

SUNA POLICY PAPER**Protecting Access to Urological Supplies****PURPOSE**

This position statement articulates the Society of Urologic Nurses and Associates (SUNA) stance on federal reimbursement and coverage policy as it applies to urological supplies, with particular focus on hydrophilic-coated urinary catheters. Hydrophilic catheters represent a clinically distinct and significant segment of the urological supply market, as reflected in CMS's creation of dedicated HCPCS codes for these products, and their inclusion in the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program raises concerns about patient access to individually prescribed, clinically necessary technology (CMS, 2024). This statement uses hydrophilic catheters as the clearest and most fully documented example of the potential consequences of applying price-driven reimbursement policies to clinically distinct, individually prescribed urological supplies. Although the available evidence is concentrated primarily on intermittent urinary catheters, there is concern that similar economic and access risks may extend to other urological supplies.

SCOPE

This statement applies to all Medicare, Medicaid, and private insurance coverage determinations affecting urological supplies classified as durable medical equipment or prosthetic devices. The clinical evidence reviewed in this statement pertains primarily to intermittent urinary catheters, particularly hydrophilic-coated catheters. However, the policy concerns raised by competitive bidding, including reduced product availability, supplier-market instability, product substitution, and barriers to individually appropriate supplies, may also affect other urological products and accessories. It is relevant to physicians, urologic nurses and advanced practice providers, healthcare facility administrators, DMEPOS suppliers, patient advocacy organizations, caregivers, and federal and state policymakers.

BACKGROUND

Urinary catheterization provides one of the most well-studied and clinically consequential examples of broader challenges in access to urological supplies. Intermittent urinary catheterization is a clinically indicated and widely used method of bladder management for many individuals who cannot adequately empty their bladders voluntarily. For individuals who require intermittent urinary catheterization, hydrophilic-coated catheters may be clinically indicated or preferred based on anatomy, functional needs, comfort, complication risk, and prior experience. Evidence suggests that these catheters may provide benefits related to urinary tract infection risk, urethral trauma, quality of life, satisfaction, and patient preference, although findings vary by outcome and patient population (Barken & Vaabengaard, 2022; Liao et al., 2022; Rognoni & Tarricone, 2017). More recent meta-analyses have likewise found hydrophilic catheters to be associated with a lower risk of urinary tract infection than uncoated catheters, particularly among adults and patients with neurological conditions (Plata et al.,

2023; Skalli et al., 2026). However, findings vary by population, and Skalli et al. (2026) identified substantial publication bias. Patients who rely on these product-specific features may be particularly vulnerable to competitive bidding policies that reduce access or restrict product choice. The causes of urinary retention requiring catheterization are broad and span the lifespan: they include neurological conditions such as spinal cord injury, multiple sclerosis, spina bifida, muscular dystrophy, Parkinson's disease, and amyotrophic lateral sclerosis (ALS); structural conditions such as enlarged prostate and urethral scarring; and bladder muscle weakness resulting from age, pregnancy, or childbirth.

The scale of need in the Medicare population reflects this diversity. In fiscal year 2020 (the most recent year for which OIG claims data are publicly available), more than 122,700 Medicare beneficiaries used urinary catheters for bladder management (U.S. Department of Health and Human Services, Office of Inspector General [OIG], 2022). Of these, 72 percent did not have a spinal cord injury or neurological condition, meaning the majority manage urinary retention from structural, age-related, or other causes (OIG, 2022). Among the remaining 28 percent, nearly 21,000 had a spinal cord injury and 17,600 had a neurological diagnosis (OIG, 2022). Veterans and active-duty service members are represented across these populations, including but not limited to those with traumatic spinal cord injury. Catheter type varied meaningfully by population: curved tip catheters were used almost exclusively by male beneficiaries, most commonly those with enlarged prostate, while sterile catheter kits were concentrated among the highest-acuity users, with 61 percent of sterile kit users having a spinal cord injury or neurological condition (OIG, 2022). In total, Medicare and its beneficiaries paid \$407 million for more than 114 million catheter units that year across three clinically distinct categories (OIG, 2022).

Catheter technology is not uniform, and product features carry direct clinical significance. In fiscal year 2020, more than half of catheters in each billing category had at least one clinically relevant feature, with hydrophilic coating being the most prevalent: present in 46 percent of straight tip catheters, 51 percent of curved tip catheters, and 59 percent of sterile kit catheters (OIG, 2022). Multiple systematic reviews and meta-analyses have examined whether hydrophilic catheters reduce complications compared to uncoated catheters. Most report a clinical benefit, though the strength of evidence varies by outcome. A meta-analysis of seven randomized controlled trials found a statistically significant lower risk of urinary tract infection with hydrophilic catheters (risk ratio = 0.84; 95% confidence interval 0.75-0.94; $p = 0.003$) (Rognoni & Tarricone, 2017). A separate systematic review and meta-analysis found hydrophilic catheters associated with lower rates of microscopic hematuria and urethral stricture, though not gross hematuria (Liao et al., 2022). An earlier systematic review and cost-effectiveness analysis found less conclusive evidence distinguishing catheter types by infection risk, but modeled hydrophilic catheters as cost-effective over a patient's lifetime (Birmingham et

al., 2013). A broader scoping review of both neurogenic and non-neurogenic populations found consistent evidence of benefit across outcomes including urinary tract infection, quality of life, satisfaction, and preference, while noting that evidence varies by population and outcome (Barken & Vaabengaard, 2022). The Centers for Disease Control and Prevention (CDC) has noted that hydrophilic-coated catheters may be preferable for intermittent catheterization (CDC, 2009). Adherence to a prescribed catheterization schedule is itself a clinical variable: patient-reported comfort and ease of insertion are associated with more consistent catheterization and better long-term adherence (Cobussen-Boekhorst et al., 2016), and non-adherence drives the very complications that price-driven product substitution is unlikely to account for.

The clinical distinctiveness of hydrophilic catheters has been formally recognized by the Centers for Medicare & Medicaid Services (CMS) itself. Effective January 1, 2026, CMS created three new dedicated Healthcare Common Procedure Coding System (HCPCS) codes specifically for hydrophilic-coated urinary catheters: A4295 (straight tip, hydrophilic coating), A4296 (coude tip, hydrophilic coating), and A4297 (hydrophilic coating with insertion supplies) (CMS, 2024). Prior to this change, over 1,300 distinct catheter products were billed under just three generic codes, masking meaningful clinical differences (CMS, 2024). The creation of hydrophilic-specific codes reflects CMS's own recognition that these products occupy a distinct clinical category, not a commodity bracket.

Urological supplies represent a unique category within DMEPOS in that they are prosthetic, continuously used, and require individualized selection for safe daily function, distinguishing them from interchangeable commodity equipment. Urinary catheters are covered under Medicare Part B as prosthetic devices because they replace the function of a body part that can no longer perform its normal role. This designation reflects that these products must be individually prescribed, clinically assessed, and professionally managed. Catheter selection is determined by patient anatomy, medical history, and functional need. Features including hydrophilic coatings, protective sleeves, and gripping aids are not elective upgrades; for many patients they are clinical requirements that directly influence infection risk and sustainable daily use.

CLINICAL RATIONALE

The concentration of available evidence on intermittent urinary catheters should not be interpreted as evidence that other urological supplies are unaffected by similar reimbursement pressures. Urological products vary substantially in their clinical purpose, design features, and patient-specific requirements. Applying a cost-management model that prioritizes price without adequately accounting for these differences may narrow product availability, destabilize supplier networks, or create barriers to clinically appropriate supplies. Some consequences may not become apparent until after implementation, when patients and clinicians begin experiencing product substitutions, supply disruptions, or reduced access.

When patients cannot obtain the hydrophilic catheter selected for their anatomy, medical history, and functional needs, they may face increased risks of urinary tract infection, urethral

microtrauma, and urethral stricture. Systematic reviews and meta-analyses have found that hydrophilic-coated catheters are associated with lower urinary tract infection risk and reductions in certain forms of urethral trauma compared with non-hydrophilic catheters, although findings vary by outcome and patient population (Liao et al., 2022; Rognoni & Tarricone, 2017). Catheter comfort and ease of use may also affect adherence to a prescribed intermittent-catheterization schedule (Cobussen-Boekhorst et al., 2016). Inadequate or inconsistent bladder drainage can result in urinary retention and urine backing up into the kidneys, potentially causing hydronephrosis, chronic kidney disease, or kidney failure (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], n.d.-a). These complications may require additional medical treatment and generate costs that offset or exceed short-term savings from price-driven product substitution; economic modeling has found hydrophilic catheters to be cost-effective when outcomes are considered over a patient's lifetime (Bermingham et al., 2013).

Nurses with expertise in catheter care, including but not limited to certified urologic nurses (CURNs), play a central role in preventing these outcomes. Physicians and advanced practice providers prescribe appropriate catheter types, while nurses with expertise in catheter care assess patient needs, support product selection, and provide education on catheterization technique and infection prevention. When that clinical oversight is removed or constrained by restrictive supplier programs, patients face measurable and avoidable harm. Current guidelines from the European Association of Urology Nurses (EAUN, 2024) likewise emphasize individualized catheter selection and the importance of nursing assessment, patient education, and ongoing support in safe intermittent catheterization.

EVIDENCE ON COMPETITIVE BIDDING FOR UROLOGICAL SUPPLIES

Competitive bidding for urological supplies is not a new policy question. CMS first tested it between 1999 and 2002 in demonstration projects in Polk County, Florida and San Antonio, Texas, which included intermittent urinary catheters and other urological supplies. In Polk County Round 2, the average price reduction for urological supplies was 7 percent, well below the 19 percent reduction for oxygen and 34 percent reduction for hospital beds and accessories; total allowed charges for urological supplies fell by only 9 percent, and among the 24 urological items included, fees for 6 items ended up higher than the Medicare statewide fee schedule (Research Triangle Institute, 2004). The federal evaluation of that demonstration raised concerns specific to urologic supplies, including a declining number of bidders, low allowed charges, and strong patient preference for specific products. More than two decades later, during the 2025 rulemaking for the CY 2026 DMEPOS Competitive Bidding Program, multiple commenters cited these same demonstration findings to argue that urological supplies remained poorly suited to competitive bidding; CMS disagreed and finalized the rule as proposed.

Independent economic analysis has raised concerns that the CMS competitive bidding auction design may not consistently produce the outcomes CMS intends. The use of composite bids across product categories can distort individual item pricing and create incentives for suppliers that diverge from truthful cost disclosure.

Economic analyses suggest the current mechanism may set prices below market-clearing levels in ways that risk supply shortages, and that alternative auction designs could achieve comparable savings while reducing supply disruption risk (Ji, n.d.; Katzman & McGeary, 2008). Studies by the U.S. Government Accountability Office (GAO) and OIG have found that Medicare payments for certain DMEPOS items have at times exceeded amounts paid by other insurers and retail prices paid by non-Medicare customers, making cost reform a legitimate policy goal (GAO, 2018; OIG, 2022). The critical question is whether competitive bidding is the right mechanism for a category with these clinical and market characteristics, and whether the access risks it carries are justified for patients whose alternative options, such as indwelling or suprapubic catheterization, carry distinct long-term clinical risks.

Despite this documented evidence, CMS displayed the final Calendar Year 2026 Home Health and DMEPOS Competitive Bidding Program rule (CMS-1828-F) on November 28, 2025, and published it in the Federal Register on December 2, 2025 (90 Federal Register [FR] 55342). The rule is effective January 1, 2026, with Competitive Bidding Program (CBP) contracts and Single Payment Amounts (SPAs) for urological supplies expected to be in effect no later than January 1, 2028, following a six-month transition period beginning on that date (CMS, 2025b). The rule mandates the inclusion of urological supplies, ostomy supplies, and tracheostomy supplies under Section 1847(a)(2) (A) of the Social Security Act (CMS, 2025b). The proposed rule drew over 900,000 public comments (Applied Policy, 2025); CMS largely maintained its positions without significant revision. The statutory basis for this inclusion is contested: multiple advocacy organizations have argued that urological supplies are prosthetic devices under Section 1861(s)(8) of the Social Security Act and were deliberately excluded from competitive bidding by Congress, and that CMS's reinterpretation of their classification constitutes a regulatory overreach.

Under the final rule, CMS plans to award a limited number of national supplier contracts for hydrophilic catheters and other urological supplies through a Remote Item Delivery model. Because contract information may be updated periodically, current details should be obtained from the CMS DMEPOS Competitive Bidding Program website (CMS, 2026). SPAs will be calculated at the 75th percentile of winning bids (CMS, 2025a). Congressional leaders including Representative Chris Smith (R-NJ) have called on CMS to delay implementation, citing concerns that any Medicare Part B savings would likely be offset by preventable hospitalizations and complications driving significantly higher Medicare Part A costs (Smith, 2026). The Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition, the Wound, Ostomy, and Continence Nurses Society™ (WOCN®), AAHomecare, United Spinal Association, and United Ostomy Associations of America (UOAA) are among the stakeholder organizations actively engaged in legislative and regulatory advocacy to reverse or delay implementation.

SUNA'S POSITION

SUNA holds that:

- Intermittent urinary catheters are prosthetic devices that replace lost urinary function and must be covered and reimbursed in a manner consistent with that designation. Related urological supplies and accessories must also remain available when they are necessary for the safe and effective use of the prescribed device.

- Physicians, advanced practice providers, nurses, and other healthcare professionals with expertise in urologic and catheter care are essential to safe device selection, patient education, and ongoing management, and their roles must be protected in any coverage or procurement framework.
- Catheter supplies are not interchangeable commodities. Catheter type, tip design, and device features are clinically determined and patient-specific; substitution based on price rather than clinical need creates direct patient harm.
- Evidence from prior demonstrations and broader durable medical equipment (DME) competitive bidding research raises serious concerns that competitive bidding for urological supplies may create supply shortages, narrow product selection, and reduce access for vulnerable beneficiaries, rather than efficiently eliminating low-value utilization. Prior federal demonstration data raised concerns about applying competitive bidding to urological supplies, including limited savings, declining bidder participation, low allowed charges, and strong patient preference considerations (Research Triangle Institute, 2004).
- Economic analyses suggest the current CMS competitive bidding auction design may set prices below market-clearing levels in ways that risk supply shortages, and that the use of composite bids across product categories may distort individual item pricing in ways that do not reflect true supplier costs (Ji, n.d.; Katzman & McGeary, 2008).
- Restricting beneficiaries to a limited number of national contractors may not adequately accommodate the clinical diversity of Medicare patients with varying anatomies, diagnoses, and device requirements
- Coverage and coding frameworks must keep pace with urological device innovation to sustain investment in technologies, including hydrophilic coatings and sterile delivery systems, that reduce infection rates and improve patient outcomes.
- Medicare, Medicaid, and private insurers must cover the full range of prescribed urological supplies at reimbursement levels that sustain a viable supplier market and do not impose unreasonable financial burdens on patients.
- Research has identified clinically meaningful differences among certain catheter types, including hydrophilic-coated and uncoated catheters. Although the evidence base is less developed for other urological supplies, limited research should not be interpreted as evidence that comparable access risks or potential harms are absent.

RECOMMENDATIONS

SUNA acknowledges that Medicare fee schedule rates for certain urological supplies contain documented pricing inefficiencies relative to non-Medicare markets, and that cost reform is a legitimate policy objective. The CMS DMEPOS demonstration evaluation (Research Triangle Institute, 2004) noted that Medicare payments have at times exceeded amounts paid by other insurers and retail prices available to non-Medicare customers. However, that same evaluation raised concerns about the feasibility of competitive bidding for urological supplies, including limited savings potential, declining bidder participation, and low allowed charges. While CMS disputed those concerns in the 2025 final rule, SUNA believes the patient safety and access risks associated with competitive bidding have not been adequately addressed for hydrophilic-coated catheters or for the broader category of individually prescribed urological supplies. Because the available evidence is concentrated primarily on intermittent catheters, additional risks affecting other urological

products may remain unidentified until after implementation. Viable alternatives to competitive bidding exist, including use of CMS inherent reasonableness authority to recalibrate fee schedule rates where they are demonstrably misaligned with current market costs, market-based fee schedule updates informed by supplier acquisition cost data such as that documented in the OIG's 2022 report, and product-specific payment reforms that preserve beneficiary access and product choice. SUNA supports evidence-based cost reform pursued through mechanisms that do not impose the patient access and supply disruption risks that competitive bidding presents for urological supplies.

SUNA calls on Congress and the Administration to:

- Repeal or delay the inclusion of urological supplies in the DMEPOS Competitive Bidding Program pending a thorough independent review that specifically addresses the supply shortage, product narrowing, and patient access harms documented in prior federal evaluations and peer-reviewed research on this program;
- Strengthen the existing beneficiary safeguard that allows access to specific brands when medically necessary, and ensure it is consistently enforced by contracted suppliers and communicated clearly to beneficiaries and prescribers;
- Invest in expanded coverage of care services delivered by members of the healthcare team with expertise in urologic and catheter care across urology clinics, rehabilitation settings, and other practice environments, ensuring that patients have access to appropriate expertise during device prescribing, selection, fitting, education, and ongoing management;
- Establish a transparent, timely coding and coverage pathway for new urological device technologies that reflects the clinical value of innovation rather than defaulting to the lowest historical reimbursement rate;
- Ensure continuity of supply and timely access by protecting reliable distribution channels and preventing disruptions that place patients at risk of complications such as infection, urinary retention, and avoidable emergency care utilization;
- Require prospective and ongoing monitoring of the policy's effects across the full range of urological supplies, including product availability, supplier participation, prescribed-product fulfillment, substitutions, delays, patient complaints, clinical outcomes, and disparities in access. Monitoring should be designed to identify unintended harms promptly rather than relying solely on problems reported after patients have already experienced adverse consequences;
- Promote policies that prioritize clinical outcomes over short-term cost containment, recognizing that inadequate access to appropriate urological supplies leads to preventable complications and increased long-term healthcare costs; and
- Encourage the integration of emerging technologies and digital health solutions that support urologic care, including innovations in monitoring, education, and device design that enhance patient safety and independence.

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NOTE ON PROVENANCE

SUNA independently developed the clinical evidence base, policy analysis, and recommendations contained in this document, which reflect the distinct clinical context of urological nursing practice and the specific regulatory and market conditions affecting urological supplies under the Medicare DMEPOS Competitive Bidding Program. This document was conceptually informed by the Wound, Ostomy, and Continence Nurses Society™ (2018) Guiding Principles for Sustainable Access to Ostomy Services, Products, Technologies, and Innovation, and has been independently developed and adapted to reflect the urologic context, the specific clinical and market characteristics of urological supplies, and the current regulatory environment.

Prepared on behalf of the Society of Urologic Nurses and Associates (SUNA) by Nicole Zhang, PhD, RN, FAUNA, President-Elect

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Effective Date: 2026 **Review Date:** 2028

Endorsed by:

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