AMERICAN COLLEGE of RHEUMATOLOGY
Empowering Rheumatology Professionals

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May 12, 2025

Russell Vought, JD
Director
Office of Management and Budget
Executive Office of the President

Submitted electronically via regulations.gov

RE: **Request for Information: Deregulation**

Dear Director Vought:

The American College of Rheumatology (ACR), representing over 10,000 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the Office of Management and Budget's (OMB) request for information (RFI) on regulations that are unnecessary, unlawful, unduly burdensome, or unsound, and thus stifle American businesses. As the OMB plays a crucial role in reviewing and shaping federal regulations, the ACR applauds its willingness to spotlight, amend, or remove regulations that have made it difficult for rheumatology practices to provide high quality care. Particularly in the current environment of high inflation and vertical integration, certain regulatory requirements have been significant contributing factors to physician burnout and shortages.

Rheumatology practices play a vital role in delivering accessible, personalized care to communities. However, the cumulative effect of regulatory mandates threatens their ability to continue doing so. Specifically, the ACR highlights the following areas of concern.

Prior Authorization in Medicare Part D and Medicare Advantage

Private insurers that administer either Medicare Part D or Medicare Advantage plans require prior authorization (PA) for a wide range of services—diagnostic imaging, prescribed medications, physical therapy, and even routine procedures. PA is intended to manage costs and ensure appropriate care. However, these administrative processes are disproportionately burdensome for rheumatologists, especially those in independent practice settings, undermining their ability to compete with large corporate healthcare systems.

Unfortunately, an ever-growing portion of rheumatologists' time is now spent navigating complex, inconsistent, and often duplicative PA processes. While these pre-authorization measures were put in place with the envisioned goal of optimizing care, they are increasingly harming the very patients they aim to protect. Many rheumatology practices do not have the luxury of dedicated PA teams or automated technologies. Each PA request requires physician time and effort, which negatively impacts their ability to provide direct patient care. The barriers

imposed by PA often result in postponed treatments, unfilled prescriptions, and denied services, thereby jeopardizing both patient outcomes and practice sustainability.

Further, these burdensome PA processes fuel physician burnout. According to a 2024 survey from the American Medical Association, physicians complete an average of 39 PAs per week, spending approximately 13 hours on the process. As a result, 89% of physicians report that PA somewhat or significantly contributes to burnout.[1] Administrative burden and physician burnout are significant contributing factors to physicians leaving medicine.[2,3] This is particularly concerning in rheumatology, where recent research has predicted that the number of rheumatologists in the United States will decrease by over 30% by 2030.[4]

The ACR urges the Trump Administration to replace or amend current regulations in the following ways:

- Replace or amend 42 CFR § 422.138, 42 CFR § 422.122, and 42 CFR § 423.120 with 1) more standardized and streamlined PA requirements across Medicare Advantage and Part D plans; 2) the elimination of additional PA for chronic patients who are stable on a specific medication or therapy by making prior authorization approvals extend for the duration of the treatment without the need for additional or annual renewal; 3) the elimination of PA for medications that do not have an equally effective alternative; and 4) the option for providers to submit a PA electronically.[5,6,7]
- Replace or amend 42 CFR § 422.568 and 42 CFR § 422.572 with language that requires more timely decision-making in PA processes.[8,9]
- Implement "gold carding" programs to reduce PA requirements, inclusive of medications, for providers with high approval rates.
- Replace or amend 42 CFR § 422.111 to mandate transparency and accountability in payer PA practices and denial data.[10]

Step Therapy in Medicare Advantage and Medicare Parts B and D

Step therapy protocols often delay access to clinically appropriate treatments. Patients are required to "fail first" on lower-cost medications before insurers authorize the treatments rheumatologists determine would be most effective for their patient. While this is aggravating for

[1] American Medical Association. 2024 AMA Prior Authorization Physician Survey. 2025. https://www.ama-assn.org/system/files/prior-authorization-survey.pdf
[2] Fred HL and Scheid MS. Physician Burnout: Causes, Consequences, and Cures. Tex Heart Inst J. 2018 Aug 1;45(4):198-202.
[3] Woolhandler S, et al. Administrative work consumes one-sixth of U.S. physicians' working hours and lowers their career satisfaction. Int J Health Serv. 2014;44(4):635-42.
[4] Battafarano DF, et al. 2015 American College of Rheumatology Workforce Study: Supply and Demand Projections of Adult Rheumatology Workforce, 2015-2030. Arthritis Care Res (Hoboken). 2018 Apr;70(4):617-626.
[5] 42 CFR § 422.138
[6] 42 CFR § 422.122
[7] 42 CFR § 423.120
[8] 42 CFR § 422.568
[9] 42 CFR § 422.572
[10] 42 CFR § 422.111

any provider, the burden is particularly severe in the many rheumatology practices that lack the administrative infrastructure to manage time-consuming appeals and documentation. These practices must divert scarce time and resources from patient care to manage bureaucratic hurdles. These inefficiencies:

- Delay treatment, leading to worse patient outcomes.
- Frustrate patients, who may seek care elsewhere.
- Threaten the viability of providers who cannot absorb the administrative and financial cost of compliance.
- Lead to physician burnout and exacerbate workforce shortages.[11]

As such, we urge the Trump Administration to do the following:

- Amend 42 CFR § 422.136 and 42 CFR § 423.104 to bar the use of step therapy in Medicare Advantage and Part D plans, and in Part B drug distribution.[12,13]
- Rescind the 2018 memorandum "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage," to ensure beneficiaries can access alternative therapies.[14]

Pharmacy Benefit Manager (PBM) Reform

The ACR is concerned about the significant impact of pharmacy benefit manager (PBM) rebate structures on private medical practices. We have urged the Department of Health and Human Services to investigate and address the distortions these arrangements cause in patient care and provider sustainability. Rheumatologists are seeing firsthand how PBM-driven rebate systems interfere with clinical decision-making, inflate drug costs at the point of care, and systematically disadvantage independent practices in favor of vertically integrated corporate entities. This is particularly the case for biosimilars, which rheumatologists often use to treat such inflammatory diseases as rheumatoid arthritis, psoriatic arthritis, and many other rheumatic diseases.

The rebate process is multi-pronged and begins when PBMs pressure pharmaceutical companies to offer rebates in exchange for preferred formulary placement. PBM formulary committees fill their preferred tier with originator biologics rather than cost-effective biosimilar alternatives due to higher rebates. Even if biosimilars are available and offer lower upfront costs, their adoption slows if formulary decision-makers are swayed by the larger rebates offered by the originator biologic manufacturer. Limited formulary access for biosimilars increases the costs for our patients as well as the healthcare system.

When the manufacturers of biosimilars are able to break through and gain formulary access, it is often because they offer these rebates, which lead to a reduction in their Average Sales Price (ASP) and forms the basis for drug reimbursement being below providers' acquisition costs.

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[11] Yates, SW. Physician Burnout. The American Journal of Medicine. 2020. Feb Volume 133, Issue 2, p160-164
[12] 42 CFR § 422.136
[13] 42 CFR § 423.104
[14] Centers for Medicare and Medicaid Services. Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. 2018. https://www.cms.gov/medicare/health-plans/healthplansgeninfo/downloads/ma_step_therapy_hpms_memo_8_7_2018.pdf

This occurs because drug manufacturers are required by law to include rebate information in their quarterly ASP reports to the Centers for Medicare and Medicaid Services (CMS), which then uses the information to calculate payment limits to providers for infusing these drugs. However, these rebates are not passed to the practices who purchase the medications through the commonly employed "buy-and-bill" mechanism. Margins for practices engaged in buy and bill are thin. When the acquisition cost of a biosimilar exceeds its reimbursement, a practice is "underwater" on that drug, and they would usually choose not to offer infusion of that drug in their clinic. The impact of this issue is multi-faceted:

- Rebates favor volume over value, prioritizing high-cost drugs with larger manufacturer rebates over clinically appropriate or more affordable alternatives. As a result, patients face higher out-of-pocket costs unless rheumatologists prescribe medications that align with PBM rebate incentives, not necessarily what is best for their health.
- Independent rheumatology practices usually lack leverage to negotiate or benefit from these rebates, making it more expensive to provide and manage care in their settings compared to large health systems or PBM-affiliated pharmacies.
- Administrative burdens, such as prior authorizations and formulary restrictions, disproportionately impact smaller practices that cannot dedicate full-time staff to navigate PBM bureaucracy. This not only delays care but also drives many rheumatologists toward employment by large systems as a matter of financial survival.
- The current system incentivizes market consolidation, shrinking the range of care options.

We also note that while a final rule in 2020 removed certain protections for these rebates from the Anti-Kickback Statute, it also created new ones: 1) a safe harbor applicable to certain prescription drug point-of-sale discounts as offered to Medicare and Medicaid beneficiaries to reduce their direct out-of-pocket prescription drug costs (the "Point-of-Sale Safe Harbor"), and (2) a safe harbor applicable to flat fee arrangements paid by drug companies directly to PBMs for PBM services (the "PBM Service Fees Safe Harbor").[15,16] However, the Anti-Kickback Statute is a law designed to prevent **any** financial incentives — such as payments from drug manufacturers that seek to encourage PBMs to give better insurance coverage to their medications — from influencing healthcare decision-making. Whether they are rebates or "flat fee arrangements," the benefits are not being passed down to providers or patients.

Finally, the combination of PBMs and antitrust issues is linked to physician burnout due to several factors, including increased workloads, reduced reimbursement, and the impact on patient care. Highly concentrated PBM markets can lead to reduced competition, potentially impacting drug pricing and access, which in turn affects rheumatologists' ability to provide optimal care and contributes to burnout.[17]

[15] 85 FR 76666. Nov. 30, 2020. https://www.federalregister.gov/documents/2020/11/30/2020-25841/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals
[16] 42 CFR § 1320
[17] PBMs Are Stacking the Deck Against Patients and Independent Physician Practices

This opaque system does not serve patients, taxpayers, or the long-term health of our healthcare ecosystem. The ACR urges the Trump Administration to do the following:

- Work with Congress to amend Section 1847A(c)(4) of the Social Security Act by removing rebates from the ASP methodology.[18]
- Work with Congress to amend Section 1847A(c)(4) of the Social Security Act to extend the Secretary's authority to use wholesale acquisition cost (WAC) + 3% until ASP reaches sustainable levels, as determined by the Secretary.[19]
- Rescind the 2018 memorandum "Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage," to ensure beneficiaries can access an alternative therapy when the biosimilar reimbursement is below the ASP payment rate.[20]
- Amend 42 C.F.R. § 1001.952(dd) to remove the safe harbor exemptions applied to rebates or flat fee arrangement paid by drug manufacturers to PBMs. [21]

Medicare Telehealth Services

While telehealth has been a vital tool in expanding access to rheumatologic care—especially during the COVID-19 Public Health Emergency—many of the temporary flexibilities that enabled rheumatology practices to serve patients effectively are now set to expire on September 30, 2025. Without permanent reforms, the current trajectory for telehealth carries the risk of reducing patient access to essential care and consolidating healthcare even further into large corporate systems.

First, if the geographic restrictions are reinstated that, prior to the COVID pandemic, disallowed Medicare reimbursement of telehealth services in urban counties, beneficiaries in these areas will be prevented from receiving rheumatologic care via telehealth at home, thereby undermining access and harming urban and suburban practices. Second, to bill Medicare for a telehealth visit, the rheumatologist must currently be licensed in the state where the patient is physically located at the time of the visit. This creates a regulatory patchwork that burdens rheumatologists trying to serve out-of-state patients via telehealth. Therefore, the ACR urges the Trump Administration to do the following:

- Work with Congress to pass legislation that permanently allows for Medicare reimbursement for telehealth services, regardless of the patient's geographic location.
- Remove current Medicare restrictions on allowing physicians to treat beneficiaries across state lines via telehealth.

Health Insurance Portability and Accountability Act (HIPAA)

The ACR fully supports HIPAA's core goals of protecting patient privacy and ensuring data security**.** However, the implementation and ongoing compliance costs are disproportionately

[18] 42 U.S.C. § 1847A
[19] ibid
[20] ibid
[21] 42 CFR § 1001.952

burdensome for rheumatologists, especially those in independent practice. Many rheumatology practices must allocate precious clinical and administrative resources to manage these complex regulations, often without specialized support. This often includes:

- Conducting and documenting security risk assessments.
- Managing third-party business associate agreements.
- Monitoring cybersecurity threats and incident response protocols.
- Training staff on evolving HIPAA rules and enforcement expectations.
- Maintaining documentation to meet audit-readiness standards.

These efforts require considerable time and financial investment, often involving external consultants and software systems that are out of reach for modestly resourced practices. We urge the Trump Administration to amend 45 CFR 164 in the following ways:[22]

- Create a scaled compliance model that adjusts HIPAA requirements based on practice size and resources, while still preserving patient protections.
- Establish protections for good-faith compliance efforts in small practices, reducing the fear of disproportionate penalties for minor or first-time offenses.

Information Blocking

Under the 21st Century Cures Act, *information blocking* is defined as any practice that is likely to interfere with access, exchange, or use of electronic health information (EHI). The ONC Final Rule (*21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program)* requires healthcare providers, developers of certified health information technology (IT) and health information networks/exchanges to give patients easier access to their data without unnecessary delay or cost.[23,24] While the ACR supports patients having unimpeded access to their medical records, the rule negatively impacts rheumatology practice owners in the following ways.

First, per the rule, patient health information must be accessible, shareable, and exportable in specific formats. Rheumatologists must offer real-time patient access to clinical notes, lab results, or imaging. However, all patient health information from a designated record set must also be made available. This includes non-clinical documentation, phone call summaries, and internal notes that are not intended for patient consumption, all of which add significant documentation burden and create legal risk for language that could be misinterpreted. Furthermore, many practices don't have modern, API-capable electronic health records (EHR), and upgrading can be costly.

Second, rheumatology practices are required to share patient data freely, even with large health systems or corporate competitors. But those systems may use legal, technical, or procedural

[22] 45 CFR § 164
[23] Public Law 114-255
[24] 85 FR 25642

barriers to limit how data flows back to the practice, creating an unbalanced one-way information flow.

Third, patients are required to have immediate access to notes, test results, and reports, often before the physician has reviewed them. Patients may be confused or alarmed by raw test results and then flood the practice with questions or complaints. Many rheumatology practices do not have dedicated staff to review and explain results as they are released.

Finally, while the ONC has published exceptions to the rule (i.e. privacy, security, etc.), they are vague and may be difficult to apply without legal help. Many practices cannot afford the necessary legal counsel to assist in interpreting and implementing these regulations, leading to a risk of penalties and patient complaints. This compounds the stress and administrative burden associated with the healthcare system's increased reliance on EHRs, which has been shown to be a significant contributing factor to physician burnout.[25,26]

The ACR urges the Trump Administration to modify the ONC Final Rule (*21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*) in the following ways:

- Allow brief, reasonable delays for providers to review and contextualize lab and test results before release to patients.
- Rescind the rule's requirement to include all direct record set data and instead limit required sharing to clinical data that directly affects patient care.
- Rescind the rule's "zero-tolerance" tone for enforcement and broaden the clinical judgment exemption**.**
- Exempt practices from API-enablement requirements until EHR vendors are uniformly certified and responsible for API compliance**.**
- Add a "Good Faith Compliance" exemption for practices under a certain size or revenue threshold.

Conclusion

The ACR has long supported policies that would alleviate administrative burden and allow rheumatologists and rheumatology health professionals to provide high quality care unimpeded. We thank the OMB for allowing us the opportunity to outline the various regulations that are barriers to the practice of rheumatology and thus should be modified or rescinded. Please contact Colby Tiner, MA, Manager of Regulatory Affairs, at ctiner@rheumatology.org if you have any questions.

[25] O'Connell R, et al. Why Do Physicians Depart Their Practice? A Qualitative Study of Attrition in a Multispecialty Ambulatory Practice Network. J Am Board Fam Med. 2024 Jan 5;36(6):1050-1057

[26] Ripp JA, et al. Association of clerical burden and EHR frustration with burnout and career intentions among physician faculty in an urban academic health system. Int J Med Inform. 2025 Mar;195:105740

Sincerely,

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