AMERICAN AMBULANCE ASSOCIATION

Caring for people—first.

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1807-P: CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure,

On behalf of the American Ambulance Association, I want to thank you for the opportunity to provide comments on the ambulance fee schedule provisions within the "CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments" (Proposed Rule).

While we are pleased that CMS recognizes the potential benefit to individuals who receive pre-hospital blood transfusions, we do not support including whole blood or blood products within the Medicare ambulance fee schedule unless the expansion of coverage includes appropriate increases in reimbursement. Second, we remain troubled that CMS has not updated the ZIP codes on which ambulance reimbursement rates are based and encourage CMS to work with the Secretary to expedite the update to the Rural-Urban Commuting Areas (RUCAs) so that the updates can be included in the CY 2026 ambulance fee schedule. As always, we appreciate CMS's engagement with the community and look forward to working on these and other ambulance coverage and reimbursement issues with you and your team.

The members of the AAA provide mobile health care services to more than 75 percent of Americans. These essential mobile health care services include the local operation of the 9-1-1 emergency/equivalent system, as well as both emergent and non-emergency interfacility care transition ambulance services and transportation. Often ground ambulance service organizations are the first medical professionals to interact with individuals in need of a health care encounter. These organizations also serve as the health care safety net for many small communities, especially those located in rural areas where other providers and suppliers have reduced their hours of operation or left the community altogether. As such, these organizations play a critical and unique role in the country's health care infrastructure.

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I. If CMS expands coverage for prehospital transfusions using whole blood and blood products, CMS needs to add sufficient dollars to the Ambulance Fee Schedule rates to cover the cost of providing these services.

The AAA appreciates that CMS recognizes that prehospital blood transfusions can improve patient outcomes under certain circumstances. As the preamble indicates, prehospital blood transfusions not only improves patient outcomes (including reduced mortality)[1], but also can reduce the need for additional transfusions[2] and reduce overall Medicare costs.[3] However, recognizing new services or items without increasing reimbursement rates will undermine the intent of the proposal. We understand that a small number of prehospital blood transfusions would be reimbursed under the proposal that are not currently today. However, as CMS notes "many ground ambulance transports providing WBT already qualify for ALS2 payment."[4] This means that no new money is available to the ground ambulance providers or suppliers who administer these transfusions.

As CMS knows from years of implementing the ground ambulance add-ons, the current AFS reimbursement rates do not cover the cost of providing existing ground ambulance services. Two reports from the Government Accountability Office (GAO)[5] and the continued extension of the ground ambulance add-ons by the Congress[6] confirm the chronic underfunding of the AFS.

This underfunding has led to serious access issues for beneficiaries throughout the United States, especially in rural areas. The Rural Health Research Gateway found that 4.5 million people lived in an ambulance desert, which means that they live in an area that is

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[1]*See* Hazelton, J. P., Ssentongo, A. E., Oh, J. S., Ssentongo, P., Seamon, M. J., Byrne, J. P., Armento, I. G., Jenkins, D. H., Braverman, M. A., Mentzer, C., Leonard, G. C., Perea, L. L., Docherty, C. K., Dunn, J. A., Smoot, B., Martin, M. J., Badiee, J., Luis, A. J., Murray, J. L., Noorbakhsh, M. R., … Porter, J. M. (2022). Use of Cold-Stored Whole Blood is Associated With Improved Mortality in Hemostatic Resuscitation of Major Bleeding: A Multicenter Study. *Annals of surgery*, *276*(4), 579–588. https://doi.org/10.1097/SLA.0000000000005603

[2]*See,* Munoz, J. L., Kimura, A. M., Xenakis, E., Jenkins, D. H., Braverman, M. A., Ramsey, P. S., & Ireland, K. E. (2022). Whole blood transfusion reduces overall component transfusion in cases of placenta accreta spectrum: a pilot program. *The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians*, *35*(25), 6455–6460. https://doi.org/10.1080/14767058.2021.1915275

[3]*See Ciaraglia, A., Myers, J. C., Braverman, M., Barry, J., Eastridge, B., Stewart, R., Nicholson, S., & Jenkins, D. (2023). Transfusion-related cost comparison of trauma patients receiving whole blood versus component therapy. The journal of trauma and acute care surgery, 95(1), 62–68. https://doi.org/10.1097/TA.0000000000003933*

[4]CMS. CY 2025 Physician Fee Schedule Proposed Rule. 89 *Fed. Reg.* 61596, 62004 (July 31, 2024)..

[5]GAO. "Costs and Medicare Margins Varied Widely; Transports of Beneficiaries Have Increased." (October 2012).

[6]The add-on payments were originally implemented under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,21 temporarily extended by subsequent acts,22 and most recently extended through the end of 2012 by the Middle-Class Tax Relief and Job Creation Act of 2012.

more than 25 minutes from an ambulance station.[7] When every second counts in the delivery of EMS care, individuals in these areas essentially have no access to life-saving and life-sustaining emergency medical services.

While adding blood and blood related products to the AFS is an important advancement in the delivery of prehospital health care provided by ground ambulance providers and suppliers, the expansion should not come at the expense of patients accessing EMS more generally. The cost of whole blood is not supported by the AFS rates. Studies have estimated annual program costs ranging between $46,250 and $69,375.[8] With the median ALS-2 base rate being approximately $660, it is simply not sustainable to add these services without adding additional funding. CMS should avoid creating a new standard of care without adequately reimbursing for it.

In addition, we agree with the broader blood community that if CMS were to modify the AFS to include whole blood and reimburse for it, the agency should not favor one type of blood or blood products that are used in prehospital blood transfusions over another. Thus, CMS should evaluate the other products and ensure equitable treatment and coverage for those items as well.

Finally, the AAA remains concerned that the AFS has not kept pace with advances in prehospital health care provided by ground ambulance providers and suppliers. As currently designed, innovative treatment options have no pathway to evaluate their utilization and cost in a way that would allow the payment system to account for the increased costs and potential efficiencies these innovations can bring to the provision of EMS. As CMS collects and analyzes the data from the Ground Ambulance Data Collection System, we ask that you and your team work with the American Ambulance Association and its members to identify specific reform proposals that could be implemented in the short-term under existing authority to find sustainable pathways to reimburse for innovative items and services while also identifying new statutory authority to support comprehensive reform. These steps are necessary to protect beneficiary access to all types of ground ambulance services throughout the United States.

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[7]Yvonne Jonk, Carly Milkowski, Zachariah Croll, Karen Pearson. "Ambulance Deserts: Geographic Disparities in the Provision of Ambulance Services. (May 2023) *available at* https://www.ruralhealthresearch.org/publications/1596 (accessed August 25, 2023).

[8] Levy, M. J., Garfinkel, E. M., May, R., Cohn, E., Tillett, Z., Wend, C., Sikorksi, R. A., Troncoso, R., Jr, Jenkins, J. L., Chizmar, T. P., & Margolis, A. M. (2024). Implementation of a prehospital whole blood program: Lessons learned. Journal of the American College of Emergency Physicians open, 5(2), e13142. https://doi.org/10.1002/emp2.13142

II. AAA urges CMS and the Secretary to expedite the Health Resources and Services Administration (HRSA) update of the Rural-Urban Commuting Area (RUCA) codes to allow CMS to update the ZIP codes that qualify as urban, rural, or super-rural under the Ambulance Fee Schedule.

The AAA and our members remain concerned that CMS has not as required updated the ZIP codes definitions under the AFS from the 2020 U.S. Census. As we have noted in previous letters, updating these ZIP codes is an important step toward improving the accuracy of identifying urban, rural, and super rural areas for AFS payments. The definitions of urban, rural, and super-rural as used in the AFS are unique to this program and not dependent upon or linked to other providers' payment systems. CMS last modified the ZIP codes last in the CY 2015 PFS final rule.[9]

Without this update, the AFS is not able to accurately categorize the payment rates based on geography. An analysis by Health Management Associates (HMA) applying the 2020 U.S. Census and subsequent OMB Bulletin describing the new geographic area delineations demonstrates why updating the ZIP code definitions is critically important to ground ambulance services in rural and super-rural areas. HMA estimates that 61 ZIP codes would move from super rural to rural status, 119 ZIP codes would move from rural to urban status, 1490 ZIP codes would shift from rural to super rural status, and 782 would move from urban to rural status.[10]

We understand that CMS needs updated RUCAs to undertake the modifications to the ZIP codes within the urban, rural, and super-rural definitions. We urge the Secretary to prioritize the update of the RUCAs to allow CMS to propose the modifications in the CY 2026 proposed rule.

As noted above, the Rural Health Research Gateway has identified "ambulance deserts."[11] It found that:

- 4.5 million people lived in an ambulance desert (AD); 2.3 million (52%) of them in rural counties.
- Four out of five counties (82%) had at least one AD.
- Rural counties were more likely to have ADs (84%) than urban counties (77%).
- Areas with the highest share and number of people living in ADs include the Appalachian region in the South; Western states with difficult mountainous terrain; coastal areas across the U.S.; and the rural mountainous areas of Maine, Vermont, Oregon, and Washington.

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[9]CY 2015 Physician Fee Schedule (PFS) proposed rule, 79 Fed. Reg. 40376 (June 11, 2014); CY 2015 PFS final rule, 79 *Fed. Reg.* 67548 (Nov. 13, 2014).
[10]A list of the ZIP codes referenced in this summary is available in the attached spreadsheet.
[11]Yvonne Jonk, Carly Milkowski, Zachariah Croll, Karen Pearson. "Ambulance Deserts: Geographic Disparities in the Provision of Ambulance Services. (May 2023) *available at* https://www.ruralhealthresearch.org/publications/1596 (accessed August 25, 2023).

- Eight states had fewer than three ambulances covering every 1,000 square miles of land area (the Western states of Nevada, Wyoming, Montana, Utah, New Mexico, and Idaho; and the Midwestern states of North Dakota and South Dakota).[12]

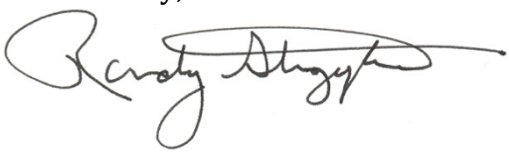
As these findings demonstrate, the definitions of rural and super-rural are critically important to provide ground ambulance providers and suppliers serving these vulnerable areas with additional funds to continue providing services.

The AAA urges CMS and the Secretary to avoid any further delays in updating the ZIP codes and the geographic definitions for the AFS.

III. Conclusion

Once again, thank you for your efforts to ensure appropriate payment for ground ambulance services under the Medicare program. If you have any questions, please do hesitate to contact Tristan North, Senior Vice President of the AAA, or our counsel in Washington, Kathy Lester.

Sincerely,



Randy Strozyk
President

[12] *Id.*