October 16, 2025

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RE: Policy Recommendations to Protect ACOs from Skyrocketing Skin Substitute Spending

Dear Director Sutton and Deputy Administrator Klomp:

Thank you for your attention to the challenges posed by increased billing for skin substitutes. As you work to finalize Medicare payment policies to address the loopholes exploited by bad actors, the National Association of ACOs (NAACOS) urges you to also address the unintended negative consequences facing ACOs due to the fraud, waste, and abuse that has occurred outside of their control. **We strongly urge the Centers for Medicare & Medicaid Services (CMS) and the CMS Innovation Center to use its existing authority to ensure that impacted ACOs are held harmless from this increased spending for performance periods beginning in 2024 and 2025.** Failure to address this issue undermines the sustainability of ACOs, ultimately threatening the ability of participating providers to deliver high-quality, coordinated care and jeopardizing beneficiary access to well-managed care.

NAACOS is a member-led and member-governed nonprofit of nearly 500 accountable care organizations (ACOs) in Medicare, Medicaid, and commercial insurance working on behalf of health care providers across the nation to improve quality of care for patients and reduce health care costs. Collectively, our members are accountable for the care of over 9.5 million beneficiaries through Medicare's population health-focused payment and delivery models, including the Medicare Shared Savings Program (MSSP) and Direct Contracting/ACO REACH.

ACOs regularly analyze Parts A, B, and D Medicare claims to find gaps in patients' care, opportunities for clinical interventions, and trends in costs and utilizations in their populations. Through their routine review of Medicare data, ACOs identified substantial increases in billing for skin grafts. The Institute for Accountable Care (IAC) confirmed this trend in the national Medicare fee-for-service data showing that allowed amounts for skin grafts rose from $1.6 billion in 2022 to $4.5 billion in 2023 and $9.9 billion in 2024. Unfortunately, ACOs continue to see increases in spending for 2025, with $7.7 billion in billing in just the first 6 months of 2025. MSSP ACOs that have higher spending trends compared to their regions tend to have slightly more complex and higher acuity beneficiaries. Those ACOs that had the highest increase in expenditures in skin grafts from 2023 to 2024 as compared to their region had higher concentration of dual eligible beneficiaries (17.0% vs. 12.8%) and long-term institutional beneficiaries (10.4% vs. 0.5%), as well as higher Hierarchical Condition Category (HCC) risk scores for both the Aged-

dual (1.00 vs.0.93) and Aged-nondual (1.13 vs 0.98) than ACOs with the lowest trends (the lowest decile) compared to their regions.

Because some skin substitute providers are holding claims for extended durations and then batch billing, ACOs often cannot detect the resulting high expenditures in claims feeds until months after egregious skin substitutes were furnished. ACOs continue to uncover numerous cases where skin substitutes are being inappropriately used in ways that are inconsistent with Medicare coverage policies or clinical practice and established guidelines. For example, ACOs have identified scenarios where grafts were being applied to patients who were poor candidates for specialty wound care, including hospice patients receiving significant wound care in the last three days of life. In some situations, ACOs have also identified cases of suspected fraud, which they have reported to CMS and its law enforcement partners. While the Department of Justice is taking steps to address these issues, criminal investigations can take years to conclude. In the meantime, the resulting increase in spending continues to negatively impact ACOs' financial performance, threatening the stability and long-term viability of many organizations.

Additionally, it has been reported that some skin substitute providers are not charging beneficiaries cost sharing. In light of high per-patient use, in which some cases have amounted to $5 million or more in individual patient claims, ACOs have engaged patients out of concern for the hundreds of thousands of dollars they would be on the hook to pay. Through this strong patient engagement, patients have shared they have not been charged cost sharing when they normally would be expected to. Improperly waiving cost sharing runs counter to Medicare statute and is illegal. Under Medicare Part B, beneficiaries generally are responsible for a 20% coinsurance on the Medicare-approved amount after meeting their annual deductible. This applies to covered services and products, including skin substitutes.

There are mechanisms within both MSSP and ACO REACH that are intended to account for and adjudicate aberrant increases in spending and to bring ACO expenditures within trend. However, these policies have fallen short in protecting ACOs from the increased spending from skin substitute expenditures. For example, within MSSP, the Accountable Care Prospective Trend (ACPT) is trending below inflation and did not account for the observed increase in skin substitute spending. The beneficiary-level truncation provides some protection from the extremely high-spend cases but does not provide protection from high volumes of less extreme spend cases. Within ACO REACH, there is no methodology to incorporate a truncation factor into financial calculations to protect fully exposed ACOs that did not opt into the CMS stop-loss reinsurance program. Also, for REACH ACOs, as discussed below, the Retrospective Trend Adjustment (RTA) may hit the risk corridors for performance year 2025, further exposing ACOs to the impact of increased spending in skin substitutes.

While policies, such as the trend factor, help protect ACOs from fluctuations in Medicare expenditures beyond their control between the benchmark and performance years, **smaller ACOs and those serving patients with complex and high needs continue to experience adverse impacts from increased spending on skin substitutes.** For example, smaller ACOs cannot withstand heightened spending from several outlying patient uses that the trend factor does not sufficiently protect against. ACOs serving high-needs and complex patients care for populations who receive more wound care at baseline and are particularly impacted by the specific actions of bad actors that are not sufficiently accounted for in the trend factor. These illegitimate actions, such as the introduction and use of new and expensive skin graft products to treat wounds beyond clinical need, have brought ACOs beyond trend.

To strengthen and retain competition in health care through sustainable accountable care models, CMS must take immediate action to ensure ACOs are held harmless for fraud, waste, and abuse that

occur beyond their control. Failure to address these issues threatens the long-term sustainability of ACOs and, in turn, the stability of the Medicare Trust Fund, as ACOs reinvest their shared savings to advance the delivery of high-value care. NAACOS recommends the following policy actions:

1. **Set a truncation factor for skin substitute spending to bring ACOs higher than trend within trend.**

   There has been wide geographic variation in spending increases between 2022 and 2024, where some states have seen a 500% increase in spending and others have less than a 100% increase in spending. While many ACOs are protected by the trend factor, smaller ACOs and those treating patients with complex and high needs have been differentially harmed by increased spending on skin substitutes and must be protected. We understand the difficulty for CMS to separate clear fraud from waste and abuse as internal investigations are ongoing. We also recognize the significant, anomalous, and highly suspect (SAHS) billing policy would not apply since all spending is not fraud and the elevated instances of increased skin substitute spending highlighted above are attributed to regional differences rather than nationwide Given that the increased spending in skin substitutes is both a fraud and payment policy issue, CMS should consider creating a clinical area of care truncation approach to protect ACOs that are differentially impacted. We recommend CMS set a truncation factor for skin substitute spending for both MSSP and REACH ACOs to accurately adjust benchmarks and bring ACOs higher than trend within trend.

2. **Allow REACH ACOs to retrospectively opt-in to the CMS stop-loss reinsurance program.**

   CMS currently offers REACH participants the option to obtain stop-loss reinsurance at the start of each performance period. Per the 2024 Financial Settlement Overview, this program serves as a risk-mitigation strategy for ACOs to protect them from financial liability for individual beneficiaries with extremely high, outlying expenditures, regardless of the risk arrangement selected by the ACO. Although the stop-loss reinsurance option for 2024 planned to utilize a residual approach that considers beneficiary performance period expenditures relative to predicted expenditures, no one could predict the negative consequences facing ACOs due to the on-going fraud, waste, and abuse of increased skin substitutes attributed to their aligned beneficiaries. As such, many REACH ACOs unfortunately did not opt into the CMS stop-loss reinsurance program at the start of performance period 2024, and for those who elected the stop-loss programs available in the private market, many carriers did not provide coverage for exposure to increased skin substitute claims due to known gaming. To accommodate REACH ACOs impacted by increased billings for skin substitutes outside of their control, we encourage CMS to allow REACH ACOs to retrospectively opt-in to the CMS stop-loss reinsurance program for the 2024 and 2025 performance periods.

3. **Remove skin substitute trend from Retrospective Trend Adjustment (RTA) for REACH ACOs.**

   As described in the ACO REACH 2025 Financial Operating Guide Overview and the 2024 Financial Settlement Overview, CMS uses prospective benchmarks based on the trend in the adjusted United States Per Capita Cost (USPCC). Due to the prospective nature of the USPCC, there may be a meaningful divergence from the observed expenditure trend in the ACO REACH National

Reference Population. If the observed expenditure trend for the ACO REACH National Reference Population differs from the prospective adjusted USPCC trend in a performance year by more than one percentage point, CMS may apply an RTA to the preliminary benchmarks.

Risk corridors determine the percentage of the savings or losses that are retained by the ACO. At the highest end of the risk band corridor within the Global Option risk-sharing arrangement, for all savings or losses up to 25% of the performance year benchmark, the ACO is responsible for 100% of savings or losses. At the highest end of the risk band corridor within the Professional Option risk-sharing arrangement, for all savings or losses up to 5% of the performance year benchmark, the ACO is responsible for 50% of savings or losses. As referenced above, the national Medicare FFS data showed that allowed amounts for skin grafts exceeded $9.9 billion in 2024. Current ACO benchmarks do not accurately reflect 2024 trends in skin substitute expenditures, and standard trend adjustments may be too broad to capture extreme exposure faced by ACOs. In the absence of the corridors, the RTA would better account for the increased spending in skin substitutes. For performance years 2024 and 2025, we recommend CMS eliminate the RTA corridors in the best interest of ACO sustainability. At a minimum, CMS should increase the corridor cut points by the amount of observed skin substitute spending for REACH ACOs. This is especially important if there is potential for ACOs to hit the symmetric corridor on upper side when the portion of the RTA accruing to ACOs exceed 50%.

4. **Allow REACH ACOs to reopen settlements from four years prior if criminal proceedings are initiated against potentially fraudulent providers who rendered services to ACO-aligned beneficiaries.**

   The timeline for which ACOs may request analysis of the impact of improper payments on financial calculations and a potential reopening of payment determinations differs between the Medicare Shared Savings Program and the ACO REACH model. In accordance with 42 CFR §425.315(a)(1)(i) and (ii), MSSP ACOs can submit a reopening request at any time in the case of fraud or similar fault, or no later than four years after the notification of the initial determination of savings or losses for the relevant performance year for good cause. Within ACO REACH, for a period of one year following issuance of a settlement report for a given performance year, or until issuance of the settlement report for the subsequent performance year, whichever comes earlier, CMS reserves the right to reopen and reissue a revised settlement report. CMS may also reopen and revise a settlement report at any time in the event of fraud or similar fault. However, the ACO REACH participant agreement does not expressly establish a procedure by which the ACO may request a reopening on grounds of fraud or similar fault.

   CMS should implement clear guidance to allow REACH ACOs to reopen settlements from four years prior if criminal proceedings are initiated against potentially fraudulent providers who rendered services to ACO-aligned beneficiaries due to the lengthy timeline for fraud, waste, and abuse investigations by CMS and the Department of Justice. At a minimum, CMS should align REACH and any future Total Cost of Care model policies with MSSP.

CONCLUSION

Thank you for the opportunity to provide insight into the pressing financial barriers ACOs face while empowering patients with solutions to manage their health and achieve their goals of providing high-

quality, cost-effective care. NAACOS and its members are committed to providing the highest quality care for patients while advancing population health goals for the communities they serve. We look forward to our continued engagement and partnership with CMS to identify and resolve future instances of fraud, waste, and abuse, and protect the federal taxpayers. If you have any questions, please contact Aisha Pittman, senior vice president, government affairs at aisha_pittman@naacos.com.

Sincerely,

Emily D. Brower
President and CEO
NAACOS