September 6, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1809-P Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems

Dear Administrator Brooks-LaSure,

Thank you for allowing us the opportunity to submit comments on the CY 2025 OPPS proposed rule. On behalf of the members of the National Association of Healthcare Revenue Integrity (NAHRI), a national organization with approximately 600 members that enhances the revenue integrity profession through standards, advocacy, networking, and the promotion of shared knowledge and resources, I submit the following comments.

C-APC 8011

SI "T" procedures

CMS states, "For CY 2025, we do not propose any changes to the overall packaging policy discussed. We propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code." We would like CMS to reconsider their packing policies for C-APC 8011, Observation services.

As you are aware, in the CY 2016 OPPS final rule, the CMS defined the parameters for payment of C-APC 8011, which includes as a requirement for payment that the claim "[d]oes not contain a procedure described by a HCPCS code to which we have assigned status indicator 'T'." We believe this requirement violates the basic tenet of your packaging concept in that when observation services are ordered and furnished, the observation services become the primary service provided to such patients and the SI "T" procedure which is provided is ancillary to that primary service.

For example, the patient who has a syncopal episode and requires a laceration repair that is coded with a SI "T" HCPCS code, such as HCPCS code 12032, and then is hospitalized for observation services for more than eight hours, and often more than 24 hours, would

result in a claim, per CMS' current conditions for C-APC 8011 payment as defined in the 2016 OPPS final rule, that is excluded for payment under C-APC 8011. In this scenario, the ancillary service, (i.e., the repair of the laceration) is treated as the primary service and the observation care is packaged; however, the mere presence of the laceration procedure does not actually make it the primary clinical service, rather the observation services for the syncopal episode are the primary service provided to the patient.

The same situation occurs with patients who receive observation services and are determined to need gastrointestinal endoscopy during their outpatient hospitalization. Once again, due to the presence of the endoscopy procedure CPT code, which is a SI "T" procedure, the claim is not paid under C-APC 8011.

In these situations, under the current payment rules, the hospital provides significant, resource-intensive services to the patient but is paid significantly less than if a SI "T" procedure was not done. For CY 2024, C-APC 8011 has a base payment rate for 2024 of $2,610.71. For the example above, the hospital will instead receive line-item payment for the ED facility visit ($270–$612), the SI "T" procedure ($370-900), and perhaps a small payment for an EKG or other minor diagnostic study—summing to an amount significantly less than the C-APC 8011 payment.

NAHRI requests that CMS remove the rule that the presence of a SI "T" procedure excludes payment of C-APC 8011 and instead package payment of SI "T" procedure into C-APC 8011, as is already done with SI "Q" procedures.[1]

Packaging of high-cost SI "K" drugs to C-APC 8011

The second issue related to C-APC 8011 that we would like to raise is that there are instances when the administration of chemotherapy or other intravenous medications and treatments assigned SI "K" could result in adverse patient reactions or complications that necessitate observation services. In these instances, is the services ordered are distinct from regular infusion monitoring, which is part of drug administration and is well understood by providers. However, in cases where adverse reactions occur, a clinician may need to order observation services to provide the well-defined set of services necessary to determine if the patient requires inpatient admission or if the patient can be safely discharged home.

In these instances, if the medically necessary observation care exceeds eight hours and other C-APC 8011 payment logic is triggered, the costs of drug administration treatment will become packaged. This packaging of high-cost drugs, biologicals, or treatments with

[1] 78 *FR* 74911

SI "K" into C-APC 8011 may trigger outpatient outlier payment, but the overall total payment for the case will be significantly less than what the provider would have received under the average sales price (ASP) +6% methodology. NAHRI does not believe it is appropriate for providers to face such a reduced payment—a reduction that can be tens of thousands of dollars per case depending on the medication(s) administered—simply because the SI is "K" instead of "G."

Therefore, NAHRI requests that CMS exclude all SI "K" drugs from not only packaging into C-APC 8011 but from all C-APCs and allow them to generate separate payment, as was recommended during the August 26, 2024, meeting of the Advisory Panel on Hospital Outpatient Payment.

NAHRI also requests that CMS provide further claims analysis of procedures that require observation services and consider either creating temporary HCPCS codes that would track the cost of the procedure and observation time, or create an add on payment, or a different C- APC for procedures that compensates adequately for the additional and necessary observation services.

Packaging of Cell and Gene Therapy SI K Drugs to C-APCs

We would also like to respond to your proposal to exclude certain cell and gene therapies from C-APC packaging for one year. In your discussion of the proposal, you state that "the C-APC policy packages payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to the primary service and provided during the delivery of the comprehensive service, including diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure [...]there are rare instances where the cell and gene therapies listed in Table 1, which are usually separately payable under the OPPS, appear on the same claim as a primary C-APC service and therefore, have their payment packaged with payment for the primary C-APC service."

The therapies in Table 1 are usually separately paid and priced using the ASP +6% methodology when not on a C-APC claim. Given the unique nature of these therapies, we agree with CMS that these biologics do not function as integral, ancillary, supportive, dependent, or adjunctive to any of the current C-APCs primary services. The cell therapies described in Table 1 are primarily for the treatment of specific cancers and are administered through an intravenous infusion. The gene therapies listed in Table 1 are generally for the treatment of certain rare ocular or spinal conditions caused by specific genetic mutations and are also either intravenously infused or administered through a subretinal injection. When these products are administered, they are the primary

treatment being administered to a patient and thus are not integral, ancillary, supportive, dependent, or adjunctive to any primary C-APC services. Additionally, most C-APCs are for surgical procedures such as breast/lymphatic surgery and musculoskeletal procedures. The cell and gene therapies listed in Table 1 are intended to treat a specific condition and would not be used to support the outcome of any primary C-APC procedure.

NAHRI agrees with CMS' rationale and proposal and fully supports exclusion of the cell and gene therapies listed in Table 1 of the proposed rule from C-APC packaging. Additionally, we request that CMS adjust its proposal by making the exclusion permanent when finalized, rather than just for CY 2025.

In addition, as part of this proposal you requested feedback on how to "structure a new C-APC, or similar packaged payment policy, for the service to administer cell or gene therapies." NAHRI does not believe that any such C-APC is necessary and requests that CMS not pursue this payment method for administration of cell and gene therapies.

OPPS Payment for CAR-T Services

NAHRI appreciates that CMS accepted our application to present on this topic during the 2024 meeting for the Advisory Panel on Hospital Outpatient Payment. In general, our request related to reimbursement for cell collection, cell processing, and dose preparation services for CAR-T therapy. Our presentation was consistent with that of the American Society of Transplantation and Cellular Therapy (ASTCT), where we both asked the Panel to recommend that CMS should assign SI "S" to CAR-T CPT codes 3X018, 3X019, and 3X020 and assign them to the most clinically appropriate APCs. The Panel agreed and made a recommendation to assign SI "S" and also provided recommended APC placement.

As described in our presentation, we are greatly concerned about the operational and financial burden of filing claims as per the recommended charging and billing scenarios included in MLN Matters® *SE19009*. NAHRI member believe that CMS has beneficiaries' best interests at heart and has worked very hard to ensure the therapies, drugs, and other services are available and covered for its beneficiaries. However, we believe that there is room for improvement in ensuring availability and access to CAR-T therapies, specifically in supporting cell collection and cell processing services. For many services, such as bone marrow transplantation and gene therapy, the cell collection and cell processing services are separately reimbursed. These services are no different than the services necessary for CAR-T: the hospital or physician's office collects the cells via leukapheresis and then processes them based on clinician orders for the cells.

The hospital bears the cost of cell collection and cell lab processing but, because CMS does not provide separate reimbursement to hospitals under the OPPS, hospitals must

cover these significant costs on their own. Ultimately, lack of payment reduces the number of hospitals that are able to provide, or continue to provide, CAR-T and negatively affects beneficiaries' access to these therapies.

To address these issues, NAHRI members recommend that CMS assign SI "S" to new CPT codes 3X018, 3X019, and 3X020, in accordance with the Panel's recommendation, so that separate payment is made to providers under the OPPS starting January 1, 2025. We also ask for a commensurate retirement of the instructions provided in *SE19009*. We further recommend that CMS replace existing CAR-T Q-codes with new J-codes and, in doing so, eliminate the distinct clinical services of leukapheresis and dose preparation from the code descriptors. Including these services in the product Q-code descriptors raises serious program integrity concerns—from a correct coding perspective and from a compliance perspective. Through these changes, beneficiaries will receive better access to these important services which are more consistent with CMS' treatment of CAR-T services and its treatment of other gene and cell therapies under OPPS policies.

RFI for Cardiac CT Services

NAHRI members very much appreciates CMS' description of the billing challenges for cardiac CT tests due to inappropriate revenue code to HCPCS code edits. We appreciate that CMS removed the edits but note that the edits remain in claims clearinghouses and with other payers and that, therefore, hospitals are not able to implement the revenue code changes even after CMS making public the removal of its edits in its January 2024 OPPS Update (*Transmittal 12421,* Change Request 13488), dated December 21, 2023. Many, if not all, hospitals are forced to bill cardiac CT tests with revenue code 035x for CT scans even though CMS issued the transmittal for MACs to eliminate the edit in January.

CMS needs to be made aware that this situation is not unique or isolated to cardiac CT services. There are many other services for which claim clearinghouse, Medicare Advantage, and other payers' HCPCS code to CPT code edits prevent hospitals from accurately following CMS' guidance in Chapter 4 of the *Medicare Claims Processing Manual* to "report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report." NAHRI members understand that this CMS guidance on proper revenue code selection is applicable to all participating hospitals.

Furthermore, NAHRI members are concerned about claims clearinghouse and other payer edits that force certain revenue codes to be billed with specific HCPCS codes when CMS billing guidance is silent. Our members ask CMS to provide extensive education in the final OPPS rule about the rationale behind its longstanding guidance regarding selection of

revenue codes. CMS should clearly direct clearinghouses and other payers to remove inappropriate edits that adversely impact the ability of hospitals to follow CMS' guidance in Chapter 4 of the *Medicare Claims Processing Manual* to "report their charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report."

Unpackaging Diagnostic Radiopharmaceuticals (RP)

NAHRI members agree with CMS that the current OPPS packaging policy for all diagnostic RPs is not logical when the invoice cost of the RP well exceeds the APC payment rates to which the RP is packaged. This is particularly problematic because there are no clinical alternatives to specialized RPs to reduce the financial losses incurred.

Our members understand CMS' proposal and offer the following comments and suggestions.

We believe that doubling the average per day cost of $314.28 for diagnostic RPs creates too high a cost threshold. Instead, we ask CMS to use the outlier multiplier of 1.75 times to calculate the threshold. Using the outlier multiplier to calculate the specific diagnostic RP packaging threshold is more consistent with CMS' high-cost payment policies and is more appropriate for a packaging threshold than using a multiplier of two.

CMS requests comments on the best method to separately pay for diagnostic RPs that exceed the packaging threshold. Our members believe the best method is for CMS to pay ASP for the RPs. We ask CMS to use ASP for separate payment of all diagnostic RPs exceeding the specific diagnostic RP packaging threshold where such data exist and only use mean unit costs (MUC) for the few diagnostic RPs where ASP data is lacking.

Sub-regulatory Guidance to Define Complex Non-Chemo Drugs

NAHRI members noted this topic in the CY 2025 MPFS proposed rule, but recognize it is applicable to OPPS payment and, therefore, are raising it in our comment letter. We appreciate that CMS confirmed that all MACs must follow AMA CPT guidance when paying for drug administration services billed with chemotherapy drugs in its 2024 rulemaking.

Despite this public confirmation and instruction to MACs, CMS continues to receive questions about variation in MAC guidance concerning the most appropriate HCPCS codes to be billed for the administration of complex, non-chemotherapy drugs. Therefore, CMS proposes to release additional sub-regulatory guidance for drug administration services for complex non-chemotherapy drugs, stating that CPT codes 96401-96549 are differentiated from the non-chemo/non-complex hydration and therapy codes because

CPT codes 96401-96549 require more staff monitoring for reactions, adverse events, and extra staff training compared to what is involved with hydration or non-chemo injection and infusion services.

NAHRI members understand that it is these clinical characteristics of complex drugs that dictate correct coding for the administration services for these drugs. For example, drugs that require staff monitoring for toxicity, reactions, adverse events, etc., are to be reported with CPT codes 96401-96549, and it is the CPT criteria that the MACs should rely upon when approving and paying for the drug administration services.

Our members are aware that the current language in Chapter 12, section 30.5 of the *Medicare Claims Processing Manual* language does not include these AMA CPT criteria for the MACs to apply consistent coverage and payment for the administration services of complex non-chemotherapy drugs. NAHRI also understands that CMS intentionally includes the AMA CPT criteria in the *Medicare Claims Processing Manual* to provide guidance to the MACs and foster consistent and appropriate coding and payment determinations.

NAHRI members ask that any future sub-regulatory guidance released by CMS on this topic acknowledges that the AMA's CPT criteria has also determined that the administration of cell therapies, such as stem cell transplant and CAR-T therapy, should not be billed with the complex drug administration codes because separate and more specific codes exist.

Caregiver Training Services and RFI on PIN and CHI Services

NAHRI members are supportive of CMS' objectives to recognize necessary services of Principal Illness Navigation (PIN), Social Determinants of Health (SDOH) assessment, and Community Health Integration (CHI). We appreciate CMS' acknowledgement and valuation of caregiver training services (CTS) in the CY 2024 MPFS and OPPS final rules. CMS is correct that CTS are furnished after a patient's treatment plan is established and it is determined a caregiver is needed.

Our members agree that additional HCPCS codes described in the CY MPFS proposed rule for caregiver training to learn techniques for infection control, wound care to prevent decubitus ulcers, and more are needed. However, NAHRI notes that these services are most often performed by qualified auxiliary staff under orders and incident to the treating practitioner's service in facility and non-facility settings. Furthermore, HCPCS codes GCTD1-GCTD3 are not present in Addendum B of the OPPS rule. NAHRI is aware that the AMA CTS CPT codes 97550-97553 are assigned SI "A," indicating MPFS payment to outpatient hospitals is applicable when therapists furnish CTS but not to hospitals billing

for CTS services furnished by nurses and other trained auxiliary personnel furnishing caregiver training under the treating clinician's orders. We believe it is important for CMS to recognize that after the treating clinician establishes the treatment plan and assesses the capabilities of the caregiver, the bulk of CTS services are furnished by auxiliary staff under general supervision. NAHRI asks that CMS make the newly proposed CTS HCPCS codes GCTD1-GCTD3 payable under the OPPS when services are furnished by auxiliary staff under orders in the facility setting.

Sincerely,

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