July 10, 2025

The Honorable Robert F. Kennedy Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically via https://www.regulations.gov/

RE: Request for Information: Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again [Docket No. AHRQ-2025-0001-0001]

Dear Secretary Kennedy,

The American Academy of Dermatology Association (AADA) appreciates the opportunity to provide comments on the Department of Health & Human Services' (HHS) Request for Information (RFI) titled, *Ensuring Lawful Regulation and Unleashing Innovation To Make American Healthy Again*.

As the leading society in dermatological care, representing nearly 17,500 dermatologists nationwide, AADA is committed to excellence in the medical and surgical treatment of skin disease, advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease.

To support deregulation in various areas under HHS' purview and promote the health and well-being of Americans, we urge HHS to consider the following regulatory issues:

I. Medicare Physician Payment Reform and Access to Care

The AADA highlights the urgent need to modernize the Medicare Physician Fee Schedule (PFS). For calendar year 2025, physicians have experienced a 2.83 percent reduction to the PFS conversion factor relative to 2024, marking the fifth consecutive year of payment cuts. These reductions come as the cost of delivering care continues to rise, with the Medicare Economic Index, which reflects practice cost inflation, projected to increase by 3.5 percent in 2025. Despite this, physician payments remain tied to a statutory update frozen at zero percent through 2025, with only minimal updates scheduled to follow for most years thereafter.[1] The Medicare PFS is the only major Medicare payment system that lacks a

[1] H.R. 1, "The One Big Beautiful Bill Act" provides for a temporary 2.5 percent payment increase to fee schedules for 2026.

CORRESPONDENCE
PO Box 1968
Des Plaines, IL 60017-1968
EMAIL: mrc@aad.org
WEB: aad.org

ROSEMONT, IL OFFICE
9500 W Bryn Mawr Avenue, Suite 500
Rosemont, IL 60018-5216
MAIN: (847) 330-0230
FAX: (847) 240-1859

WASHINGTON, DC OFFICE
1201 Pennsylvania Avenue, NW, Suite 540
Washington, DC 20004-2401
MAIN: (202) 842-3555
FAX: (202) 842-4355

regular, inflation-based update, leaving physician practices without a reliable path to financial stability. Without sufficient updates, many practices are forced to scale back services, stop accepting new Medicare patients, or close. This directly affects access to care for beneficiaries and undermines the goal of a healthy America.

Reports from federal advisors reinforce concerns about physicians' ability to provide care under the current payment system. In June, the Medicare Trustees again warned that payment updates are not keeping pace with practice costs and that access to Medicare-participating physicians could become a significant challenge.[2] Similarly, the Medicare Payment Advisory Commission (MedPAC) called for replacing scheduled 0.25 and 0.75 percent updates beginning in 2026 with a single permanent inflation-based update tied to a portion of the growth in the Medicare Economic Index.[3] These recommendations reflect a growing consensus that the current approach for updating payments under the PFS is unsustainable.

Additionally, annual payment updates are subject to statutory budget neutrality adjustments that must be applied if certain policy changes are expected to increase or decrease payments under the PFS by more than $20 million relative to what payments would have been absent such changes. However, Congress has not updated this $20 million threshold since 1992, despite significant increases in total PFS spending over this time. Notably, such budget neutrality adjustments can result in significant reductions to the PFS conversion factor when policy changes have significant payment impacts, as has occurred in recent years. For example, in the CY 2021 Medicare PFS final rule, CMS finalized changes to office and outpatient (O/O) evaluation and management (E/M) codes that would have led to a 10.2 percent budget neutrality reduction in the PFS conversion factor for the year and steep payment cuts for a broad swath of the physician community. Congressional intervention averted the majority of these cuts and what would have been substantial financial losses for many physicians and, more importantly, maintained access for patients. However, Congressional intervention is not guaranteed – as demonstrated by lack of Congressional action to avert the 2025 payment reduction – and the risk to physician payments is real.

Furthermore, it is worth noting that the budget neutrality adjustments are often overstated, and high utilizations assumptions that are built into the calculation of the adjustments do not materialize; when an overestimation occurs, it contributes to budget neutrality reductions that remain uncorrected under current policy, resulting in unwarranted yet sustained reductions in the Medicare physician payment pool. For example, in 2013, transitional care management services were added to the PFS. While CMS estimated 5.6 million new claims, actual utilization was under 300,000 in the first year and less than a million after three years. This overestimation led to an estimated $5.2 billion reduction in Medicare

[2] Centers for Medicare & Medicaid Services, Office of the Actuary. 2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Baltimore, MD: Centers for Medicare & Medicaid Services; 2025. Published June 18, 2025. Accessed July 3, 2025. Available at: https://www.cms.gov/oact/tr/2025

[3] Medicare Payment Advisory Commission. June 2025 Report to the Congress: Medicare and the Health Care Delivery System. Washington, DC: Medicare Payment Advisory Commission; June 12, 2025. Accessed July 3, 2025. Available at: https://www.medpac.gov/document/june-2025-report-to-the-congress-medicare-and-the-health-care-delivery-system/ medpac.gov+7bgrdc.com+7medpac.gov+7

physician payments from 2013 to 2021.[4]

While we recognize that these challenges are largely based on statutory requirements that apply to the PFS, we bring them to your attention given the significant burden they impose on physician practices and the direct impact they have on beneficiary access. Solo and small-group dermatology practices, in particular, report challenges retaining staff because they cannot offer wages that compete with local hospitals or even retail employers. Members frequently say that experienced staff leave for better pay and benefits, leading to constant turnover, increased training demands, added pressure on physicians, and decreased capacity to manage patient loads.

To preserve access to care for Medicare beneficiaries, the AADA recommends that HHS work with Congress to establish a reliable, inflation-based update mechanism for physician payments and to increase the budget neutrality threshold to reflect inflation, as well as pursue corrections of erroneous utilization assumptions that contributed to unjustified budget neutrality adjustments.

II. Drug Shortages

Ongoing drug shortages continue to pose serious challenges for dermatology practices in the United States. Even routine, generic dermatologic drugs are affected by these shortages, including sodium bicarbonate and lidocaine with epinephrine. These local anesthetics are necessary for a range of office-based dermatologic procedures, including skin biopsy, excision, wound closure, tissue rearrangement, skin grafting, cauterization, non-ablative lasers, and ablative skin resurfacing.

Access to local anesthetics is critical to ensuring patient comfort and safety during dermatologic procedures. However, persistent national shortages of medications, like lidocaine, have forced dermatologists, especially those in solo and small group practices, to ration supplies or delay care. In fact, dermatologists practicing in underserved areas have reported limited to no supplies of lidocaine and lidocaine with epinephrine. Some are also facing shortages of sodium bicarbonate, which is often used to buffer lidocaine and reduce the pain of injection. These supply challenges are particularly burdensome for small and solo practices, as wholesalers tend to prioritize hospitals, health systems, and larger groups.

Although supply chain issues contribute to drug shortages, regulatory barriers are often a more significant factor. Delays in FDA approvals, limited transparency around manufacturing disruptions, and burdensome post-approval requirements reduce manufacturers' ability to respond to supply challenges. This is particularly true for commonly used dermatologic medications, such as sterile injectables, which are more complex to produce and less profitable, making them less attractive for sustained production. These regulatory challenges don't just impact manufacturers, they have direct clinical consequences. When essential medications are in limited supply, physicians may be forced to modify treatment plans, delay procedures, or adjust clinical workflows, all of which can impact the efficiency and delivery of high-quality care. Ongoing shortages of essential medications threaten patients' access to high-quality care and undermine the stability of clinical practice. Without regulatory reform, the drug supply will remain

[4] American Medical Association. Medicare Basics: Budget Neutrality. Chicago, IL; American Medical Association; 2024. Published online. https://www.ama-assn.org/system/files/medicare-basics-budget-neutrality.pdf. Accessed July 3, 2025.

vulnerable to future disruptions.

To address drug shortages that disrupt patient care and practice, the AADA urges HHS to direct the FDA to undertake regulatory reforms that strengthen the drug supply chain, reduce administrative burden, and prevent drug shortages. Additionally, we urge the FDA to prioritize diversifying the generic drug manufacturing base by reducing reliance on single-site production, increasing redundancy, and ensuring a minimum number of manufacturers for essential medications. Finally, the AADA urges the FDA to make facility inspection reports publicly available to help purchasers assess supply-chain risk, and to continue evaluating the use of buffer supply models to reduce shortages.

III. Conclusion

Thank you again for the opportunity to provide comments on HHS's deregulation efforts. We look forward to collaborating with you to reform Medicare payment and strengthen the drug supply chain, ensuring that dermatologists and their patients have timely access to safe and effective treatments. Please do not hesitate to contact Jillian Winans, Associate Director of Health Policy and Payment, at jwinans@aad.org if you have any questions or require additional information. Thank you for your time and consideration.

Sincerely,

Susan C. Taylor, MD, FAAD
President, American Academy of Dermatology Association