Submitted via: Ann.Maxwell@oig.hhs.gov

January 27, 2023

Ann Maxwell
Deputy Inspector General for Evaluation and Inspections
DHHS/OIG/Office of Evaluation and Inspections
330 Independence Avenue, SW
Washington, DC 20237

Re: AAHomecare Response to OIG Report on Urological Supplies: CMS Should Instead Take Action to Ensure Beneficiaries Have Access to the Appropriate Intermittent Catheter

Ms. Maxwell,

AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare/home medical equipment (HME) community. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe, and reliable home care products and services. Our membership includes manufacturers, distributors and providers of intermittent catheters and related services to patients.

In August 2022, the Office of Inspector General (OIG), issued a report, "Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year" (OEI-04-20-00620). Unfortunately, this report fails to identify the significant deficiencies in Medicare's coding, coverage, and payment system for intermittent catheters. We would like to provide a summary of the current key policy issues affecting appropriate access and includes recommendations for CMS to address them.

About Catheters

Catheters are medical supplies used to drain the bladder when an individual cannot control the process of urination or is unable to empty their bladder. A catheter is a thin, hollow tube inserted into the urethra or inserted into surgically created stomas/Mitrofanoff valves to drain the bladder into a drainage bag or toilet. There are many varieties of catheters available depending on an individual's unique medical needs.

- **Intermittent catheters (ICs)** are used to drain the bladder at certain intervals throughout the day by inserting the catheter into the bladder via the urethra or via a surgically created stoma.
- **Indwelling catheters** are catheters that are inserted into the urinary bladder via urethra, left

in the bladder, and connected to a closed collection system.

- **External urinary catheters** are urine collection devices with tubing that either use gravity or suction to drain urine away from the urethral opening (not inserted into the body).

Urinary retention and incontinence issues may develop as result of conditions such as spinal cord injury, spina bifida, multiple sclerosis, Parkinson's disease, late-stage diabetes, stroke, cancer, enlarged prostate, and pelvic floor dysfunction or prolapse. While there are many medical conditions, the population requiring catheterization is relatively small but clinically diverse.[1] These individuals often also have complex comorbidities, cognitive issues, neuropathy, and impaired motor skills, all of which can influence their ability to carry out intermittent catheterization easily and will inform the type of catheter that they require. The Society of Urological Nurses and Associates recommends that intermittent self-catheterization be performed at regular intervals through the day, every 4-6 hours (4-6 times per day) to keep the amount of urine in the bladder less than 400-500mL.[2] It is important that individuals have access to sterile catheters.

It is imperative that patients use the most medically appropriate catheter to avoid bad outcomes and increased health spending

Clinicians and beneficiaries together determine the most medically appropriate catheter for the individual. Patients that use catheters often have other health issues present. Due to the patient's health situation, it is important that they are prescribed the proper catheter because depending on their situation, they may not be aware when their catheter is causing pain and other health issues. Beneficiaries may have trouble inserting catheters or clinical complications, like catheter-associated urinary tract infections (CAUTIs), hematuria, sepsis/bacteremia. Within the first 30 days after starting intermittent catheterization, studies report that 16% of patients utilize the emergency department and 10% of patients require an overnight hospital readmission.[3] This can be very expensive especially in older patients with multiple comorbidities. UTIs are a common cause of healthcare visits. One study stated, "[I]n the United States, UTIs result in an estimated 7 million office visits, 1 million emergency department visits, and over 100,000 hospitalizations with an associated annual cost of $1.6 billion."[4] Overall, medical costs for the total treatment phase for complex UTIs are reported to be $17,914 in outpatient and $82,153 in inpatient/emergency department clinical settings (per patient).[5] Using proper catheters can reduce some risk factors for UTIs, such as urethral and bladder trauma from catheters, and post void residual urine due

[1] IBM Watson Market Data (2020)

[2] Society of Urological Nurses and Associates (2019). *Intermittent Self-Catheterization:* Patient Fact Sheet

[3] Zhao JZ, et al. "Patient-Reported Outcomes and Health Care Utilization Following Participation In a Patient Support Program For Intermittent Catheterization." ISPOR Annual Meeting, New Orleans, May 18-22, 2019.

[4] Simmering JE, et al. The Increase in hospitalizations for urinary tract infections and the associated costs in the United States, 1998-2011. Open Forum Infect Dis. (2017)

[5] Turner, Ralph. et al, "Assessment of Outpatient and Inpatient Antibiotic Treatment Patterns and Health Care Costs of Patients with Complicated Urinary Tract Infections." vol 37, no 9, 2015.

to product design.[6,7] The method and type of catheterization must be matched to the patient's preferences and their ability to maintain cleanliness.[8]

There are only three HCPCS codes for over 1,300 products

HCPCS codes for ICs are quite generic. There are a wide range of products with differing features that fit within a single HCPCS code. HCPCS codes that align to specific catheter characteristics would not only recognize advanced features that support higher patient satisfaction and better outcomes but would also streamline CMS' reimbursement to appropriate products. Creating more specific HCPCS codes would account for differences in acquisition costs, product quality, features, and promote innovative catheter development that make a difference in the catheterization procedure and/or patient outcomes. See attached Intermittent Catheters Overview.

Following are the three HCPCS codes that describe over 1,300 different products, according to the Medicare Pricing, Data Analysis and Coding (PDAC) Contractor:

i. A4351 is a straight tip catheter and can range from no lubrication to hydrophilic coating, firmness levels vary. Some manufacturers even have products with a touchless insertion (tip and sleeve) and often products cannot be brought into the United States due to the low levels of reimbursement. Overall, there are 603 various products grouped under this HCPCS code.
ii. A4352 has the same issues as A4351, however the type and shape of the tip and any additional markings on the catheter to ensure the insertion is made correctly and does not cause unintentional harm from false passage. There are currently 221 products grouped under this HCPCS code.
iii. A4353 has the same issues, however the challenge with this code is that it includes everything from a non-coated straight catheter with a separate insertion supply kit shipped together to those that are packaged together to those that are hydrophilic coated, with a touch free insertion. The cost to acquire these very diverse products varies widely for suppliers. Overall, there are 514 various products grouped under this HCPCS code.

There are significant additional costs that Medicare DMEPOS suppliers incur beyond acquisition costs

- **Indirect costs include intensive education and follow-up with patients**, delivery, compliance, training, and documentation retrieval from clinical records. During the public health emergency (PHE), suppliers have experienced increased acquisition and shipping costs, delays in the supply chain, and difficulty obtaining personal protective equipment (PPE).

- **Case management of patients and education are a large component of the IC cost.** In addition to the standard customer service, some suppliers have established case management programs

[6] Kennelly et al. "Adult Neurogenic Lower Urinary Tract Dysfunction and Intermittent Catheterization in a Community Setting: Risk Factors Model for Urinary Tract Infections." Advances in Urology, 2019, Article ID 2757862, Article ID 2757862.
[7] Rognoni, Carla and Tarricone, Rosanna. (2017). "Intermittent Catheterization With Hydrophilic And Non-Hydrophilic Urinary Catheters: Systematic Literature Review And Meta-Analyses." BMC Urology, vol 17. 10.1186/s12894-016-0191-1.)
[8] Wound, Ostomy and Continence Nurses Society. (2016). *Care and management of patients with urinary catheters: A clinical resource guide.*

that include welcome calls, lifestyle education materials, and check-in calls every 30-60 days to encourage access to educational materials at critical times. Supplier customer service representatives must be specifically trained in this complex product category to help patients. There is no separate billing code for the specific education suppliers provide. New patients often need to try different types of catheters before they find the right product that meets their needs. This trial-and-error process is time and resource consuming for suppliers.

- **Manufacturers Invest in Significant Patient Support Programs**. Some catheter manufacturers have recognized the need to complement supplier support programs and have created more comprehensive patient support programs with individualized support, nurse-validated product and lifestyle education resources, troubleshooting challenges with product and catheterization technique as well as self-assessment tools critical for compliance to guideline recommended self-care routines. Many patient support programs are free of charge to the patient and some are open to all catheter users regardless of the product brand. These programs are critical to supporting catheter users on their path from confusion to confidence, of how to use the catheters, information on different product attributes and options, availability, and how to develop self-support habits. There has been a significant reduction in readmissions and emergency department visits recently reported due to patient support program for intermittent catheterization.[9] Manufacturers have no mechanism to charge for these patient support programs. Implementing competitive bidding or any fee schedule reduction will have an adverse effect on the ability of manufacturers to offer these patient support programs. See attached Patient Support Program Elements.

- **A Wide Range of Products Means High Inventory Costs.** As mentioned above, there are a wide range of products available in these 3 HCPCS codes. One manufacturer indicated they have 65 different products coded as A4351. Suppliers must maintain a large variety of products in their inventory to be able to provide urological supplies to their diverse group of patients. One supplier shared that they have 32 different products in stock for A4351 alone. The need for many different products greatly increases the inventory management costs for suppliers.

- A DMEPOS cost study conducted by Dobson Davanzo & Associates found that on average, Medicare reimbursement covers only 87.68% of a DMEPOS' supplier costs.[10]

- **Suppliers Incur Significant Medicare Audit Costs**. As this product category is audited frequently by the DME Medicare Administrative Contractors, Recovery Audit Contractor, and Supplemental Medical Review Contractor. On average, it takes a supplier approximately 45 minutes per patient audit to respond.

---

[9] Zhao JZ, et al. "Patient-Reported Outcomes and Health Care Utilization Following Participation In a Patient Support Program For Intermittent Catheterization." ISPOR Annual Meeting, New Orleans, May 18-22, 2019.

[10] Dobson DaVanzo & Associates, LLC, Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding (2016).
https://www.aahomecare.org/uploads/userfiles/files/documents/Studies/DME%20Cost%20Study/Full_Report_-_AAHomecare_Dobson_DaVanzo_True_Cost_Study_Report_10.18.16_FIN.pdf

HHS has recognized that urological supplies are not suitable for Medicare Competitive Bidding

- HHS' 2004 Report to Congress on the competitive bidding (CB) demonstration indicated that urological supplies are not a good candidate for CB due to the availability of quality products and patient preferred products availability declined caused by the decrease in rates. There were numerous complaints from beneficiaries throughout the demonstration. Ultimately, HHS recommended that urological supplies not be included in CB because of the negative impact on beneficiary access to quality products. Urological supplies product category was one of the few product categories that HHS has specifically identified as not being appropriate to include in the Medicare competitive bidding program.[11]

- The Medicare Payment Advisory Commission (MedPAC) has acknowledged that the authority to add urological supplies is unclear, and that CMS would likely need additional legislative authority.[12] AAHomecare and several patient advocacy groups have strongly opposed adding urological supplies to CBP due to concerns with possible beneficiary access issues. All the recent advances in the access to intermittent catheterization for individuals with special needs, such as increased risk of infections, limited dexterity, and challenging anatomy will likely be put at risk by the CBP.

- CMS fails to consider patient experience when including products in the CB program. The patient/supplier relationship is important for urological supplies as these patients have many medical conditions and specific needs. Urological supplies are not like other DMEPOS items that require fewer concomitant service costs due to the complexity of the patient population. These patients have many other DME needs and adding urological supplies to CB would require a patient to work potentially with multiple suppliers as there are often different contracted suppliers for each product category. Due to the large volume of products in each HCPCS code and the need for patients to have their preferred product, urological supplies should not be considered for CB. In the National Mail-Order Program for diabetic supplies, many patients chose to get their supplies through retail pharmacies rather than the mail order companies so they could access their preferred brands not offered by mail order companies.[13] Retail pharmacies do not stock the various urological products that patients need and therefore would not be an avenue for patients to get preferred brands.

- On October 27, 2020, CMS announced that CB would not move forward with 13 of the 15 product categories originally included in Round 2021.[14] This most recent round of CB included significant changes to the program such as requiring bidders to secure a bid surety bond, switching bidding

[11] Tommy G. Thompson, Secretary of Health and Human Services. "Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies." 2004
[12] Medicare Payment Advisory Commission. "Chapter 6 Issues in Medicare's medical device payment policies." June 2018.
[13] A report by Acumen for the Medicare Payment Advisory Commission. "Examining Impacts of the National Mail-Order Program on Medicare Service Utilization and Beneficiary Health Outcomes." April 2020.
[14] Centers for Medicare and Medicaid Services. "Round 2021 DMEPOS Competitive Bidding Program Single Payment Amounts and Contract Offers." October 27, 2020.

methodology to lead item bidding, and establishing the single payment amount at the clearing price. CMS has acknowledged that the program needed significant modifications to ensure the program is sustainable for the long-term.[15] *Before including additional product categories to CB, CMS must make sure the program is sustainable.*

- AAHomecare and the industry oppose any reductions to the current Medicare fee schedule for urological supplies. Any payment reductions would hinder suppliers' ability to provide the quality products, the variety of different products that these patients require, and the necessary support services upon which patients rely. As stated previously, due to the constraints of the reimbursement rates, there are several products that are available internationally that are not available in the U.S. market. Lowering the payment rate will further limit access to advanced products for patients and will greatly impact the ability of manufacturers to continue to innovate.

Additional Recommendations

- *CMS should create additional HCPCS codes for those products that have demonstrated improved patient outcomes* Currently, the entire universe of intermittent catheters is described by only three HCPCS codes (A4351, A4352 and A4353), which creates myriad problems for beneficiaries, healthcare providers, manufacturers and suppliers, and the Medicare program itself. For decades, manufacturers, suppliers, medical professionals, and patients have had serious reservations with the limited coding options available to describe the universe of intermittent catheters under the HCPCS system. We believe the limited HCPCS code set has contributed to a lack of patient access to specific catheters with advanced features. The three HCPCS codes cover such a broad range of intermittent catheters that the Centers for Medicare and Medicaid Services (CMS) and its contractors often do not know specifically what they are paying for, which leads to vulnerabilities in the administration of the Medicare program. Therefore, AAHomecare has developed a comprehensive proposal to replace and reform the HCPCS codes that are currently covered by A4351, A4352, and A4353 to address CMS's program operating need to better identify and administer intermittent catheter claims. Creating new HCPCS codes will further incentivize manufacturers to invest in innovative solutions that further support better clinical and quality of life outcomes for the patient.

- *Medicare should allow patients to continue to use A4353 coded products when they transition from another payer source and NOT require them to have their health jeopardized by requiring the use of lesser products that caused UTIs.* Our members have significant concerns about the care transition when a patient becomes Medicare eligible. Medicare requires patients to prove that they meet medical necessity requirements for the exact HCPCS code that is being billed. These patients have already tried and failed on products coded to A4351 and A4352. They have been

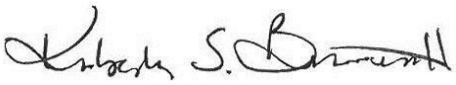
[15] Centers for Medicare and Medicaid Services. "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS" (CMS-1691-F). November 14, 2018.

approved for products coded as A4353 by the managed care plan or Medicaid. Medicare requires patients to revert back to products coded as A4351 or A4352 and to experience UTIs in order to then requalify for products coded as A4353.

- *CMS or the DME MACs should conduct a formal reconsideration of the Local Coverage Determination (Urological Supplies L33803) to revise qualifications for A4353 catheters for individuals living with diseases and injuries of the spinal cord by eliminating the documentation of two UTIs*. Increasing the utilization of A4353 catheters amongst these populations may decrease costly dependence on caregivers for bladder management, enable independence, and decrease the need for indwelling catheters. Decreasing the utilization of indwelling catheters may reduce UTI incidence. Attached Addendum C is an advocacy letter to Utah Medicaid about this issue.

Thank you for the opportunity to share the DMEPOS industry's concerns with the OIG's report. Please feel free to contact me with any additional questions or concerns and if we can assist in connecting you with state leaders and other industry stakeholders.

Sincerely,



Kim Brummett
VP, Regulatory Affairs
American Association for Homecare