

June 15, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0062–P
7500 Security Blvd
Baltimore, MD 21244-1850

Submitted electronically via www.regulations.gov

Re: File Code [CMS–0062–P] RIN 0938–AV44; Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges

Dear Administrator Oz,

The American Society of Retina Specialists (ASRS) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services’ (CMS) Proposed Rule.

ASRS is the largest retina organization in the world, representing over 3,500 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

ASRS thanks CMS for issuing this proposed rule and strongly supports proposals included in it to extend existing requirements that insurers implement interoperable standards and application programming interfaces (APIs) to all drugs—especially those administered by physicians—for prior authorization. Retina specialists administer drugs that are regularly subject to prior authorization in the office setting, commonly known as Part B drugs, to patients suffering from chronic, blinding eye disease. When CMS made its previous proposal to establish these policies for non-drug services, we requested the agency include Part B drugs because their claims are adjudicated and reimbursed through the same system as other included items, such as imaging or surgical procedures. We greatly appreciate that CMS is now proposing to modify these regulations and include drugs to ensure patients receive timely access to care and physician practices experience some relief from insurers’ onerous administrative requirements. **We encourage CMS to finalize these proposals.**

Please find a summary of our comments on provisions of the proposed rule as well as our full comments below.

- **General support for CMS’ proposals to require included payers to implement electronic interoperability and prior authorization standards for all drugs, but a continued recommendation that CMS discourage the use of prior authorization for**

drugs and services that are routinely approved. ASRS supports established deadlines for routine and urgent prior authorization requests but recommends CMS work toward facilitating the framework to mandate real-time prior authorization decisions.

- ASRS supports including drug formularies, whether prior authorization is required for certain drugs, and information about the patient’s current authorizations as required payer-to-provider and payer-to-payer interoperable information.
- ASRS supports the proposal to require insurers provide a clear reason for denials.
- ASRS agrees with CMS that it should maintain a centralized registry of payer API endpoints.
- CMS should increase enforcement of existing prior authorization and step therapy requirements to prevent patients from having to restart treatment if they move or change plans. In addition, it should prohibit plans from requiring additional utilization management for bilateral disease.
- ASRS supports increasing transparency through public reporting of payer drug prior authorization statistics, including updates to existing data reporting requirements for non-drug items and services.
- Responses to requests for information:
 - **ASRS maintains its strong opposition to step therapy in the Medicare Advantage (MA) program, and across payer types. We reiterate our concerns that administrative burdens that may be alleviated by this proposed rule do not outweigh the potential harm to patients caused by step therapy. We continue to recommend that CMS revoke MA plans’ ability to use step therapy.**
 - ASRS appreciates that CMS aims for the Original Medicare fee-for-service program to be a “market leader” in prior authorization but strongly opposes expanding prior authorization into traditional Medicare.
 - ASRS encourages CMS to develop tools that assist physicians, particularly those in small or independent practices, like many retina specialists, prevent and recover from the increasing threat of cyber-attacks.

ELECTRONIC PRIOR AUTHORIZATION FOR DRUGS

As noted above, ASRS thanks CMS for the provisions in the proposed rule that would extend existing electronic prior authorization requirements to all drugs. In general, we support their implementation to ensure beneficiaries receive faster access to medically necessary care. Before commenting on individual proposals, however, ASRS would be remiss without restating our long-standing opposition to the utilization management tactics regularly employed by MA and other private plans that delay care and lead to worse outcomes for patients.

We strongly believe that prior authorization, like step therapy discussed later in this comment letter, is over-used by plans and leads to no measurable benefit for beneficiaries. Furthermore, retina practices

regularly report that insurers are not even adhering to the existing guardrails around prior authorization and step therapy by regularly requiring both for patients established and stable on a treatment. In MA, CMS currently requires approvals for a course of treatment to remain valid for as long as medically reasonable and necessary (42 C.F.R. § 422.101(b)(7)); and requires continuity-of-care protections for patients in active treatment that move or change plans (42 C.F.R. § 422.112(b)(8)). In addition, CMS's step therapy policy for Part B drugs applies only to patients beginning treatment rather than patients established and stable on therapy (42 C.F.R. § 422.136). Proposals in this rule may facilitate the exchange of information to ensure these policies are applied only to the patients that are truly eligible, but CMS must make a commitment to hold insurers accountable and seek to limit the use of these tactics.

Retina specialists who treat chronic, blinding eye disease, such as age-related macular degeneration and diabetic eye disease, must regularly seek authorization from insurers to administer or change anti-neovascular growth factor (anti-VEGF) medications. Since nearly all patients with chronic retinal disease are Medicare-eligible, the growth in MA has led to an exponential increase in the administrative work required to secure coverage for drugs with a strong track record of clinical efficacy of helping patients maintain independence and preventing other serious complications, such as falls or depression.^{1, 2, 3}

Delaying care for chronic retinal disease not only risks those other complications, but it also creates a significant burden on patients. When a patient is diagnosed with retinal disease or their disease progresses, retina specialists are ready to treat them on the spot. But payer-mandated authorizations mean the typically elderly patient, and a caregiver, will have to come back another day for treatment. That risks further progression of their disease and takes away an appointment slot that could be used by another patient.

Evidence also suggests insurers agree that retina specialists provide necessary care. A study found that retina specialists' requests for authorization were approved 96% of the time. Yet the work involved in obtaining authorization amounted to a median time of 100 minutes of clinical staff time and more than half of patients experienced a delay in care.⁴ The HHS OIG has also found that prior authorization is overused, and many MA plans deny care that would otherwise be covered by original Medicare.⁵

To manage the overwhelming task of dealing with MA plans' prior authorization, retina specialists have had to redesign their practices. ASRS members recount that plans often have poorly defined coverage policies or do not honor existing authorizations when a patient changes plans or moves. Since many patients experience bilateral eye disease, the administrative process is frequently doubled for retina

¹ Fonteh, C.N., Mathias, M.T., Mandava, N. *et al.* Mental health and visual acuity in patients with age-related macular degeneration. *BMC Ophthalmol* 22, 391 (2022). <https://doi.org/10.1186/s12886-022-02602-9>

² Demmin, D. L., & Silverstein, S. M. (2020). Visual Impairment and Mental Health: Unmet Needs and Treatment Options. *Clinical Ophthalmology*, 14, 4229–4251. <https://doi.org/10.2147/OPHTH.S258783>

³ Virgili G, Parravano M, Petri D, Maurutto E, Menchini F, Lanzetta P, Varano M, Mariotti SP, Cherubini A, Lucenteforte E. The Association between Vision Impairment and Depression: A Systematic Review of Population-Based Studies. *Journal of Clinical Medicine*. 2022; 11(9):2412. <https://doi.org/10.3390/jcm11092412>

⁴ Dang, et. al. "Anti-VEGF Pharmaceutical Prior Authorization in Retina Practices" *JAMA Ophthalmol*. 2024;142(8):716-721. doi:10.1001/jamaophthalmol.2024.2217

⁵ U.S. Department of Health and Human Services, Office of the Inspector General. "High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care" July, 17, 2023, <https://oig.hhs.gov/reports/all/2023/high-rates-of-prior-authorization-denials-by-some-plans-and-limited-state-oversight-raise-concerns-about-access-to-care-in-medicaid-managed-care/>

specialists, requiring separate authorizations for each eye. Managing all these varying requirements has led most practices to hire dedicated staff for prior authorization or forced some to give up independent practice by consolidating into larger or multi-specialty groups to meet rising costs.

The cost of prior authorization and other payer demands is threatening practice viability. A large practice in Tennessee notes that comparing 2019 to 2024, it employed 12-13 administrative staff per physician and now 15.28 administrative employees per physician. The practice notes that because of the complexity of the tasks required, staff costs were up 63% between 2024 and 2025. A mid-size practice in New York reports that it has had to increase the number of administrative employees from 6.25 per physician in 2019 to 7.4 in 2024. Despite these increases, practices are still struggling to meet insurer demands due to limited labor supply in most markets.

We believe that the proposals in this rule will go a long way toward addressing some of these issues, but they do not change the underlying fact that prior authorization has failed to prevent unnecessary care and is in fact limiting patient access. At a minimum, we encourage CMS to push insurers to implement systems that can provide real-time coverage decisions to ensure patients can receive the care when they need it. And we ask that if CMS finalizes the transparency measures included in this rule, that it use data collected to crack down on over-used or unnecessary utilization management by MA plans.

Required Interoperable Information

ASRS strongly supports CMS' proposals to require that information regarding drug formularies, whether prior authorization is required for certain drugs, and the status of current authorization for drugs be available in an interoperable, electronic format. These proposals will provide beneficiaries with key consumer information as they select plans, and they will assist physicians as they develop treatment plans for patients. For insurers, not only do we recommend that the proposal to make this information sharable between payers be made available, but we urge CMS to require plans to access and honor that information. As mentioned above, plans habitually ignore existing regulations that protect patients from having to seek re-authorization or re-start step therapy if they are stable on a medication and switch plans. If these proposals are finalized, plans will have no excuse not to access this information and should be held accountable for acting on it.

Clear Denial Rationale

ASRS also strongly supports CMS' proposal to require plans provide a clear reason for denying a request for prior authorization. With the data referenced above showing that almost all authorizations are approved, on the rare occasions they are not, it is often due to poor communication from the insurer on what information or documentation was required, or what clinical circumstances would lead to an authorization. Clear parameters on what information the insurer needs and how it will be evaluated should be provided in advance, but at a minimum, specific reasoning for a denial could facilitate a smoother appeals process or prevent future misunderstanding.

Centralized Payer API Endpoint Registry

ASRS strongly supports the proposal for CMS to create and manage a centralized payer API endpoint registry. This proposed registry will allow EHRs and app developers easier access to payer prior authorization information for patients and physicians. As with other examples in our comments, ASRS is concerned that insurers may not adhere to the regulations proposed in this rule. Providing a public database with requirements for regular updates will assist in holding insurers accountable. We recommend CMS move quickly to establish this registry.

ENFORCEMENT OF EXISTING REGULATIONS

As noted above, retina specialists and their patients frequently encounter MA plans that are not following the existing rules around prior authorization. Prior authorization is meant to prevent ineffective or unnecessary care; however, payers apply it indiscriminately and often do not honor existing determinations that have established the care a patient is receiving as necessary. When patients move, or switch plans, retina specialists are often required to obtain reauthorization or restart step therapy for treatment of stable patients. Another frequent occurrence when treating retinal disease is a requirement for prior authorization or step therapy for treatment of the fellow eye when a patient is already stable and responding to treatment in the initial eye treated. Retinal disease is often bilateral but may not progress at the same rate in each eye. Obtaining reauthorization, new fellow eye authorization and re-starting step therapy all have the same impact of delaying treatment, potentially worsening disease, and further burdening patients. **We strongly recommend that CMS vigorously enforce the proposals in this rule and ensure that payers are adhering to existing regulations.**

PRIOR AUTHORIZATION DATA TRANSPARENCY

ASRS strongly supports the updated and expanded proposals in this rule for mandatory reporting of key prior authorization data. We believe these data will assist beneficiaries as they comparison shop for coverage. It will provide the agency with evidence to prevent plans from requiring prior authorization for items that are almost always approved or for physicians who are consistently providing clinically appropriate care. Specifically, ASRS supports proposals to expand the current prior authorization data collection requirements by including new measures:

- The numerical count of prior authorizations, denials, and appeals, a plan processes, instead of the current requirement of just reporting percentages;
- The total number and percentage of prior authorization requests that remain denied after appeal;
- The total number and percentage of expedited prior authorization requests that remain denied after appeal;
- The total number and percentage of standard prior authorization requests for which the timeframe for review was extended, and the request was denied during the reporting period; and
- The total number and percentage of approvals after denials.

ASRS believes that these new reporting requirements will make plain the scope and overwhelming volume of additional administrative work plans have placed on physician practices simply to allow them to treat patients according to the standard of care. There is no evidence to suggest that the exponential rise in prior authorization mandates from MA and other payers over the last few decades has led to lower costs or better clinical outcomes. ASRS hopes that these new data points will finally prove that prior authorization is little more than an exercise in paper shuffling that forces patients to wait for care that is nearly always approved.

CMS has floated the idea of a “gold card” program to exempt providers from some prior authorization if they have a consistent track record of approvals. We believe that the data CMS proposes to collect, at least for retina specialists, will indicate that nearly every physician should be exempted from these onerous requirements and that CMS and payer program integrity efforts should solely focus on true

outliers. We recommend CMS finalize these proposals and use the data collected to advance policies that will speed access to care.

REQUESTS FOR INFORMATION

Step Therapy

ASRS has long-standing, established opposition to step therapy. While we appreciate that CMS is attempting to streamline its administrative elements by expanding the mandatory use of electronic standards to drugs, like for prior authorization this proposed rule does nothing to address the underlying problem that MA beneficiaries and patients outside of traditional Medicare, are being routinely deprived of medically necessary sight-saving care. **We continue to urge CMS to revoke plans' ability to apply this form of utilization management.**

Patients suffering from chronic retinal disease are routinely subjected to step therapy by MA and other insurers. They are required to begin treatment with Avasin (bevacizumab) that is off-label and must be repackaged for ocular use and demonstrate a lack of improvement—or “failure”—with up to three monthly doses before FDA-approved treatments are covered. With the advent of biosimilars, many plans have added multiple “steps” to their policies before patients can access the newest generation of more durable medicines. Patients must endure this for each eye and prior authorization—and all the hassles and delays outlined above—is required at each step.

Other factors routinely complicate the process further. The fragile supply chain for Avastin has led to several shortages over the last few years and there is limited commercial availability for some biosimilars. Exceptions or appeals, even when a required drug is unavailable, are rarely granted. This all results in a typical patient having to wait months before receiving the medication his or her retina specialist has determined is most appropriate.

Streamlined, electronic standards proposed in this rule will have some positive impact on the work practices must do to advance patients through a step therapy regimen, but allowing step therapy to continue prevents patients from not only achieving the best current possible outcomes, but also stands in the way of developing better, more cost-effective treatments. It is well established that early intervention to stop or slow progression, paired with ongoing treatment, leads to the best outcomes and helps maintain patients' quality of life. Since the treatment burden associated with chronic retinal disease can be high, retina specialists are researching ways to cut down on visits, imaging, and injections. Recent breakthroughs have focused on addressing this, and so the newer generation of treatments such as Vabysmo (faricimab) and Eylea HD (aflibercept), are longer-lasting and lead to better clinical outcomes. Still more research is underway to reduce treatment burden, such as through gene therapy, but it is unclear whether insurers will embrace innovations on the horizon or maintain step therapy policies solely dictated by price.

ASRS continues to urge CMS to prohibit plans' ability to implement step therapy. At a minimum, however, we recommend that CMS extend some of our suggested reforms to prior authorization discussed above to step therapy as well. The interoperability of these proposed electronic standards should facilitate the same payer-to-payer data exchange so that patients who move or switch plans will not have to restart step therapy. Similarly, if a patient has gone through step therapy and is stable on a particular medication in one eye, they should not have to repeat the steps to receive the same treatment in the other eye. CMS should also look at trends in the data plans will be required to report to

indicate where step therapy may not be warranted due to a high percentage of patients ultimately needing drugs from the last steps. As with prior authorization, we also urge CMS to investigate and hold plans who do not comply with these regulations accountable.

Prior Authorization in Original Medicare

For the reasons described above, ASRS strongly opposes any effort to implement or expand prior authorization into traditional fee-for-service Medicare. We recognize that CMS seeks to be a “market leader” in this area but would argue that Original Medicare *already is* the market leader whereby it honors the patient-physician relationship to decide on the most appropriate treatment plan and does not impose barriers to care.

Even with the new standards proposed in this rule, we are dubious that an Original Medicare prior authorization program would be any more effective or efficient than those administered by private plans. Retina specialists do not perform any of the surgeries that currently require prior authorization in Medicare, such as blepharoplasty, and no ophthalmic procedures are included in the WISeR model. However, accounts from other ophthalmic sub-specialists and across medicine indicate that these programs are no improvement over private plans. The artificial intelligence (AI) element of the WISeR model is also especially concerning as it potentially removes physician judgement from prior authorization decisions and incentivizes vendors to deny care.

Beneficiaries who are in Original Medicare have chosen it because it provides the most comprehensive and timely care. We caution CMS from potentially harming its reputation and value to beneficiaries by introducing ill-conceived elements from the private market like prior authorization.

Cybersecurity RFI

ASRS strongly supports CMS’ efforts to strengthen, protect, and increase the resiliency of our healthcare system through cybersecurity. Over the past few years, retina practices nationwide have been the victim of cybercrimes and ASRS members have taken significant action to prevent attacks that jeopardize patient personal data, clinical operations, and the financial health of their practices. We thank CMS for prioritizing this subject and recommend the agency work with the medical community to develop solutions that are practical and feasible for all practice sizes and settings to implement.

Physician practices should not be held responsible for the cybersecurity lapses by other actors in the healthcare system. We encourage CMS to consider ways to incentivize cybersecurity protections across the system, including payers, device manufacturers, and software vendors. Last year, retina specialists and providers across the system were paralyzed by an attack on the Change Healthcare clearinghouse—through no fault of their own. This massive attack demonstrated the interconnectedness of the healthcare system, showing that one seemingly isolated incident where basic security protocols were not followed had major repercussions for patients and providers nationwide. We urge CMS to identify ways to hold insurers, vendors, and other intermediaries with access to electronic patient data accountable for cybersecurity risks.

In addition, CMS should focus on supporting physician practices through flexible, non-punitive cybersecurity policies rather than imposing additional compliance burdens. We join with others in the medical community recommending CMS assist practices by expanding technical assistance, offering financial support and hardship relief following cyberattacks, and promoting cybersecurity best practices appropriate for practices of varying sizes and resources. CMS should also seek to limit physician liability when practices are acting in good faith to implement reasonable safeguards, recognizing that many

cyber incidents originate through vulnerabilities in third-party vendors and external healthcare infrastructure outside physicians' direct control. Incentive-based approaches that strengthen preparedness and recovery across the healthcare ecosystem will be more effective than additional punitive requirements placed solely on physician practices.

CONCLUSION

Thank you again for the opportunity to provide comments on this proposed rule. If you have questions, please contact Allison Madson, vice president of health policy, at allison.madson@asrs.org.

Sincerely,



Geoffrey G. Emerson, MD, PhD, FASRS
President
American Society of Retina Specialists