RRC
Regulatory Relief Coalition

Protecting patients' timely access to care.

April 16, 2024

William N. Parham, III
Director, Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs Division of Regulations Development
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Submitted electronically to regulations.gov

Re: Prior Authorization Demonstration for Certain Ambulatory Surgical Center (ASC) Services (CMS-10884)

Dear Mr. Parham,

The Regulatory Relief Coalition (RRC) is pleased to have the opportunity to comment on CMS' notice (the PA ASC Notice) announcing its intention to collect information from the public in conjunction with a potential demonstration project that would require Ambulatory Surgical Centers (ASCs) to obtain prior authorization (PA) before providing certain surgical procedures (Selected Procedures) to Medicare beneficiaries. The RRC is a coalition of national physician specialty organizations seeking to reduce regulatory burdens that interfere with patient care. Our recent activities focus on ensuring that utilization review policies are not a barrier to timely and equitable access to care for the patients we serve. The RRC has several questions and concerns regarding the proposed information collection activity.

Summarizing:

- It has become evident that the use of PA may result in significant barriers to access—barriers that have been recognized both by Congress and by CMS itself.
- The objective of the proposed demonstration project is to address a surge in ASC utilization of the Selected Procedures—a surge which, based on data gathered by the the Ambulatory Surgery Center Association (ASCA)-- has not occurred.
- The use of PA in hospital outpatient departments, upon which the proposed demonstration is modeled, still is not working as intended.
- The ASC PA Notice significantly understates the costs of the proposed demonstration project for providers.
- The proposed demonstration project is highly likely to cost more than it saves.
- CMS has cited no evidence of fraud and abuse to support the proposed demonstration project.

- CMS does not have clear statutory authority to implement the proposed demonstration project without complying with notice and public comment rulemaking procedures.

First, the RRC is extremely concerned that CMS is incorporating PA — traditionally a utilization control process used by managed care organizations — into the Medicare Fee-for-Service (FFS) Program. Over the past 10 years, health plans have increasingly used PA to inappropriately delay and deny patients access to medically necessary care while simultaneously significantly increasing provider burden and administrative costs. In fact, in light of the growing number of Medicare beneficiaries enrolled in MA plans and their ubiquitous use of PA, legislation — the *Improving Seniors' Timely Access to Care Act* (S. 3018/H.R. 3173) — advanced in Congress to streamline and increase oversight of PA in MA. Endorsed by more than 500 patient and provider organizations and supported by 350 members of the House and Senate, these bills demonstrate the clear consensus that PA must be reformed and right-sized, not expanded. Thus, the RRC believes it is inappropriate for Medicare to further extend the use of these same processes to ASCs or any other FFS provider without clear and convincing evidence that requiring PA is the only way to curb medically unnecessary utilization or address other pressing public policy concerns that cannot be addressed by more targeted and specific approaches.

Second, based on data cited by the ASCA in their comments on the PA ASC Notice, it appears that there is some dispute regarding the whether, and to what extent, there has been an increase in ASC utilization for the 40 procedures targeted by the proposed demonstration project. CMS indicates that data "from 2019 to 2021 shows these services have experienced significant increases in utilization in the ASC setting." It is based on this analysis that CMS evidently suspects fraud. However, we understand from ASCA that, of the forty codes listed, there is only **one** code, J0585, which saw an increase from 2019 to 2021, and the increase for that code over the 2019-2021 timeframe was 1.5%. Based on this data, it does not appear that the need for the proposed demonstration has been established.

Third, the initial adoption of hospital outpatient PA requirements in the CY 2020 Hospital Outpatient Prospective Payment System (HOPPS) Final Rule (CMS-1717-FC) for five procedures[1] constituted a significant departure from traditional Medicare claims processing practices. Nevertheless, before the agency and the Medicare Administrative Contractors (MACs) even had an opportunity to assess this new system, effective July 1, 2021, CMS added certain spine-related procedures to the list of hospital outpatient services subject to PA.[2] Even now, there is significant evidence that the HOPPS PA program still is not working as intended.[3] Under these circumstances, we do not believe extending the PA requirements modeled on the HOPPS program to the ASC setting is appropriate.

Fourth, we are concerned that CMS is significantly underestimating the costs involved for both ASCs and physicians to secure PA for the selected procedures. CMS estimates that physicians and their staff will spend an average of 30 minutes on PA clerical activities for PA for the Selected Procedures and that PA will not increase the time already required to document the medical necessity of the Selected Procedures. While CMS has recognized the extraordinary burden posed by PA for both providers and

[1] Blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.
[2] Implanted spinal neurostimulators and cervical fusion with disc removal.
[3] We understand that, since 2021, ophthalmologists shared reports of confusing and improper PA denials of medically necessary injections of botulinum toxins, resulting from Medicare Administrative Contractors' dated and restrictive of FDA labeling. We believe that expansion of prior authorization requirements to the ASC setting has the potential to complicate professional society efforts to ensure the outdated coverage policies for these services are updated and extra label applications of botulinum toxins are covered in accordance with professional society guidelines and contemporary standards of practice.

patients in other contexts, the PA ASC Notice fails to recognize the nature and extent of this burden. Surveys conducted by both the AMA and the RRC provide extensive data on PA costs that evidently were not considered in preparing the PA ASC Notice estimate.[4] In fact, CMS itself conducted a comprehensive analysis of the costs of PA in conjunction with its analysis of the potential economic impact of the electronic PA (e-PA) Proposed Rule,[5] which, unlike the PA ASC Notice, recognizes not only the costs of PA to providers, payers, and patients but also the impact that PA has on patient access to medically necessary services. In fact, the Regulatory Impact Statement accompanying the e-PA Proposed Rule found that streamlining PA would reduce provider administrative costs, resulting in savings of $16 billion over 10 years.

Fifth, it does not appear that the imposition of PA for the Selected Procedures will be cost-effective. CMS estimates the proposed demonstration project will cost approximately $4.6 million annually. Furthermore, payment for several of the Selected Procedures appears to be packaged, with no separate payment allowed. Therefore, requiring PA for these procedures imposes costs for providers and the Medicare program with no potential savings. Likewise, it appears that at least some of the Selected Procedures are performed in ASC settings relatively infrequently. For example, only 0.1% of two ophthalmic procedures involving the administration of botulinum toxin are performed in ASC settings, with the great bulk of procedures performed in physicians' offices. This practice pattern strongly suggests that the ASC setting is utilized only when a patient's condition requires a more intensive practice setting.

Sixth, while the ASC PA Notice suggests that the imposition of PA requirements for the Selected Procedures is necessary due to concerns about fraud and abuse, CMS has not cited any evidence supporting this rationale for the proposed demonstration project, and the utilization pattern for at least some of the Selected Procedures undermines the implication of fraud. For example, based on data from the AMA RVS Update Committee database, total Medicare FFS claims volumes (across all settings of care) for the two highest-spend ophthalmic procedures (15823 and 67904) included on the list proposed to be subjected to PA have *decreased* over the last decade. Furthermore, many of the procedures on the list are frequently performed in office settings, where no facility fee is available, suggesting that financial considerations are not motivating physicians' choice of site of service. Rather than inferring fraud, it would be far more reasonable to assume that imposing burdensome PA requirements on the Selected Procedure incentivized a shift from hospital outpatient departments to the ASC setting.

Finally, we do not believe that the statutory authority cited by CMS for the proposed demonstration project authorizes the agency to proceed without publishing the proposed demonstration project as a Proposed Rule for public comment. The ASC PA Notice cites 42 U.S.C § 1395b–1(a)(1)(J) as the statutory authority for the proposed ASC PA demonstration project. That provision of the Medicare Act authorizes the Secretary to engage in demonstration projects "to develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under {Medicare and Medicaid Programs}." As set forth above, CMS has not cited any evidence of fraud that would support the imposition of PA requirements on ASCs for the Selected Procedures. Again, to the extent that the site of service has shifted from hospital outpatient departments to ASC settings, that shift is much more likely

[4] The AMA survey indicates that physicians spend an average of 14 hours weekly on PA and that nearly two in five physicians employ staff who work exclusively on PA, while the RRC survey found that that nearly three in five physicians employ staff to work exclusively on PA, most of which spend between 10-20 hours per week on PA.
[5] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes, 87 Fed. Reg. 76238 (Dec. 13, 2022).

a response to the delays and burdensome administrative requirements imposed by the HOPPS PA program than evidence of fraud by either ASCs or performing surgeons. CMS has not performed any focused audits or other studies that would suggest that those procedures that shifted from hospital outpatient to ASC settings would have been denied if they had been performed in hospital settings. Without additional evidence of fraud, we do not believe the proposed demonstration project is supported by the statutory authority cited in the ASC PA Notice.

However, even assuming (but not conceding) that the site of service shift observed by CMS constitutes sufficient evidence of fraud to warrant the ASC PA demonstration project, the governing statute requires that the Secretary undertake certain steps before instituting the demonstration. Specifically, 42 U.S.C. §1395b–1(b) requires that, before instituting such a demonstration, the Secretary must:

> Obtain[] the advice and recommendations of specialists who are competent to evaluate the proposed experiment or demonstration project as to the soundness of its objectives, the possibilities of securing productive results, the adequacy of resources to conduct the proposed experiment or demonstration project, and its relationship to other similar experiments and projects already completed or in process.

So far as RRC is aware, no ASC or PA "specialists" were retained to conduct the required analysis and if they were, no report has been made available to the public.

Moreover, even if such a study were obtained, the governing statute does not explicitly authorize the Secretary to institute a demonstration project under the authority of Section 1395b-1 without undertaking notice or comment rulemaking where, as here, an otherwise applicable regulation is implicated. In this case, if an ASC fails to obtain PA, the proposed demonstration project impacts a beneficiary's right to have payment made on his or her behalf for medically necessary Select Procedures. While the statute provides the Secretary authority to waive payment and reimbursement rules, it does not explicitly or implicitly authorize such waiver without notice and comment rulemaking, especially where, as here, a demonstration implicates established coverage and claims processing rules.

In light of the potential for the proposed demonstration project to result in significant delays in providing medically necessary care and considering the other concerns detailed above, the RRC respectfully requests that CMS refrain from implementing the proposed ASC PA demonstration project. Rather, we suggest that CMS consider alternative ways to address concerns about potential overutilization in ASC settings for performing procedures subject to PA in hospital outpatient settings by, for example, conducting special audits or retroactive reviews when utilization patterns suggesting fraud are detected.

Thank you for considering our comments and recommendations. Please contact Diane Millman (Diane.Millman@PowersLaw.com), RRC's Regulatory Counsel, if you have any questions or need additional information.

Respectfully,

American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Orthopaedic Surgeons
American Academy of Physical Medicine & Rehabilitation

American Association of Neurological Surgeons
American College of Surgeons
American Gastroenterological Association
American Osteopathic Association
Congress of Neurological Surgeons
Medical Group Management Association