentially implicate anti-kickback. This outcome is different from a normal "group practice" where these referrals are protected from Stark and Anti-Kickback violations through exceptions and safe harbors.

Virtual groups, by definition, are not "group practices" as that term is specifically defined under the Stark regulations at 42 CFR §411.352 because virtual groups do not constitute a "single legal entity." Virtual groups consist of at least two legal entities. Thus, because virtual groups do not meet this definition, the Stark in-office ancillary services exception and the physician services exception do not apply. Furthermore, the anti-kickback safe harbor for investments in group practices also does not apply. Accordingly, physicians in a virtual group with a financial relationship with such virtual group may not be eligible to make referrals for designated health services payable by Medicare to the virtual group.

A potential solution is to amend 42 CFR §411.352 (Group Practice) by adding an additional subsection (j) stating something like "notwithstanding the above, a virtual group (as defined by 42 CFR §414.1305) is considered a group practice for the purposes of this subpart." While this solution will allow virtual groups to operate in the same manner as group practices, the AMA is also encouraging changes under the Stark law and Anti-kickback statute to allow both virtual groups and group practices to be successful as the health care system transitions to more value-based care models.

MIPS Audits

The AMA urges CMS to carefully evaluate the burden of complying with the MIPS audits, particularly considering the onerous cost to participate in MIPS overall. Requests for medical records and other documentation will add to the administrative burden of participating in MIPS. Additionally, this will be a significant burden on small practices who do not have staff to pull chart requests or other documentation, and we think they should be given additional assistance and time to respond to the audit request. We offer the following recommendations to improve the MIPS audits:

- The AMA urges CMS to audit the vendors rather than increasing the burden of MIPS on physicians and practices.
- We urge CMS to support small and rural practices by providing them with additional assistance if selected for an audit.

- Finally, it would be helpful if CMS publicly posted a copy of the audit request letter so practices, state, and national medical specialty societies have more clarification of what is expected of them in order to be successful in responding to the audit.

Moving Beyond FFS

Many of the value-based arrangements currently managed by CMS are largely FFS-based approaches. Accountable Care Organization (ACO) participants, for example, are still paid based on Medicare FFS payment schedules for hospitals and physicians, but the ACO has some ability to also earn shared savings or may be required to pay CMS for shared losses. If and when CMS implements arrangements that involve bundled payments for episodes of care, however, the program integrity issues will be different than those under FFS. The main concern in a bundled payment or capitation arrangement should be the potential for patients to be undertreated. Any model that allows participants to keep the money that they do not use to provide health care services has the potential to lead to unethical participants providing fewer services than patients need. To prevent this from occurring, CMS should require organizations participating in value-based arrangements that rely on bundled or capitation payments to have quality measures as part of the model that will ensure that participants are meeting professionally developed standards of high-quality care for the episodes that they are accountable for under the model. CMS should also ensure that there is sufficient participation by and access to the various physician specialties and other health professionals that would need to be included in the organization's network in order to provide high-quality management of the episodes of care included in the model.

CMS needs to also recognize that while concerns are raised about lemon-dropping or cherry-picking patients. In one study of large physician practices, those practices that served more socially high-risk patients had lower quality and lower costs, and practices that served more medically high-risk patients had lower quality and higher costs.[1] These patterns were associated with fewer bonuses and more penalties for high-risk practices. As value-based payment programs continue to increase in size and scope, practices that disproportionately serve high-risk patients may be at particular risk of receiving financial penalties. Moreover, physicians do not dismiss patients and limit their practice to those for whom they can readily demonstrate value to maximize revenue in a value-based payment system.[2]

Medicare Advantage

- *What specific changes should CMS consider as part of its program integrity strategy to fight fraud, waste and abuse related to the Medicare Advantage program?*

Increase Medical Record Review of Preauthorization Denials

CMS should consider conducting medical record review to determine the extent to which beneficiaries and providers were denied preauthorization or payment for medically necessary services covered by Medicare. Capitated payment models are based on payment per person rather than payment per service provided. A central concern about the capitated payment model used in Medicare Advantage (MA) is the

[1] Chen LM, Epstein AM, Orav EJ, Filice CE, Samson LW, Joynt Maddox KE. Association of Practice-Level Social and Medical Risk With Performance in the Medicare Physician Value-Based Payment Modifier Program. JAMA. 2017;318(5):453–461, https://doi.org/10.1001/jama.2017.9643.

[2] O'Malley AS, Swankoski K, Peikes D, et al. Patient Dismissal by Primary Care Practices. JAMA Intern Med. 2017;177(7):1048–1050, https://doi.org/10.1001/jamainternmed.2017.1309.

incentive to inappropriately deny access to, or reimbursement for, health care services in an attempt to increase profits for managed care plans.

When beneficiaries and providers appealed preauthorization and payment denials, MA plans overturned 75 percent of their own denials during 2014-16, overturning approximately 216,000 denials each year. During the same period, independent reviewers at higher levels of the appeals process overturned additional denials in favor of beneficiaries and providers. The high number of overturned denials raises concerns that some MA beneficiaries and providers were initially denied services and payments that should have been provided. This is especially concerning because beneficiaries and providers rarely used the appeals process, which is designed to ensure access to care and payment. During 2014-16, beneficiaries and providers appealed only 1% of denials to the first level of appeal.

CMS audits highlight widespread and persistent MA plan performance problems related to denials of care and payment. For example, in 2015, CMS cited 56 percent of audited contracts for making inappropriate denials. CMS also cited 45 percent of contracts for sending denial letters with incomplete or incorrect information, which may inhibit beneficiaries and providers ability to file a successful appeal. In response to these audit findings, CMS took enforcement actions against MA plans, including issuing penalties and imposing sanctions. Because CMS continues to see the same types of violations in its audits of different MA plans every year, however, more action is needed to address these critical issues.

Focus MA Star Ratings on Assessing Health Plans

As the Star Ratings program has expanded and plays a larger financial role on health plans' bottom lines, the administrative demand has simultaneously increased on physicians and is impeding clinical care and thus does not provide a beneficiary benefit. A large percentage of the measures within the MA Star Ratings program are based completely on physician action, compliance and communication. For health plans to increase their Healthcare Effectiveness Data and Information Set (HEDIS) scores and earn greater incentives from CMS, plans are requiring practices as part of their clinical data submission requirements to submit data on all patient lab results and tests and the plans state it is due to the Star Ratings HEDIS requirements. Many of the measures, particularly the HEDIS Effectiveness of Care measures, have more to do with physician quality than assessment of a health plan. The Effectiveness of Care measures are really targeting clinical quality, which is a physician or facility issue—and therefore physicians and facilities have the data. In addition, the patient experience ratings are heavily based on Health-Plan, Consumer Assessment of Healthcare Providers & Systems (CAHPS) that focus on physician communication and behavior. While communication between a physician and patient is important, asking the questions in a de-identified survey does not lead to quality improvement or address potential challenges patients experience when seeking care. Similar questions are also in the hospital and clinician-group CAHPS survey and the more appropriate avenues for addressing provider communication in the context of patient experience. Without a better focus, the MA ratings program is just one more burden on physicians and does not provide beneficiaries with the information they need to determine the most appropriate and high-quality MA or drug plan.

Recommendations:

- CMS should refine Star Ratings to better measure the quality of plans and things over which the plan has control and the supporting data (e.g., access);

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

Streamline Data Requests that Support MA Risk Adjustment Scores

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

To remove waste and administrative burden, the AMA recommends:

- CMS should accept physician attestations to support MA beneficiaries' diagnoses instead of requiring documentation from medical records;
- Once beneficiaries have been diagnosed with a permanent condition (e.g., multiple sclerosis, quadriplegia, arthritis), this diagnosis should follow them from year-to-year and not have to be re-designated each year;
- 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, and
- Are there lessons from program integrity programs implemented by managed care plans under the Medicare Advantage program that CMS should consider?

Despite the fact that Medicare Advantage plans have the flexibility to pay physicians differently, most of them pay physicians and other providers using standard FFS systems. When they do implement APMs, they often use different quality measures, attribution systems, risk adjustment formulas, and other components than other payers do, which increases administrative burdens for physicians. Although CMS has tried to encourage multi-payer participation in some of its APMs by selecting states and regions

where payers other than CMS are willing to participate, this makes it impossible for physicians to participate in a CMS APM if they are located in a region with high MA penetration where the MA plans are unwilling to participate. We recommend that CMS reverse the approach—it should allow willing physicians to participate in an innovative APM even if only Medicare patients participate in it, but then both CMS and the participating physicians should encourage Medicare patients to choose a health plan (whether it be an MA plan or traditional Medicare) that pays physicians using an APM that supports effective care.

Prior Authorization in Medicare FFS

The AMA understands there may be a role for prior authorization in health care, including FFS Medicare, but we believe it must be right-sized and used judiciously. Any prior authorization program applied to a service, device, or drug should be based on accurate and up-to-date clinical criteria and never cost alone.

Our principal concern is the potential effect on Medicare beneficiaries' ability to receive quality, timely care. These tools create significant treatment barriers by delaying the start or continuation of necessary treatment, which may in turn adversely affect patient health outcomes. The results of the 2018 AMA Prior Authorization Physician Survey of 1,000 practicing physicians detail the impact of prior authorization on care delivery.[3] As detailed in the survey summary, 65 percent of surveyed physicians reported waiting at least one business day for prior authorization decisions from health plans, while 26 percent reported waiting at least three business days. Unsurprisingly, 91 percent of physicians said that prior authorization can delay access to necessary care. These delays may have serious implications for patients and their health, as 75 percent of physicians reported that prior authorization can lead to treatment abandonment, and 91 percent indicated that prior authorization can have a negative impact on patient clinical outcomes. Most alarming, 28 percent of physicians report that prior authorization has led to a serious adverse event (e.g., hospitalization, disability, death) for a patient in their care. We believe that these statistics suggest the potential for new Medicare utilization management requirements to result in significant patient burdens and harms. Beyond the obvious negative impact in human terms, beneficiaries who deteriorate clinically due to prior authorization-related care delays would likely incur greater health care costs, meaning that this program could have the unintended consequence of raising overall Medicare expenditures.

The AMA's survey results also detail the existing administrative burdens associated with prior authorization. Practices report completing an average of 31 prior authorizations per physician per week, with this workload consuming 14.9 hours—nearly two business days—of physician and staff time. Moreover, over one-third (36 percent) of physicians employ staff who work exclusively on prior authorization. An overwhelming majority (86 percent) of physicians characterized prior authorization-related burdens as high or extremely high. Moreover, prior authorization hassles have been growing over time, with 88 percent of physicians reporting that prior authorization burdens have increased over the past five years. These data reflect the significant administrative costs associated with practices' current prior authorization workload. We are very concerned that the creation of new prior authorization requirements in the Medicare FFS program could lead to substantial growth in these burdens that already challenge the limited resources of financially strapped smaller physician groups. Furthermore, the utilization management tools are unnecessary because physicians already have ample incentives to reduce unnecessary services under the QPP.

[3] 2018 AMA Prior Authorization Physician Survey, https://www.ama-assn.org/media/42426/download.

Because of the potential negative impact of prior authorization on both patient clinical outcomes and physician practice burdens, we urge CMS to use a targeted, selective approach when considering instituting new requirements in the Medicare FFS program. Specifically, prior authorization should be limited to (a) only those providers with ordering patterns that consistently and significantly differ from same specialty or subspecialty peers and/or (b) those services that show significant variation in utilization across Medicare providers. This focused approach will ensure that Medicare is investing administrative dollars in only those prior authorizations that offer potential value to the program vs. employing a broad-based approach that will increase burdens and costs for both physicians and CMS.

- *What program integrity activities should CMS consider to ensure that items or services are provided as approved through the prior authorization process?*

Inappropriate Use of Prior Authorization as Fraud Deterrent

CMS has identified fraud deterrence as the primary reason for expanding use of prior authorization in the Medicare FFS program. Health plans traditionally use prior authorization to ensure that services are appropriate and medically necessary for a particular patient, not to identify and address fraudulent billing. CMS already devotes significant resources specifically to eliminating fraud, and it is unclear what additional value prior authorization will bring to CMS' fraud detection program. More importantly, it is unlikely that prior authorization will eliminate criminal activity in the Medicare program, as a fraudster masquerading a service as therapeutically necessary in claims billing would be equally inclined and capable of doing so through the prior authorization process. Rather than serving as an effective fraud deterrent, it is far more likely that implementing prior authorization in the Medicare FFS program will create a barrier to timely, medically necessary patient care.

- *Can clinical decision support tools play a role in prior authorization? If yes, how?*

Prior authorization requirements are a burdensome way of confirming clinically appropriate care and managing utilization, adding administrative costs for all stakeholders across the health care system. Moreover, as stated previously, prior authorization can lead to significant delays in patient care, treatment abandonment, and negative clinical outcomes.

Clinical decision support (CDS) tools should be viewed as an alternative method of confirming that a service is medically necessary and clinically appropriate. In such cases, usage of CDS tools should be optional, and participation in a CDS tool program should exempt physicians from prior authorization, as completing both CDS and prior authorization protocols would be duplicative and waste valuable physician time. Additionally, CDS tools should be integrated into the EHR clinical workflow to promote increased efficiency. Of note, CDS tools that require the physician to exit the EHR, log in to a separate portal, and re-enter data from the EHR are essentially as burdensome as proprietary health plan web portals for prior authorization, which follow a similar disruptive workflow.

When considering use of CDS tools in lieu of prior authorization, the AMA recommends that:

- CDS tools should employ evidence-based appropriate use criteria and/or clinical guidelines, such as those developed by national medical specialty societies;
- The guidelines/criteria on which the CDS tools are based should be transparent and readily available to physician users;

- Physicians should be able to override the recommendation of the CDS tool based on the unique clinical needs of a particular patient; and
- Additional reporting requirements, such as inclusion of CDS consultation data on claims, should not be required with these tools, as this can significantly increase administrative burdens and complexities for physicians—especially when both ordering and rendering providers are involved in treatment.

- *How can we apply prior authorization without adding to provider and supplier burden? How can we apply prior authorization while maintaining timely and complete access to medically reasonable and necessary covered services for our beneficiaries?*

Over the last several years, the AMA and other physician organizations have repeatedly been asked by various congressional committees and executive agencies for suggestions on how Medicare's paperwork burden could be reduced. In response, virtually every physician group has identified prior authorization requirements as a serious burden that takes time away from patient care, delays treatment, and—in the most extreme cases—can lead to permanent impairment or even death. The AMA is encouraged by the discussions we are having with senior CMS leadership regarding prior authorization, and we urge it to lead by adopting the following principles, developed in consensus with other national provider associations and insurer trade organizations in 2018 (Consensus Statement on Improving the Prior Authorization Process),[4] into all of its prior authorization policies:

1. Selective application of prior authorization to only "outliers;"
2. Review/adjustment of prior authorization lists to remove services/drugs that represent low-value prior authorization;
3. Transparency of prior authorization requirements and their clinical basis to patients and physicians;
4. Protections of patient continuity of care; and
5. Automation to improve prior authorization and process efficiency.

Selective Application of Prior Authorization

The AMA supports the selective application of prior authorization requirements to outlier physicians whose ordering history routinely does not meet clinically based authorization criteria. Differentiating the application of prior authorization based on provider performance helps ensure that the requirements can be targeted where they will be impactful while reducing the administrative burden for compliant physicians. Criteria for selective application of prior authorization requirements may include, for example, ordering/prescribing patterns that align with evidence-based guidelines and historically high prior authorization approval rates. An example of such selective application of prior authorization is the process created under the CY 2020 Outpatient Prospective Payment System (OPPS) final rule that exempts providers who achieve an approval rate of at least 90 percent from prior authorization requirements for certain hospital outpatient procedures. Ideally, CMS would prospectively exempt physicians from any new prior authorization requirements prior to implementation by leveraging claims data to identify outliers. This would avoid unnecessarily burdening physicians who are following

[4] Consensus Statement on Improving the Prior Authorization Process, https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

evidence-base guidelines with completing prior authorizations until they establish an approval "track record" on which to base an exemption.

Avoidance/Elimination of Low-Value Prior Authorizations

Judicious application of prior authorization requirements also means that restrictions should only be placed on those services that show a consistent pattern of high variation in utilization and/or inappropriate use. The AMA urges CMS to use this targeted approach when considering new services on which to place authorization requirements to avoid unnecessarily delaying patient care and creating additional practice burdens. Limiting prior authorization to only those services with high variation in utilization patterns and/or inappropriate use will also ensure the best use of CMS' administrative dollars and prevent wasting significant resources on processing requests for services that are almost always approved and ordered appropriately.

Transparency in Prior Authorization Requirements, Documentation, and Denials

The AMA is concerned about the ability of physicians to easily determine any services newly requiring prior authorization under the Medicare FFS program, as it is currently difficult to clearly identify treatments needing these approvals, as well as other applicable coverage, coding, and payment rules. Indeed, in the AMA's survey, nearly seven in 10 physicians (69 percent) reported that it is difficult to determine whether a prescription or medical service requires prior authorization.[5] Individuals need to first understand the intricacies of CMS policies to even know where to find this information or to combine statements from multiple CMS manuals to attempt to find a potential answer for questions regarding payment and coverage. Unfortunately, no one set of rules exists that physicians can go to for clarity. Instead, physicians must navigate a patchwork of state and federal regulations and contractor-specific requirements that govern what information is necessary to support a service and who can perform elements of the service. Therefore, the AMA recommends that CMS or its contractors must make any prior authorization requirements and restrictions readily accessible on its website to beneficiaries, health care professionals, and the general public. This includes the written clinical criteria. Requirements must be described in detail but also in easily understandable language. We appreciate CMS' work to date on its Documentation Requirement Lookup Service and look forward to when it may be integrated into the provider's EHR so that he or she does not need to exit his or her workflow to use the tool. We support efforts underway to enable exactly this type of EHR integration through the Da Vinci Project Coverage Requirements Discovery and Documentation Templates and Rules use cases.

The AMA believes that another critical component of prior authorization program transparency is inclusion of the specific clinical criterion, coverage, coding, and/or payment rule that was not met in any denial. Thus, physicians would know what the applicable additional relevant documentation would be for resubmission. While the need for this transparency in denials may seem intuitive or superfluous, the AMA is concerned that without an explicit provision in Medicare FFS prior authorization requiring this level of detail in denials, contractors will only provide the minimal amount of information required. We note that this would also support the third Consensus Statement concept encouraging program transparency, as stated above.

[5] AMA, Industry Checkup: Measuring Progress in Improving Prior Authorization (2019), https://www.ama-assn.org/system/files/2019-03/prior-auth-survey.pdf.

Ensuring Continuity of Care

Changes in health plans, or changes in coverage under an existing plan, can lead to dangerous disruptions in chronic, effective treatment. While plan changes may not be a common scenario under Medicare FFS, we urge CMS to consider the potential for new prior authorization requirements to interrupt or delay ongoing treatment. For example, instituting prior authorization for drugs covered under Part B could delay administration of a scheduled infusion, with a subsequent (and perhaps permanent) loss in disease control. Delays in receiving post-surgical care, such as durable medical equipment or physical therapy, due to new prior authorization requirements could lead to similar care disruptions and negative clinical outcomes for Medicare beneficiaries. We ask CMS to carefully consider these potential patient harms when weighing the costs and benefits of any new prior authorization requirements in Medicare FFS.

Automation to Improve Efficiency: Valuable but Incomplete Complete Solution

The AMA fully supports automation of the prior authorization process using standard electronic transactions and recognizes that current advancements in health information technology can be leveraged to reduce the practice burdens associated with prior authorization. We also fully appreciate that CMS has invested heavily in the Da Vinci Project, which leverages technology to facilitate electronic exchange of clinical data by extracting information from physicians' EHRs. The lack of a mandated electronic standard to support the exchange of clinical documentation has been a long-standing, rate-limiting impediment to automation of prior authorization for medical services. The AMA believes the Da Vinci Program efforts hold promise to improve prior authorization transparency and efficiency. However, we harbor significant reservations about exclusive reliance on this technology to fully address prior authorization burdens, as automated data exchange will not address many of the AMA's policy concerns with the entire prior authorization process (which we define holistically, beginning with the decision about which providers and services to apply requirements, encompassing complete program transparency, and concluding with standardized electronic communications). We note the following key points regarding overreliance on technology to fully address prior authorization challenges:

- *Data privacy/security and usage*: Da Vinci processes may allow payers unprecedented access to EHRs. Protections are needed so that plans will not inappropriately access information, coerce physicians into using the technology, or interfere with medical decision making.
- *Clinical criteria variation and opacity*: The lack of uniformity and transparency in prior authorization clinical criteria between payers will hinder automation efforts.
- *Technology access and costs*: Da Vinci represents nascent technologies that have yet to be widely implemented. Moreover, the costs and time-frame for availability across EHR vendors are unclear. It is unclear if Da Vinci prior authorization support tools will be routinely used across practice types by the time CMS would implement any new prior authorization requirements in the Medicare FFS program. We must also stress that Da Vinci offers no prior authorization relief for small practices in the near future. Most practices impacted by these new prior authorization requirements are small businesses that will face major challenges in managing this additional workload. We have strong concerns that CMS may be focusing on automation as the only vehicle for implementing PA reforms. Moreover, small practices do not have the resources needed to invest in the newer technologies that could improve process efficiency.
- *Patient care delays*: A fully automated/electronic prior authorization process will not eliminate or prevent dangerous care delays, as manual review of medical documentation will still be required by CMS contractors following the electronic exchange of data.

- *Ease leading to increases:* We are concerned that overreliance on automation will set the stage for increased volume of prior authorization in the Medicare program because it will be "easier."

Review Timelines and Enforcement

While we believe that adherence to the Consensus Statement concepts outlined above will support timely access to medically necessary care for Medicare beneficiaries, we urge CMS to also give careful consideration when establishing processing time requirements in any new Medicare FFS prior authorization program. The AMA has previously expressed strong concerns about the prior authorization processing times allowed under previous Medicare FFS prior authorization demonstrations programs, as well as recently finalized in the CY 2020 OPPS rule. Under both programs, patients in need of non-urgent care have to wait up to 10 business days for a prior authorization decision. This lengthy waiting period is unacceptable, especially given the fact that the requirement is defined in business days. Weekends and holidays could therefore extend care delays by more than 15 days, leaving the patient in limbo while waiting for medically necessary care. In addition, many practices may not schedule a service until authorization is received, meaning that patient care will be even further delayed—with the associated increased risk of negative clinical outcomes. We recommend that CMS establish a 48-hour processing time for routine prior authorization requests.

We also object to the characterization of and processing time requirements regarding prior authorizations for urgent care used for both the Medicare DMEPOS demonstration projects and the OPPS final rule. Both programs indicate that physicians can seek expedited prior authorization reviews when a delay could seriously jeopardize the beneficiary's life or health, and that such requests will be considered within two business days. First, we note that cases involving a patient's life being in jeopardy should be characterized as emergency care and therefore never require prior authorization. CMS should clearly state that emergency care is exempted from any prior authorization requirements. In cases in which the need for treatment would be characterized as urgent, we agree that expedited processing should be required. However, the allowance of two business days is unacceptable for patients requiring urgent treatment, especially when the additional time added by weekends and holidays is considered. In any future Medicare FFS prior authorization program, we urge CMS to set the deadline for responding to urgent requests at 24 hours. Additionally, we object to the requirement in the OPPS rule that physicians must submit documentation establishing the need for expedited processing of the request, as this will both further burden the practice and slow the processing time due to CMS or its contractor needing to make determinations related to both treatment urgency and medical necessity. A physician's judgment that a patient needs urgent treatment should be sufficient to trigger an expedited processing time-frame, and CMS should not impose additional burdensome documentation requirements in such cases.

Enforcement of Time-Frame

The AMA recommends that CMS include a regulatory provision in any new Medicare FFS prior authorization program that allows for prior authorization approval when the contractor or CMS fail to meet regulatory defined time-frames. There must be recourse for the physician (and patient) and consequences for CMS or a contractor when an affirmation is not issued within the allowed time-frame of receipt of the prior authorization request. We note that most state laws and regulations involving prior authorization provide for the recourse of payer noncompliance with a deadline to be that the service be deemed authorized. Accordingly, CMS should include a regulatory provision in any new Medicare FFS program that when a contractor or CMS fails to comply with the deadlines specified in the regulation, it

will result in any service subject to review being automatically deemed authorized by the contractor or CMS.

- *While prior authorization helps ensure that services or items to be furnished comply with all applicable coverage and coding rules at the time of the prior authorization request, some requirements cannot be assessed until after care delivery. What information cannot be captured by a prior authorization process? Does this limit or restrict prior authorization?*

The goal of prior authorization and other prepayment cost-control mechanisms is to ensure that the physician provides appropriate, medically necessary care. Physicians who adhere to authorization requirements should be assured that they will be compensated for their services, since the information available at the time of treatment supported the procedure. To subsequently restrict payment after providing approval unfairly threatens a physician's expected revenue stream and business operations. It is therefore critical that CMS consider and address any other factors that may lead to claim nonpayment after prior authorization approval to ensure that this situation is avoided in the Medicare FFS program. Scenarios that should be evaluated include:

- CMS or its contractor authorizes a service, but other payment policies/restrictions (e.g., limit on the number of services delivered over a specific period of time) lead to later denial of the claim. If other payment rules apply to a particular service, CMS or its contractor should verify that the service being authorized also qualifies for payment under these additional rules to ensure that the approval guarantees that the claim will be paid.
- In certain scenarios, the exact procedure or service that is delivered to the patient may change from what was originally authorized due to an emerging clinical situation. For example, a physician may determine when a surgery or procedure is already in process that a different or additional service is necessary, based on new clinical findings. In such cases, it would be unsafe—and highly impractical—for the clinician to halt the procedure to request an additional or new authorization based on the changing clinical circumstances. If CMS establishes new Medicare FFS prior authorization requirements, provisions should be made to address such scenarios through allowing flexibility in authorizations (e.g., allowing an authorization to apply to a range of related procedure codes).

- *Are there other issues with respect to prior authorization that CMS should consider?*

Transparency into Prior Authorization Program Metrics

Data are critical to evaluating the effectiveness, potential impact, and costs of prior authorization processes on patients, providers, health insurers, and the system as a whole; however, limited data are currently made publicly available for research and analysis. CMS should provide the health care community with relevant data, which may be used to improve efficiency and timely access to clinically appropriate care. Therefore, CMS should make statistics regarding prior authorization approval and denial rates, as well as the number of practitioners exempted from prior authorization requirements, available on its website (or another publicly available website) in a readily accessible format. The statistics should include (but not be limited to) the following categories related to prior authorization requests: (1) health care provider type/specialty; (2) medication, diagnostic test or procedure; (3) indication; (4) total annual prior authorization requests, approvals and denials; (5) reasons for denial such as, but not limited to, medical necessity or incomplete prior authorization submission; and (6) denials overturned upon appeal.

These data should inform efforts to refine and improve the prior authorization program such as additional provider exemptions or suspension of prior authorization process or services.

No Appeal Rights

The AMA has repeatedly and strongly opposed provisions in CMS' prior authorization programs (Medicare DMEPOS demonstrations and OPPS) that offer no appeal rights with a non-affirmation decision. The AMA is unaware of any other payer not having some form of appeal available of an adverse decision regarding prior authorization. Instead, CMS requires the physician to either (1) constantly re-submit the same request anew until the contractor accepts the claim, further delaying medically necessary care, or (2) provide the service without receiving affirmation.[6] If CMS does not provide appeal rights to a non-affirmation decision in any future Medicare FFS prior authorization program, this lack of prior affirmation should not be sufficient to deny an appeal of a negative Medicare coverage determination. In other words, if CMS (or a contracted claims adjudicator) denies payment for a service that the physician believes to have been medically necessary, the physician must be able to appeal the payment denial with assurance that the appeal will not be denied solely because of a non-affirmation decision. Rather, the appeal must consider whether the item or service was indeed medically necessary and reasonable.

Non-Binding Affirmations

Under both Medicare DMEPOS and the OPPS, prior authorization is defined as a process through which providers obtain a provisional affirmation of coverage. Provisional affirmation is described as "a preliminary finding that a future claim for the service would meet Medicare's coverage, coding, and payment rules." CMS retains the right to later deny a claim after such a provisional affirmation. This allowance is extremely troubling, as it explicitly leaves open the ability for Medicare to change its application of rules and reconsider the medical necessity of a service after it has been provided, which clearly creates financial risk for the practice. In any future Medicare FFS prior authorization program, a "provisional affirmation" should be binding in the absence of fraud, and the physician should be able to rely on the authorization as a guarantee of future payment. If medical necessity determinations are required prior to treatment, CMS must accept those decisions as final and not allow the possibility for reconsideration later during billing. Physicians, and more importantly Medicare beneficiaries, should not be presented with the possibility that CMS will change its affirmation after going through the burdensome PA process. Contrary to CMS' previous statements on this issue, the addition of prior authorization requirements does nothing to protect a practice's cash flow, as an authorization does not ensure that CMS or its contractor will not later reverse a coverage decision and recoup payment.

Physician-Determined Decisions

Health care providers want nothing more than to provide the most clinically appropriate care for each individual patient. Prior authorization programs must therefore have a clinically accurate foundation for provider adherence to be feasible. The referenced clinical information should be readily available to the prescribing/ordering provider and the public. For any future Medicare FFS prior authorization program,

[6] The latter would result in a denial of payment for the service because the claim would not meet a condition of payment due to the lack of prior authorization. CMS states this denial is the initial determination and where appeal rights attach. However, any appeal would ultimately be meaningless because, regardless of whether the service was medically necessary, the physician still would not meet a condition of payment—the lack of prior authorization. Accordingly, the AMA recommends that CMS consider the non-affirmation decision to be an initial determination.

the AMA urges CMS to set forth requirements as to the qualifications of the personnel authorized to make adverse determinations. Without such requirements, anyone—including those without clinical knowledge or experience—could decide whether a service is medically reasonable and necessary. Accordingly, the AMA recommends that the adverse decisions be made by a physician who: (1) possesses a current and valid non-restricted license to practice medicine; (2) is of the same specialty as the physician who typically manages the medical condition or disease or provides the health care services involved in the request; (3) has experience treating patients with the medical condition or disease for which the health care service is being requested; and (4) makes the adverse decision under the clinical direction of one of CMS' or the contractor's medical directors (who also possesses an active license).

Provider Education

- *What strategies, tools, or technologies exist to help CMS better connect ordering physicians, rendering providers, and suppliers with respect to their responsibility to provide proper documentation? What strategies, tools, or technologies exist to help providers and suppliers become more aware of the necessary documentation requirements earlier in the claim process?*

CMS should adopt a strategy that provides a single source of information for physicians or administrators looking for clarification of a CMS policy or the necessary documentation requirements.

Eliminating and streamlining reporting, monitoring, and documentation requirements will improve the health care delivery system by reducing unnecessary burdens for physicians and making the health care system more effective, simple, and accessible. Medicare documentation requirements are a major imposition that delay care with redundant requirements for verifying physician orders and voluminous medical records, where the salient patient information is buried in reams of purposeless, formulaic language. In particular, CMS should review subregulatory guidance documents and the burden they can have on physicians. Moreover, individuals need to first understand the intricacies of CMS policies to even know where to find information or to combine statements from multiple CMS manuals to attempt to find a potential answer for questions regarding payment and coverage. Unfortunately, no one set of rules exists that physicians can go to for clarity. Instead, physicians must navigate a patchwork of state and federal regulations and carrier-specific requirements that govern what information is necessary to support a service, who can perform elements of the service, and who can enter the information into the medical record.

CMS should 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.

Additional Considerations

CMS can take additional steps to unburden physicians to allow them to put patients first or to provide better care to patients.

Exclude Educational Materials from Reporting in the Open Payments System

The Sunshine Act excludes several types of "payments" from the reporting requirements, including "[e]ducational 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. This conclusion is not consistent with the reality of clinical practice where patients benefit directly from improved physician medical knowledge and is not supported by the statutory language on its face or congressional intent.

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. The exclusion for items that directly benefit patients was designed with medical textbooks and scientific medical journal supplements and reprints in mind since these clinical tools are often used side-by-side with a patient as a first resource to help diagnose and treat unfamiliar medical issues. The inclusion of these resources as reportable transfers of value 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.

CMS' decision not to exclude medical textbooks or journal reprints has not only made doctors less likely to accept these materials but also, according to medical societies that develop many of these educational materials, has made industry less likely to distribute these materials due to the reporting burden. We believe the Sunshine Act was designed to support the dissemination of this type of educational material without unnecessary reporting. We recommend that CMS update its interpretation to include educational materials, such as peer-reviewed journals, journal reprints and abstracts, and medical textbooks as "educational materials that directly benefit patients" and, therefore, these items should not be reported under the Open Payments program.

2 Midnight/Observation Care

The two midnights rule was put in place to curb hospitals' use of observation status as an alternative classification to short duration hospital stays which were subject to Recovery Audit Contractor (RAC) audits. Hospital stays of two midnights or more are presumed appropriate for the inpatient setting. Any stay less than two midnights is subject to RAC audit. By substituting a physician's clinical expertise with a time-based requirement, the two Midnights policy favors a FFS payment mentality. Physicians should be focused on delivering personalized medicine individualized to the patient's needs, not watching the clock. The two midnights policy remains an artificial time-based 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 AMA urges CMS to withdraw the "2-Midnight"and support clinical judgement.

We thank you for the opportunity to provide input on this request for information. 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