

October 5, 2020

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

Re: File Code CMS-1736-P. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

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) on the 2021 Hospital Outpatient Prospective Payment (OPPS) proposed rule, published in the *Federal Register* on August 12, 2020 (85 Fed. Reg. 48772).

The AMA continues to support the stated goals of CMS to reduce regulatory burden and increase flexibility for physicians and patients, especially during the SARS-CoV-2 or COVID-19 public health emergency (COVID-19 PHE). The AMA continues to put the concerns of our physicians, our medical students, and the patients they serve at the forefront of everything we do. We are particularly concerned that the impact of some proposals combined with COVID-19 will continue to widen the gap for marginalized and minoritized communities. The AMA is committed to not only reducing health disparities, but to increasing health equity in the wake of the pandemic, the public health emergency, and beyond.

The following is a summary of our key comments and our detailed comments follow:

- The AMA urges CMS to adopt a more measured approach to the Inpatient Only (IPO) list of services than what is proposed, and to continue the removal of services off the IPO list when supported by data and medical evidence, rather than eliminate the list entirely. The AMA is concerned that CMS' proposal in the CY 2021 rule to eliminate the IPO list entirely may decrease patient safety and increase physician documentation burden.
- The AMA supports the proposed change from direct supervision to general supervision for non-surgical extended duration therapeutic services (NSEDTS), noting CMS has indicated that hospitals can continue to retain higher levels of supervision based on their own needs and their own determination.

- The AMA supports direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services via virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician.
- The AMA supports CMS' proposal to add 11 procedures, including total hip arthroplasty, to the Ambulatory Surgical Centers (ASC) Covered Procedures List (ASC-CPL).
- We urge CMS not to finalize its proposal to modify the existing general exclusion criteria, which would exclude procedures designated as requiring inpatient care due to the proposed elimination of the IPO. Instead, the AMA urges CMS to allow specialty societies to nominate procedures to the ASC-CPL if those procedures can be performed safely in the ambulatory setting, including procedures that may have been on the IPO list in CY 2020.
- The AMA recommends that CMS stop its practice of rescaling the ASC relative weights to achieve a perceived budget neutrality objective. Instead, the ASC services should apply the OPPS relative weights.
- The AMA believes CMS should increase ASC payments to level the playing field between hospital outpatient departments (HOPDs) and ASCs. The AMA continues to strongly support CMS replacing the CPI-U with the hospital market basket as the annual update mechanism for ASC payments.
- The AMA does not support the CMS proposal to add two categories of services to the Hospital Outpatient Department Prior Authorization Program effective for services July 1, 2021. The proposed rule did not attempt to quantify the physician and patient burden that will result from adding prior authorization to HOPD services on Medicare beneficiaries.
- The AMA also strongly supports repealing the federal ban on physician-owned hospitals. The AMA supports the flexibilities that CMS proposes for physician-owned hospitals serving greater numbers of Medicaid patients. Expanded capacity of physician-owned hospitals would increase competition and choice as well as patient access to high-quality care.

I. Inpatient Only (IPO) List

The AMA fully supports providing physicians with more autonomy to determine the most appropriate site-of-service in which a patient's procedure should be performed. In addition, the AMA supports moving services off the IPO list when medical evidence and data indicate that the service can safely be performed in an outpatient setting. The AMA is concerned, however, that CMS' proposal in the CY 2021 rule to eliminate the IPO list entirely may decrease patient safety and increase physician documentation burden. In addition, CMS' proposal lacks detail regarding how services previously on the IPO list will be reimbursed in the outpatient setting. **Therefore, we urge CMS to adopt a more measured approach and continue to remove services off the IPO list when supported by data and medical evidence, rather than eliminate the list entirely.**

Specifically, CMS proposes to eliminate the IPO list over three calendar years, beginning with the removal of 266 musculoskeletal-related services in CY 2021. The IPO list was created in 2000 to identify services requiring inpatient care because of their invasive nature, the need for at least 24 hours of postoperative recovery time, or the underlying condition of the patient. To date, CMS has reviewed the list annually and, through its rulemaking, proposed services that should be removed or added to the list based on data and medical evidence.

CMS justifies its proposed change by citing comments submitted over the years that have requested elimination of the IPO list, generally based on the tenet that decisions regarding the appropriate site-of-service for a procedure are best made by physicians. The AMA agrees that decisions critical to high quality patient care should always be the ultimate responsibility of the physician, including the determination of the appropriate site-of-service. However, hospitals, as well as private payors, often influence determinations regarding the appropriate site-of-service for procedures and services. The burden then falls on the physician to convince a hospital or payor that a particular patient should receive a given procedure in an inpatient setting due to patient safety concerns. For example, CMS' decision to remove hip and knee arthroplasty from the IPO list has led, in many instances, to an increased provider burden, requiring physicians to provide documentation and proof of medical necessity when a patient requires a hip or knee arthroplasty in an inpatient setting. While the AMA supports allowing physicians—together with their patients—to determine the appropriate site-of-service for a procedure or service, we also believe that patient safety and quality of care are paramount. **We have concerns that removing the IPO list entirely may lead to diminished patient safety and quality of care as facilities and/or payors pressure physicians to perform services in lower cost sites of service.**

In addition, the AMA has concerns that provider burden will greatly increase once services are no longer excepted from the two-midnight rule. Currently, IPO services are excepted from the two-midnight rule and, as such, considered appropriate for inpatient admission and payment under Part A regardless of expected length of stay. IPO services are also not subject to medical review. CMS proposes to continue its policy of exempting procedures removed from the IPO list from site-of-service claim denials, Recovery Audit Contract (RAC) referrals, and patient status reviews for two years. However, after that two-year exemption, the burden will fall on physicians to provide appropriate documentation for Part A payment when the physician determines that it is medically reasonable and necessary to conduct these procedures on an inpatient basis. The proposed policy will significantly increase provider documentation burden, which is counter to CMS' recent stated efforts to reduce physicians' administrative burden. **We also believe the two-midnight rule is counter to CMS' intention to rely on clinician judgment to determine the appropriate site-of-service and inpatient or outpatient status of a patient.** We continue to recommend that CMS rescind the two-midnight rule by terminating observation status. Furthermore, the AMA is concerned that decisions to perform procedures in an inpatient setting may be scrutinized more vigorously, leading to increased medical necessity denials and increased harms and burdens of prior authorization.

Finally, the AMA is concerned with the lack of information provided in CMS' proposal regarding reimbursement of procedures as they are moved off the IPO list and performed in the outpatient setting. The AMA generally supports the shift of procedures from the hospital to the outpatient setting, which can potentially be more cost effective. However, CMS' proposal lacks adequate reimbursement information and data for providers to be able to fully understand how services removed from the IPO list will be reimbursed under the outpatient prospective payment system. While CMS notes that it proposes to reassign codes that were previously on the IPO list to clinical Ambulatory Payment Classifications (APCs), it fails to provide any information on the actual level of reimbursement for each service and procedure under OPPTS. Therefore, it is very difficult for stakeholders to provide feedback regarding whether the level of reimbursement provided will reflect the true cost of performing procedures in an outpatient setting. Furthermore, CMS states it will monitor changes in site-of-service to determine whether changes may be necessary to certain CMS Innovation Center models. CMS should not take a wait-and-see approach to the impact of this proposal on alternative payment models (APMs), as well as MIPS cost measures. Instead, when proposing to remove a service from the IPO list, CMS should assess the impact of this proposal on APMs and cost measures and their target prices and benchmarks. **Finally,**

the AMA is concerned about potential implications of the proposed IPO change on patient cost-sharing as well as patient awareness and understanding of the impact site of care choices have on their cost-sharing responsibilities.

The AMA supports CMS' intention to rely on physicians' clinical judgment regarding the appropriate site-of-service for procedures and services to be performed. However, the AMA has significant concerns that due to pressures from payors or facilities to provide services in a lower cost setting, the elimination of the IPO list could lead to decreased patient safety. In addition, the removal of the IPO list may significantly increase providers' administrative burden if physicians are now required to provide documentation supporting the need for a procedure to be performed in an inpatient setting every time a service is provided. Finally, CMS fails to provide adequate information regarding how procedures previously on the IPO list will be reimbursed in the outpatient setting and whether the reimbursement will truly reflect the cost of performing the procedures and services. **Therefore, the AMA urges CMS to continue to remove services off the IPO list when supported by data and medical evidence, rather than eliminate the list entirely.**

II. Proposed Nonrecurring Policy Changes

A. Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

The AMA supports the proposal to allow general supervision of outpatient hospital therapeutic services currently assigned to the non-surgical extended duration therapeutic services (NSEDTS) level of supervision from direct to general supervision.

In 2010, CMS stopped enforcing direct supervision requirements for certain services at critical access hospitals (CAHs) and small rural hospitals (fewer than 100 beds). This expansion of amending supervision requirements continued in 2014, when Congress passed formal legislation preventing CMS from enforcing direct physician supervision requirements for CAH and small rural hospitals. As a result, extensions of this policy were passed in subsequent years.

In the 2020 OPSS final rule, CMS finalized its proposal to move all OPSS therapeutic services, except diagnostic services, NSEDTS, and several cardiology services, from a combination of general and direct supervision to solely general supervision.

Presently, CMS acknowledges three levels of supervision: (1) general, (2) direct, and (3) personal.¹ General supervision requires the procedure to be furnished under the physician's overall direction and control. Direct supervision varies depending on location and the service being provided, but typically requires that a physician be present in the location the service is being performed and is available for immediate assistance and direction. Personal supervision entails the physician being physically present in the room during the procedure.²

Now, CMS is looking to change the required level of supervision for NSEDTS from direct supervision to general supervision. The AMA supports the proposed change from direct supervision to general

¹ <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM11043.pdf>.

² <https://www.law.cornell.edu/cfr/text/42/410.32>.

supervision for NSEDTS services, noting CMS has indicated that hospitals can continue to retain higher levels of supervision based on their own needs and their own determination.

Overall, the AMA believes that “general supervision,” rather than “direct supervision,” should be established as the requirement for Medicare payment for most, but not all, outpatient therapeutic services. However, radiation therapy services and hyperbaric oxygen services should be exempt from requiring only general supervision; direct supervision should be required for hyperbaric oxygen therapy services. Since hyperbaric oxygen therapy and radiation therapy services are not included within NSEDTS, the AMA supports the proposed change from direct to general supervision for NSEDTS services, noting CMS has indicated that hospitals can continue to retain higher levels of supervision based on their own needs.

The AMA supports direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services via virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician.

The AMA applauds the decision to allow physicians to use audio/video real-time communications technology to directly supervise pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services during the pandemic, and we support the proposal to make these changes permanent.

Throughout COVID-19, the necessity for improved access to telehealth services has been highlighted and heightened. In an effort to provide timely access to care, adoption of this policy will promote continued innovations to advance telehealth services and improve patient care. As the medical community continues to evaluate best practices to improve provider accessibility, especially in rural and underserved areas, these modifications to CMS policy will expand patient access and improve physicians’ capabilities to care for patients. Allowing for virtual physician presence permanently, especially throughout the duration of the current public health emergency, will help to decrease the risk of unnecessary infectious disease exposure for both the patient and physician. This will improve morbidity and mortality rates among high risk populations during COVID-19 and any other future public health crises.

Expanding the virtual physician presence will improve the ability of physicians to efficiently monitor patients and quickly respond to any questions or concerns. **However, the AMA does believe that the billing physician needs to meet all of the requirements associated with direct supervision including first seeing the patient and the site of treatment, initiating the course of treatment, and providing subsequent services at a rate that shows active participation in, and management of, the course of treatment.** Moreover, virtual supervision must follow evidence-based practice guidelines, to the degree they are available, to ensure patient safety, quality of care, and positive health outcomes. Additionally, emergency protocols must be established in advance to ensure that proper care can be administered in a timely and competent manner should an urgent situation occur. The physician must also maintain responsibility for, and authority of, the safety and quality of services provided to patients by nonphysician providers through telemedicine. The services rendered must also adhere to state scope of practice laws in the state where the patient receives the services.

Since this provision will allow physicians to continue to efficiently monitor patients after their initial in-person visit, the AMA supports permanently allowing for the direct supervision for pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services via virtual presence of the physician through audio/video real-time communications technology subject to the requirements described above and clinical judgment of the supervising physician.

III. Updates to the Ambulatory Surgical Center (ASC) Payment System

A. *Changes to the List of ASC Covered Surgical Procedures*

The AMA supports CMS' proposal to add 11 procedures, including total hip arthroplasty, to the ASC-CPL. Many ASCs are equipped to perform these procedures. Orthopedic surgeons in ASCs are increasingly performing these 11 proposed procedures safely and effectively on non-Medicare-fee-for-service patients and appropriate Medicare patients. CMS notes that the COVID-19 PHE has highlighted the need for more health care access points throughout the country, yet many ASCs have temporarily closed or scaled back their operations based on federal and state recommendations to delay non-essential procedures. We agree with the agency that it is critical to provide more flexibility to physicians and patients to choose ASCs as the appropriate site of care during and after this COVID-19 PHE.

CMS also solicits comments on two proposals to expand the ASC-CPL. CMS proposes a public nomination process during which stakeholders would recommend new procedures be added to the ASC-CPL and CMS would provide a rationale for accepting or excluding the service during the annual rulemaking cycle. Alternatively, CMS proposes to revise the regulatory criteria for adding services to the ASC-CPL and add approximately 270 potential surgery or surgery-like codes as covered procedures in 2020. The agency indicates it will finalize one of these alternatives.

The AMA appreciates both proposals to provide greater flexibility to physicians, in consultation with their patients, to exercise their medical judgement in determining the appropriate setting of care. The AMA sees advantages to establishing a formal nomination process as it would streamline the process for specialty societies to suggest procedures that can be safely performed in the ASC setting based on the latest evidence available, as well as input from their members. This process would also increase transparency in how CMS determines whether to add procedures to the covered list as the agency would provide a specific rationale about the determination in the final rule.

We have concerns, however, about CMS' proposal to modify the existing general exclusion criteria at 42 CFR 416.166(c)(6) to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020, due to the proposed elimination of the IPO. In other words, CMS would not accept any nominations for procedures to add to the ASC-CPL if the procedure is on the CY 2020 IPO list. We believe this proposal is counter to CMS' intention to expand physician and patient choice. **We urge CMS not to finalize this proposal and to allow specialty societies to nominate procedures to the ASC-CPL list if they can be performed safely in the ambulatory setting, including procedures that may have been on the IPO list in CY 2020.**

B. *Updating the ASC Relative Payment Weights*

CMS provides its annual update to the ASC relative payment weights by first factoring the national OPPS relative payment weights (including the Medicare Physician Fee Schedule non-facility practice expense relative value units-based amounts, as applicable), and then uniformly scaling the ASC relative payment weights. The calculated OPPS relative payment weights are scaled to remain budget neutral for OPPS, and then are rescaled to establish the ASC relative payment weights. The weight scalar is applied so that projected expenditures from the updated ASC payment weights in the ASC payment system equal the current expenditures based on the scaled ASC payment weights.

CMS has calculated the proposed weight scalar for 2021 to be 0.8494, and proposes to apply this scalar to the ACS relative payment weights of covered ancillary radiology services, certain diagnostic tests, and covered surgical procedures.

The AMA recommends that CMS stop its practice of rescaling the ASC relative weights to achieve a perceived budget neutrality objective. ASC services should apply the OPSS relative weights. CMS should adopt a consistent payment methodology to level the playing field across all sites-of-service. The weight scalar site-of-service differential impedes the provision of high-value care because it incentivizes payment based on the location where a service is provided. No evidence has demonstrated any growing differences in capital and operating costs in hospital outpatient departments (HOPDs) compared to ASCs. Thus, ASC services should apply the OPSS relative weights to promote outpatient services that are site-neutral without lowering total Medicare payments. Notably, CMS already has the authority to apply the OPSS relative weights to ASC services. CMS previously implemented the scalar pursuant to its own authority and, importantly, this implementation was not pursuant to any identified statutory requirement. Thus, CMS has the similar, discretionary authority to discontinue the scalar and align payment methodologies across these sites-of-service.

C. Updating the ASC Conversion Factor

The AMA fully supports the ability of physicians to select the most appropriate site-of-service for their patients, in consultation with patients and families, for surgical procedures as well as other services. To ensure the ability of physicians to select the most appropriate site for their patients, we believe **CMS should increase ASC payments to level the playing field between HOPDs and ASCs.**

The AMA continues to strongly support CMS replacing the CPI-U³ with the hospital market basket as the annual update mechanism for ASC payments. The CPI-U is not suitable for updating ASC payments because it measures changes in the prices of consumer goods, only a very small portion of which is related to health care and is therefore flawed for the purposes of the ASC payment system.

IV. Hospital Outpatient Quality Reporting (OQR) Program

CMS continues to emphasize high quality and more efficiency among its goals for Medicare beneficiaries. An integral component of quality reporting includes Hospital Outpatient Quality Reporting (OQR). While CMS does not propose new measures for the Hospital Outpatient Quality Reporting (OQR) program in this rule, we offer the following measure specific feedback:

1. OP-8: MRI Lumbar Spine for Low Back Pain.

We urge CMS to carefully consider the concerns previously raised during the last two reviews by the National Quality Forum (NQF) when developing and testing this revised measure in 2017. Specifically, at that time, the NQF questioned whether the list of exclusions was sufficient and expressed concerns that administrative claims data would not capture all antecedent, conservative therapies received by a patient. These questions on the validity of the data must be adequately addressed prior to any implementation of this measure. If claims data do not provide valid information on a facility's performance, then the measure should not be finalized.

³ The CPI-U, the Consumer Price Index-Urban All Consumers, is calculated by the US Bureau of Labor Statistics.

The AMA also recommends that the measure exclude individuals with chronic steroid use and osteoporosis. In addition, we request that the measure exclusions account for the fact that there are circumstances where advanced imaging—particularly dynamic films, CT, and CT myelography—are extremely valuable and should not be excluded from surgical workup. For example, these modalities may be useful for problem solving in cases where MRI is either non-diagnostic or contraindicated.

2. Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy

While the AMA agrees that it is useful to understand the rate of complications following outpatient colonoscopies for quality improvement, we remain concerned with the lack of adequate analysis of the inclusion of social risk factors in the risk adjustment approach. It is unclear to us why the developer would continue to test social risk factors after adjusting for clinical risk factors rather than assessing the impact of both clinical and social risk factors in the model at the same time. These variations in how risk adjustment factors are examined could also impact how each variable (clinical or social) performs in the model and remain unanswered questions. In addition, the lack of information on the degree to which a facility's rate would shift across the three categories on which performance is currently publicly reported (better than the national rate, no different than the national rate, or worse than the national rate) when the social risk factors are applied is troubling and should be considered prior to endorsement of this measure.

V. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

While CMS does not propose new measures for the Ambulatory Surgical Center Quality Reporting Program (ASCQR) in this rule, we offer the following measure specific feedback:

1. *ASC-12: Facility 7-Day Risk Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539)*

While the AMA agrees that it is useful to understand the rate of complications following outpatient or ASC colonoscopies for quality improvement, we remain concerned with the lack of adequate analysis of the inclusion of social risk factors in the risk adjustment approach. It is unclear to us why the developer would continue to test social risk factors after adjusting for clinical risk factors rather than assessing the impact of both clinical and social risk factors in the model at the same time. These variations in how risk adjustment factors are examined could also impact how each variable (clinical or social) perform in the model and remain unanswered questions. In addition, the lack of information on the degree to which a facility's rate would shift across the three categories on which performance is currently publicly reported (better than the national rate, no different than the national rate, or worse than the national rate) when the social risk factors are applied is troubling and should be considered prior to endorsement of this measure.

Furthermore, this measure was developed for use in the outpatient setting, not ASC. CMS should only utilize quality measures that have been validated for use in the ASC setting.

VI. Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

The AMA does not support the CMS proposals to add two categories of services to the Hospital Outpatient Department Prior Authorization Program effective for services July 1, 2021.

CMS proposes to add the following two categories of services to the Hospital Outpatient Department (OPD) Prior Authorization Program beginning for dates of service on or after July 1, 2021: (1) Cervical fusion with disc removal, and (2) implanted spinal neurostimulators. **The AMA opposes this proposal and urges CMS to withdraw it.** Our principal concern with adding prior authorization requirements to these new categories of OPD services is the potential effect on Medicare beneficiaries' ability to receive medically necessary, timely care. Utilization management tools such as prior authorization create significant treatment barriers by delaying the start or continuation of necessary treatment, which may in turn adversely affect patient health outcomes and quality of care. The AMA understands there may be a role for prior authorization in health care, including in Medicare fee-for-service, but we believe it must be right-sized and used judiciously. **The proposed rule did not attempt to quantify the physician and patient burden that will result from adding prior authorization to hospital OPD services on Medicare beneficiaries and, in our view, did not justify the need to add these additional services to the hospital OPD prior authorization program.**

Patient and Physician Impact of Prior Authorization

AMA research quantifies the impact of prior authorization requirements on both patients and physicians. In a December 2019 survey of 1,000 practicing physicians, 64 percent of respondents reported waiting at least one business day for prior authorization decisions from health plans, while 29 percent reported waiting at least three business days.⁴ Unsurprisingly, but disturbingly, 91 percent of surveyed physicians said that prior authorization can delay access to necessary care. **These delays have serious implications for patients and their health, as 74 percent of surveyed physicians reported that prior authorization can lead to treatment abandonment, and 90 percent indicated that prior authorization can have a negative impact on patient clinical outcomes. Most alarming, 24 percent of surveyed physicians report that prior authorization has led to a serious adverse event (e.g., disability, death) for a patient in their care, with 16 percent saying that this process has led to a patient's hospitalization.** We believe that these statistics capture the potential patient harms associated with prior authorization and suggest a significant patient burden associated with creating additional requirements to Medicare's utilization management program. 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 33 prior authorizations per physician per week, with this workload consuming 14.4 hours—nearly two business days—of physician and staff time. Moreover, about one-third (30 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 86 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 increasing the number of OPD services subject to prior authorization could lead to substantial growth in these burdens that already challenge the limited resources of financially strapped, smaller physician groups, particularly at a time when practices are reeling from the economic impact of the COVID-19 pandemic. Even if the COVID-19 PHE officially

⁴ 2019 AMA Prior Authorization Physician Survey, available at <https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf>.

ends before the proposed implementation date for the expanded OPD prior authorization program, physician practices and hospitals will still face a long financial recovery process that will be impeded by these additional administrative burdens.

Prior Authorization Reform Efforts

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 our ongoing discussions with senior CMS leadership regarding prior authorization. We urge CMS to lead the industry by adopting the following concepts, developed in consensus with other national provider associations and insurer trade organizations in the 2018 Consensus Statement on Improving the Prior Authorization Process, 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.⁵

Although we applaud CMS for including some of these principles in its OPD prior authorization program, **we encourage CMS to reconsider the proposed additional utilization management requirements for these particular services, as we believe they do not align with the above-referenced industry efforts to reform prior authorization or, more specifically, the goals of the newly created CMS Office of Burden Reduction and Health Informatics.** We urge CMS to fully consider the concerns outlined below before finalizing the additional prior authorization requirements for OPD services.

Singular Focus on Cost Control

CMS has identified financial concerns as the primary reason for expanding prior authorization to these OPD services. Specifically, CMS states the following:

For both services categories, we researched possible causes for the increases in volume that would indicate the services are increasingly necessary, but we did not find any explanations that would cause us to believe the increases were necessary. Moreover, other than the recent changes in the Current Procedural Terminology Code and Ambulatory Payment Classification assignments described above, CMS has not taken any action that would explain the significant increases identified. We also conducted reviews of clinical and industry-related literature and found no indication of changes that would justify the increases observed. After reviewing all available

⁵ AMA, Consensus Statement on Improving the Prior Authorization Process (2018), available at <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf>.

data, we found no evidence suggesting other plausible reasons for the increases, which we believe means financial motivation is the most likely cause. We believe utilizing codes because of financial motivations, as opposed to medical necessity reasons, has resulted in an unnecessary increase in volume.⁶

The AMA strongly disagrees with CMS' conclusion that the observed increased volume for these two categories of services represents overutilization and medically unnecessary care. While the figures cited in the rule do illustrate increased use of these service categories, CMS offers no evidence supporting its suspicion that this growth in volume represents clinically inappropriate treatment. In fact, CMS acknowledges that "[a] rate of increase higher than the expected rate is not always improper," and there is no indication that the appropriate national medical specialty societies were engaged to determine if there was a clinical rationale for change in claim volume for these services. Without clear evidence establishing that the increased utilization of these services represents medically unnecessary care, we must assume that CMS' primary motivation for this proposal is cost reduction. This is highly concerning, as cost-containment provisions that do not have proper medical justification can put patient outcomes in jeopardy. **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.** Moreover, by delaying medically necessary care for OPD services, these proposed requirements have the potential to increase overall Medicare spending, as patients' conditions may worsen while waiting for approval and ultimately require more intensive—and expensive—care.

Clinical Rationale for Increased Utilization in Hospital OPD Services Targeted for Prior Authorization

Instead of assuming that the rising volume of the targeted OPD service categories represents inappropriate care, we urge CMS to consider several convincing, clinically valid reasons for this increased utilization. For example, implanted spinal neurostimulators provide a valuable alternative therapy to opioids in the treatment of certain chronic pain diseases. It should therefore come as no surprise that utilization of spinal neurostimulators has grown in recent years to coincide with intensive efforts to address the national opioid epidemic. Physicians are consistently prescribing fewer opioids: the number of opioid prescriptions decreased nationally by more than 90 million—a 37.1 percent reduction—between 2013 and 2019.⁷ The increased utilization of spinal neurostimulators observed by CMS aligns with the concerted efforts by physicians to pursue non-opioid options to effectively treat patients suffering from chronic pain while avoiding the risk of opioid use disorder in this vulnerable population. **The AMA urges CMS to reconsider prior authorization requirements on spinal stimulation procedures, given their important place in pain management during our nation's ongoing efforts to combat the opioid epidemic.**

We also encourage CMS to consider the effect of technological evolution on the recent increased volume of implanted spinal neurostimulators. Spinal cord stimulation therapy performed via implanted spinal neurostimulators has achieved higher success rates and improved efficacy resulting from recent technological advancements. Specifically, dorsal root ganglion stimulation therapy, a newer and more focused type of spinal cord stimulation, allows physicians to target specific painful areas or damaged

⁶ 85 Federal Register (FR) 49029.

⁷ IQVIA Xponent market research services. (c)IQVIA 2020.

nerves, which both improves treatment efficacy and avoids stimulating unwanted areas.⁸ In addition, the availability of rechargeable batteries for spinal neurostimulators has significantly extended battery life, reduced costs, and improved patient adoption and acceptance of this alternative form of pain management.⁹ Placed in this context of evolving technology and related improvements in treatment outcomes and convenience, the recent growth in utilization of implanted spinal neurostimulators is both logical and justified.

Prior Authorization's Impact on Access to Non-Opioid Pain Care and Patient Suffering

In its second annual survey, the American Board of Pain Medicine sought to quantify how the opioid epidemic in this country is affecting patients with pain and the pain medicine specialists who treat them. The survey specifically touched on the impact and unintended consequences of prior authorization regulations on the ability of physicians seeking non-opioid pain care for their patients.¹⁰ The survey found the following:

- 92 percent of pain medicine specialists said that they have been required to submit a prior authorization for non-opioid pain care—with the physicians and their staff spending hours per day on such requests; and
- 66 percent of pain medicine specialists said that they have had to hire additional staff to handle the prior authorization requirements.

Even more concerning than these administrative burdens are the serious and prolonged negative health impacts, such as withdrawal, anxiety/depression, and suffering, experienced by patients unable to obtain non-pharmacologic pain treatment due to stringent prior authorization restrictions. An anesthesiologist specializing in pain management provides a troubling account of how prior authorization requirements for a permanent implanted spinal neurostimulator led to months of unnecessary distress for a patient who had successfully tapered off of long-term opioid treatment for back pain after a successful trial with a temporary implant: “She went through eight months of additional pain, depression and anxiety when we had a proven treatment that was clearly helping her.”¹¹ Only after months of delay, numerous appeals, and countless hours of the physician’s time was the patient able to receive the treatment she desperately needed: “. . . But since the permanent implant, she’s back to being a mom, goes on walks with her husband, and is working toward getting back in the job market. She is not using any opioids at all.” **We strongly urge CMS to prevent more such cases of human suffering and clinician burden by reevaluating its rationale for the addition of these two new service categories to the hospital OPD prior authorization program and removing these provisions from the OPDS proposed rule.**

The AMA also requests that CMS consider how the proposed changes to the OPD prior authorization program may have the unintended consequence of undermining the success of the many efforts underway to curb the opioid epidemic while still effectively managing patients’ pain. For example, the U.S.

⁸ Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain*. 2017;158(4):669-681. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5359787/pdf/jop-158-669.pdf>.

⁹ Mitchell KT, Volz M, Lee A, et al. Patient Experience with Rechargeable Implantable Pulse Generator Deep Brain Stimulation for Movement Disorders. *Stereotact Funct Neurosurg*. 2019;97(2):113-119. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6689445/pdf/nihms-1044066.pdf>.

¹⁰ <http://abpm.org/uploads/files/abpm%20survey%202019-v3.pdf>.

¹¹ <https://end-overdose-epidemic.org/stories/prior-authorization-of-non-opioid-pain-care-prolongs-patient-suffering/>.

Department of Health and Human Services (HHS) Pain Management Best Practices Inter-Agency Task Force Report highlights barriers to accessing optimal pain care and notes that “[i]nconsistencies and frequent delays exist in insurance coverage for interventional pain techniques that are clinically appropriate for a particular condition and context.”¹² Notably, the Task Force includes the following recommendation in its report: “Encourage CMS and private payers to provide consistent and timely insurance coverage for evidence-informed interventional procedures early in the course of treatment when clinically appropriate.”

Similarly, a CMS fact sheet released in June 2020, entitled “CMS Roadmap: Strategy to Fight the Opioid Crisis” recognizes that “CMS has a vital role in addressing the opioid epidemic and is focused [on prevention by managing] pain using a safe and effective range of treatment options that rely less on prescription opioids.”¹³ CMS’ proposal to expand the Hospital OPD prior authorization program to include implanted neurostimulators will only exacerbate the current challenges posed by variable coverage and care delays for effective, evidence-based, non-opioid pain therapies. **The AMA urges CMS to revisit the proposed changes to ensure alignment with the HHS Task Force and other CMS recommendations on the opioid crisis to ensure that the OPD prior authorization program does not create additional barriers to medically necessary pain management.** The current COVID-19 pandemic heightens the urgency of supporting timely access to non-opioid pain treatments, as 40 states have reported increases in opioid-related mortality in recent months, and we continue to hear reports from patients with pain that they experience ongoing challenges in obtaining nonopioid pain care.¹⁴

Finally, considering that this policy could increase barriers to receipt of nonopioid pain treatment, we encourage CMS to consider the additional burden this could place on American Indians/Alaskan Natives (AI/AN), African American, Latinx, and Asian American populations, who already face barriers in receiving certain treatments for opioid use disorder (OUD) and experience disproportionate fatality from overdose. For example, a *JAMA Psychiatry* [research letter](#) written by researchers at the University of Michigan and the Veterans Affairs Ann Arbor Healthcare System found that buprenorphine treatment “is concentrated among white persons and those with private insurance or use self-pay.”¹⁵ The letter noted that there were 13.4 million patient visits resulting in a buprenorphine prescription between 2012 and 2015, with white patients accounting for 12.7 million of those visits and minoritized patients accounting for only 363,000. Accordingly, even though OUD rates are similar for the two groups (3.5 percent for blacks, 4.7 percent for whites), 35 white patients received a buprenorphine prescription for every patient of another race or ethnicity who received one. Compared with white patients, black patients had 77 percent lower odds of having an office visit that included a buprenorphine prescription. Additionally, the Indian Health Service has highlighted findings from the Centers for Disease Control and Prevention, showing that AI/AN populations have the second highest overdose rates from all opioids in 2017 (15.7 deaths/100,000 population) among racial/ethnic groups in the US.¹⁶ **CMS should not implement a policy that could make it even more difficult for minoritized and marginalized populations to access nonopioid pain care.**

¹² <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>.

¹³ <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf>.

¹⁴ <https://www.ama-assn.org/system/files/2020-09/issue-brief-increases-in-opioid-related-overdose.pdf>.

¹⁵ Lagisetty PA, Ross R, Bohnert A, Clay M, Maust DT. Buprenorphine Treatment Divide by Race/Ethnicity and Payment. *JAMA Psychiatry*. 2019;76(9):979–981. doi:10.1001/jamapsychiatry.2019.0876.

¹⁶ <https://www.ihs.gov/opioids/data/>.

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. However, the OPD prior authorization program does not establish required qualifications for the personnel authorized to make adverse determinations and allows anyone—including those without clinical knowledge or experience—to decide whether a service is medically reasonable and necessary. This issue is particularly concerning in regard to spinal stimulation procedures needed to reduce opioid use as described above. As noted in the HHS Task Force report, clinicians performing interventional procedures as alternatives to opioid treatment require specialized training.¹⁷ The physician who provided the clinical vignette cited above describes the problems created when reviewers lacking appropriate training and expertise make authorization decisions on these highly specialized cases: “. . . [H]ealth plans are using physicians to deny care when that physician has never practiced pain medicine, never trained as an anesthesiologist nor used [spinal cord stimulation] or other interventional therapies. . . . It’s ludicrous and maddening.”¹⁸

Accordingly, if CMS proceeds with finalizing these new prior authorization requirements, 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 (i.e., anesthesiology/pain medicine for implanted neurostimulators); (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).

Transparency into the Process and Program Evaluation

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, only limited data are currently made publicly available for research and analysis. We note that CMS has yet to evaluate the impact of the prior authorization requirements finalized in the CY 2020 OPDS final rule. Without a thorough study of how the existing OPD prior authorization requirements have affected care access, clinical outcomes, utilization, overall Medicare costs, and administrative burdens, it is premature to expand this program. As the AMA research detailed above clearly illustrates, concerns about the negative effect of prior authorization on patients and physicians are not speculative. **We therefore urge CMS to undertake this necessary and important impact analysis before requiring prior authorization for any additional categories of OPD services.**

Specifically, CMS should provide the health care community with relevant data about the impact of the OPD prior authorization program to date, which may be used to improve efficiency and timely access to clinically appropriate care. 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

¹⁷ <https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf>.

¹⁸ <https://end-overdose-epidemic.org/stories/prior-authorization-of-non-opioid-pain-care-prolongs-patient-suffering/>.

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; (6) denials overturned upon appeal; and (7) average processing times for initial authorization requests and appeals. These data should inform efforts to refine and improve the OPD prior authorization program, such as additional provider exemptions or suspension of prior authorization process or services, as well as be thoroughly evaluated before implementing the proposed requirements on additional services.

Understatement of Practice Expenses Associated with Prior Authorization

In its calculation of the average practice labor costs that would be incurred with these new prior authorization requirements, CMS used an average hourly rate of \$16.63 (loaded rate of \$33.26).¹⁹ We disagree and believe this seriously underestimates the administrative costs associated with completing prior authorizations. This rate reflects the compensation for a clerical employee; however, we note that clinical staff, from nurses up to and including physicians, are often involved in completing the documentation required for prior authorizations. As these clinicians would be paid significantly higher hourly wages than the clerical staff rate used in CMS' calculations, we must stress that the actual increased labor costs associated with these additional prior authorization requirements would be much higher and exacerbate the existing problems with administrative waste in our health care system. In addition, we note that CMS only includes the time spent on completing and submitting a prior authorization response in calculating labor costs. One major and time-consuming burden associated with prior authorization is determining which services require authorization and the documentation requirements associated with a particular procedure code. Indeed, nearly seven in 10 physicians (67 percent) report that it is difficult to determine whether a prescription or medical service requires prior authorization.²⁰ The AMA has also conducted physician focus groups where it was reported that physicians increasingly have to engage in peer-to-peer prior authorization communications with plans which also contribute to costs.

Premature Effective Date

CMS proposes to implement prior authorization for additional OPD services effective July 1, 2021. If CMS proceeds with implementing prior authorization for the new services identified in the proposed rule, we urge reconsideration of the timeline for this program change to ensure sufficient time for physician and staff education and preparation on this new policy and its associated administrative processes. We have significant concerns that the proposed timeline does not support an adequate education and training period, which leaves physicians at major financial risk if they unknowingly provide one of the services newly requiring prior authorization without obtaining the needed authorization. **Additionally, we reiterate our significant concerns with increasing administrative burdens for physicians and their staff in the wake of the COVID-19 crisis.** We anticipate that physicians and hospitals will face a long road to recovering financial stability even after the official end of the public health emergency, and we urge CMS to seriously weigh the potential harms to both patients and clinicians of imposing additional administrative tasks on our health care system during this difficult and unprecedented time.

¹⁹ 85 FR 49041.

²⁰ <https://www.ama-assn.org/system/files/2020-06/prior-authorization-reform-progress-update-2019.pdf> Because physicians and staff will be adjusting to these new prior authorization requirements, the time and labor costs associated with identifying these newly restricted services and the correct documentation to support a prior authorization request should not be overlooked.

VII. Physician-Owned Hospitals

Prohibition on Facility Expansion

The AMA appreciates the opportunity to provide comments on physician-owned hospitals (POHs). CMS proposes to ease some of the restrictions on physician-owned hospitals that qualify as high Medicaid facilities²¹ and wish to seek exceptions to the prohibition on expanding facility capacity.

Specifically, CMS proposes to:

- Permit POHs that are high Medicaid facilities to apply for an exception more frequently than once every two years, which regulations currently allow, as long as no other exception request is awaiting decision by CMS;
- Remove limits on the number of additional operating rooms, procedure rooms, and beds that can be approved by an exception; and
- Remove the restriction that expanded facility capacity must occur only in facilities on the hospital's main campus.

The AMA believes that POHs provide quality care to patients and needed competition to the health care industry. The AMA supports competition between and among health care providers and facilities as a means of promoting the delivery of high quality, cost-effective health care. Providing patients with more choices for health care services stimulates innovation and incentivizes improved care, lower costs, and expanded access. **In short, the AMA supports the flexibilities that CMS has made in this proposed rule for POHs serving greater numbers of Medicaid patients. The AMA believes that expanded capacity of POHs would increase competition and choice as well as patient access to high-quality care. The AMA also strongly supports repealing the federal ban on POHs.**

Sections 6001 and 10601 of the Patient Protection and Affordable Care Act (ACA) and section 1106 of the Health Care and Education Reconciliation Act of 2010 (HCERA) prohibit the establishment of new physician owned hospitals and restrict the ability of those existing as of March 23, 2010 to expand. Specifically, Congress modified the “whole hospital exception” of the Stark Law in three ways, adding (a) limits on the growth of POHs in the medical marketplace, (b) requirements to disclose investment terms and investor identities, and (c) requirements to provide emergency services.²² Although the law does allow community POHs limited expansion if they are in an underserved area, approved by CMS, and qualify as a “high Medicaid facility”²³ or an Applicable Hospital,²⁴ it is our understanding that only six hospitals nationwide have been granted one of the two exceptions to-date.²⁵ The resulting impact of these provisions we believe has been—limiting competition, job growth, and patient choice.

²¹ A “high Medicaid facility” means a hospital that: (1) Is not the sole hospital in a county; (2) with respect to each of the 3 most recent 12-month periods for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. 42 Code of Federal Regulations (CFR) §411.362(c)(3).

²² 42 United States Code (U.S.C.) §1395nn(d)(3)(c).

²³ 42 U.S.C. §1395nn(i)(3)(F).

²⁴ 42 U.S.C. §1395nn(i)(3)(E).

²⁵ https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Physician_Owned_Hospitals

Recognizing the need to increase access to health care for Medicaid beneficiaries, Congress in drafting the ACA, chose not to impose certain additional restrictions on “high Medicaid facilities” that it did apply to hospitals qualifying as an “Applicable Hospital.” Despite Congress intentionally exempting high Medicaid facilities from these additional restrictions, CMS has imposed, through rulemaking, these additional restrictions on high Medicaid facilities causing unnecessary regulatory burden. CMS’ current proposed rule seeks to fix this error.

A rule that unburdens physician owned high Medicaid facilities from the restraints imposed on applicable hospitals is necessary. On December 3, 2018, the HHS released a report titled, *Reforming Americas Healthcare System Through Choice and Competition*.²⁶ The report, created by HHS in partnership with the Departments of the Treasury and Labor, the Federal Trade Commission, and the White House, details the impact of state and federal laws and regulations that limit choice and competition in the health care market and makes recommendations to improve the health care system for patients across this country. Under the heading, “ACA Rules Restricting Physician-Owned Hospitals Reduce Competition,” the HHS Report states that, “According to the Physician Hospitals of America, 37 planned hospitals have not been constructed, and over 30,000 planned healthcare jobs have gone uncreated because of these PPACA restrictions on physician-owned hospitals.”²⁷ Lifting restrictions on POHs could be a key to widening access to care.²⁸

The HHS Report notes that the costly restrictions were enacted at the behest of general hospital interests to address alleged potential financial conflicts of interest with physicians referring patients to their own hospitals (so-called “self-referral”) and concerns that physicians may be referring the healthiest patients to their own hospitals (so-called “cherry picking”).²⁹ While we more fully address those erroneous concerns below, we note here that the HHS Report concludes that “those concerns may have been overstated, considering that many studies suggest physician-owned hospitals provide higher quality care and that patients benefit when traditional hospitals have greater competition.”³⁰

The HHS Report goes on to state that, “[A]ccording to a study published by the *Journal of the American College of Surgeons*, physician-owned surgical hospitals outperform other hospitals in the Medicare value-based purchasing program.³¹ More than 40 percent of physician-owned hospitals received the top 5-star rating in a 2015 release by the CMS, compared to only five percent of general hospitals.^{32, 33} Further, patients are 3-to-5 times less likely to experience complications at a physician-owned specialty hospital

²⁶ <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>. (See PDF page 73-74)

²⁷ *Id.*, citing Leonard K. Obamacare wounds doctor-owned hospitals. Washington Examiner. July 10, 2017. <http://www.washingtonexaminer.com/obamacare-wounds-doctor-owned-hospitals/article/2627880>.

²⁸ Dickson V. Lifting restrictions on physician-owned hospitals could be key to widening access to care. Modern Health Care. June 27, 2017. <http://www.modernhealthcare.com/article/20170627/NEWS/170629899>.

²⁹ *Id.* at 74.

³⁰ *Id.*

³¹ Ramirez AG, Tracci MC, Stukenborg GJ, Turrentine FE, Kozower BD, Jones RS. Physician-owned surgical hospitals outperform other hospitals in Medicare value-based purchasing program. *J Am Coll Surg*. 2016 Oct; 223(4):559-567. <https://www.sciencedirect.com/science/article/pii/S1072751516307207?via%3Dihub>.

³² Turner G. Lift the ban on physician-owned hospitals. *Forbes*. November 6, 2015. <https://www.forbes.com/sites/gracemarieturner/2015/11/06/lift-the-ban-on-physician-owned-hospitals/#5311bcd11531>.

³³ Note CMS released an updated star rating approach in 2017 that expanded the number of hospitals that qualify for top 5-star ratings.

than at a general hospital.”³⁴ These recent quality studies confirm older studies, including an exhaustive one performed by CMS, finding that physician owned hospitals achieve higher quality of care, greater patient satisfaction, reduced costs, and improved infection rates.³⁵

Accordingly, the HHS Report recommends that “Congress should consider repealing the ACA changes to physician self-referral law that limited physician-owned hospitals.”³⁶

In an exchange between former U.S. Representative Sam Johnson (R-Texas) and HHS Secretary Alex Azar during a House Ways & Means Committee hearing on the HHS 2019 budget, Secretary Azar was asked about the impact of ACA on POHs and stated, “I do believe physician-owned hospitals can provide effective competition for other hospitals... [and] that many physician-owned hospitals deliver superb quality care, and we ought to be inspiring competition among providers.”³⁷ The AMA could not agree more.

Many hospital markets are highly concentrated and noncompetitive.³⁸ This results in hospital services that are higher in price and lower in quality than in competitive hospital markets.³⁹ Unfortunately, embedded hospital market concentration protected from new entry is becoming a stubborn issue for which antitrust provides no remedy.⁴⁰ Health care competition and antitrust scholar Professor Thomas Greaney laments that “the ACA all but put an end to one source of new competition in hospital markets by banning new physician -owned hospitals that depend on Medicare reimbursement.”⁴¹ This government created restraint on new hospital competition should end. It is radically inconsistent with the general thrust of the ACA, which is to encourage competition, such as the creation of health insurance exchanges and the formation of new delivery systems.

³⁴ Turner G. Lift the ban on physician-owned hospitals. *Forbes*. November 6, 2015.

<https://www.forbes.com/sites/gracemarieturner/2015/11/06/lift-the-ban-on-physician-owned-hospitals/#5311bcd11531>.

³⁵ See e.g. Study of Physician-owned Specialty Hospitals Required in Section 507(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, pp 36-55 (2005) (CMS Report). Available at <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/RTC-StudyofPhysOwnedSpecHosp.pdf>.

³⁶ *Id.*

³⁷ <https://docs.house.gov/meetings/WM/WM00/20180214/106856/HHRG-115-WM00-Transcript-20180214.pdf>. (See PDF page 17)

³⁸ See Martin Gaynor and Robert Town, *The Impact of Hospital Consolidation-Update*, the Synthesis Project, Robert Wood Johnson Foundation (June 2012) (Synthesis Project).

³⁹ Testimony of Professor Martin Gaynor, Ph.D., “Diagnosing the Problem: Exploring the Effects of Consolidation and Anticompetitive Conduct in Health Care Markets,” before the Judiciary Committee of the US House of Representatives, March 7, 2019, available at https://www.researchgate.net/publication/331594597_Martin_Gaynor_testimony_Diagnosing_the_Problem_Exploring_the_Effects_of_Consolidation_and_Anticompetitive_Conduct_in_Health_Care_Markets_House_Judiciary_Committee_March_7_2019; Gaynor, M and Town, R. (2012) “Competition in Health Care Markets,” in *Handbook of Health Economics*, Vol 2, Pauly, M., Borras, P. and McGuire, T., eds., Amsterdam: Elsevier. One study estimates that the average prices and hospitals without local competitors are 12.5% higher than prices at hospitals with four or more competitors. See Cooper, Craig, Gaynor, and Van Reenen, “The Price Ain’t Right. Hospital Prices and Health Spending on the Privately Insured,” National Bureau of Economic Research 218815, May 2018.

⁴⁰ See e.g. Thomas Greaney, “The Affordable Care Act and Competition Policy: Antidote or Placebo?”, 89 *ORLR* 811 at 840 (2011) (Antitrust law does not break up legally acquired monopolies or oligopolies).

⁴¹ *Id.* at 841.

The Established Efficiencies of the Physician Owned Hospital (POH)

Accounting for the high performance of POHs are a number of efficiencies that CMS identified in its report. They include specialization (physician -owned hospitals are typically single specialty organizations), improved nursing staff ratios and expertise, patient amenities, patient communication and education, emphasis on quality monitoring, and clinical staff perspectives on physician ownership.⁴² For example, POH staff have the ability to focus on a limited number of procedures and diseases. Nurses do not have to be pulled to different types of inpatient wards to care for patients with a broad range of clinical problems. Clayton M. Christensen, a noted Harvard scholar on disruption in industry, has observed that the hospital industry is the only industry worldwide where the factory (a hospital) is not specialized. He projects that specialty hospitals could reduce costs for hospitalizations by 15 to 20 percent and is the disruptive solution for health care.⁴³

Perhaps the most essential efficiency of the POH as characterized by CMS is the fact of physician ownership itself:

In our site visits, staff at specialty hospitals described the physician owners as being very involved in every aspect of patient care. The physicians monitored patient satisfaction data, established a culture that focused on patient satisfaction and were viewed by the staff as being very approachable and amenable to suggestions that would improve care processes.⁴⁴

These CMS observations are consistent with the field of organizational economics that has long recognized that the performance of an organization may critically depend on who owns it. As explained in *Economics of Strategy*, ownership can affect critical incentives to invest in the future of the organization.⁴⁵

In a nutshell, workers may be unwilling to make critical investments in a firm if they do not trust ownership to reward them for it. At a practical level in the context of hospitals, this might manifest itself in terms of the time invested by physicians to work with ownership to develop treatment protocols, implement and enhance the performance of electronic health records, and develop and maintain relationships with patients. Physicians might trust physician owners to keep implicit promises regarding compensation and other aspects of job satisfaction, and a physician-owned hospital might therefore perform better than a hospital with more traditional ownership structures where relationships with medical staffs may be more tenuous.

In sum, physician ownership represents an important alternative that provides a different, potentially superior, opportunity to create efficiencies in the provision of health care.

Potential Promising Role for POH in New Delivery and Payment Models

Lifting the ban on POHs could also allow physicians who run other new care models to acquire hospitals, to better control hospital costs, and to supervise the overall health care product sold. The existing hospital

⁴² See CMS report, *supra* note 15, at 48-50.

⁴³ See *The Innovators Prescription: A Disruptive Solution for Healthcare*, Christiansen et al. McGraw-Hill (2008).

⁴⁴ See CMS report, *supra* note 15 at 50.

⁴⁵ Besanko, D. et al., 2013 *Economics of Strategy*, 6th Edition. Chapter 4. New York: Wiley

systems have responded to the call for ACO's, bundled payments, and other forms of value purchasing by vertically integrating with physician practices, raising the concern of noncompetitive vertically integrated markets.⁴⁶ Why not allow an alternative to the existing hospital-dominated integration by permitting physicians to acquire hospitals and to compete as vertically integrated systems delivering an overall health care product?

The “Cherry Picking” and “Self-Referral” Fallacies

Opponents of POHs point out that they tend to treat patients who are less severely ill and less costly to treat than patients treated for the same conditions in general hospitals. They misleadingly call this “cherry picking” conduct that they ascribe to the physician owners. CMS studied referral patterns associated with specialty hospitals and concluded that it “did not see clear, consistent patterns for referring to specialty hospitals among physician owners relative to their peers.”⁴⁷ CMS concluded “we are unable to conclude that referrals were driven primarily based on incentives for financial gain.”⁴⁸

CMS found that while patients treated in general hospitals are more severely ill than those treated in specialty hospitals, this was true both for patients admitted by physicians with ownership in specialty hospitals and by other physicians without such ownership. That is, CMS’ analysis found no difference in referral patterns to general hospitals between physician owners and non-owners. CMS concluded that the lower severity levels seen in specialty hospitals “may be an indicator of quality in the sense that it shows that the hospital has focused on a particular type of patient. A hospital that accepts patients that it cannot properly treat may not exhibit good quality healthcare.”⁴⁹

If in 2005, when CMS conducted its comprehensive POH study there was no evidence of physician abusive referral practices for financial gain, there should be even less likelihood of abusive referrals today when reimbursement practices are transitioning from fee for service to value-based methods. Physicians operating POHs and competing with established general hospitals are constrained from over utilizing by the new payment programs.

Clearly, the advantages of POHs should not be lost to the unsubstantiated fears of “cherry picking” or self-referral. This is especially true presently when new entry into many hospital markets is critical to their competitiveness and when alternative delivery and payment models requiring physicians to control hospital costs are the order of the day.

The AMA strongly urges the Administration to take steps to encourage new entry into the hospital market.⁵⁰ We urge the Administration to remove any barriers to hospital market entry. Low hanging fruit are the barriers that the government itself has erected. This includes eliminating the restraints the ACA placed on physician-owned hospitals. A step in the right direction is the proposed CMS rule that unburdens physician owned high Medicaid facilities from the restraints imposed on applicable hospitals.

⁴⁶ Synthesis Project, *supra* note 19, at 6.

⁴⁷ CMS Report, *supra* note 15, at 26.

⁴⁸ *Id.*

⁴⁹ *Id.* at 61.

⁵⁰ *Id.*

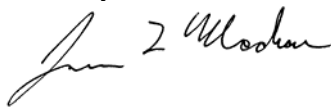
Opportunity for Community Input When a High Medicaid Facility Applies For An Exception To The Prohibition on Expansion of Facility Capacity

Section 1877(i)(3)(A)(ii) of the Social Security Act (the Act) requires CMS to provide an opportunity for community input when an applicable hospital applies for an exception to the prohibition on expansion of facility capacity. Through regulation, CMS made the community input opportunity applicable to facility expansion requests submitted by high Medicaid facilities.⁵¹ However, the statute does not expressly require CMS to furnish an opportunity for community input when a high Medicaid facility has applied for such an exception. As a result, CMS is asking for public comment on whether the Agency should eliminate the opportunity for community input in the review process with respect to high Medicaid facilities.⁵² Specifically, in its proposal CMS states, “We note that obtaining independent confirmation of the data furnished by a high Medicaid facility could delay or add complexity to the review process.”⁵³

The AMA agrees with CMS. The AMA believes that obtaining independent confirmation of the data furnished by a high Medicaid facility could in fact delay, hinder, and unnecessarily complicate the review process. As discussed above, studies show that POHs provide their communities with significant benefits, including higher quality care at a lower cost. In addition, a CMS study comparing the community benefits of physician owned specialty hospitals with community general hospitals found that the total proportion of net revenue that specialty hospitals devoted to uncompensated care and taxes combined exceeded the proportion of net revenues that community hospitals devoted to uncompensated care. Accordingly, the study concluded that the physician-owned specialty hospitals exhibited higher levels of net community benefits.⁵⁴ **Therefore, the AMA urges CMS to eliminate the community input opportunity for requests by high Medicaid facilities.**

The AMA appreciates the opportunity to provide input on this proposed rule. 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

⁵¹ 76 Federal Register (FR) 74523.

⁵² 85 FR 49038.

⁵³ *Id.*

⁵⁴ CMS Report, *supra* note 15, at 63