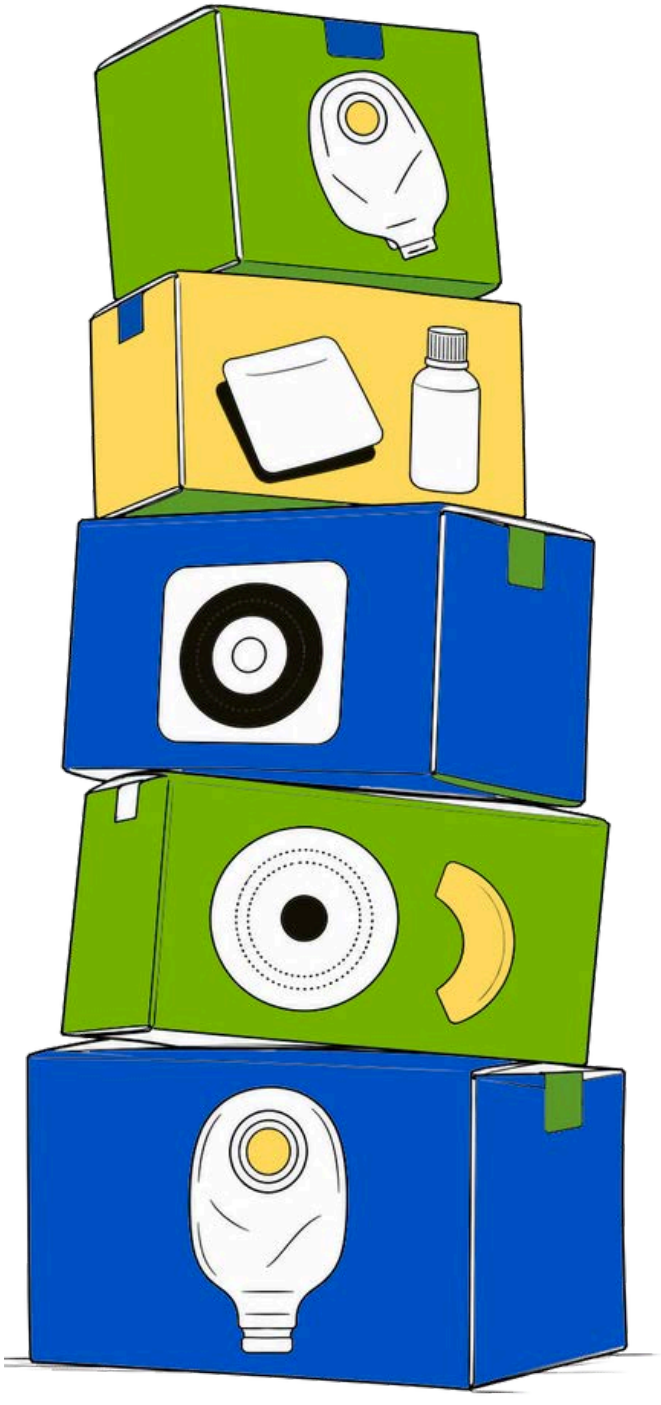
October 2026

Protecting Access, **Preserving Stability**

Ostomy care is a delicate balance; Medicare policy changes could disrupt it

A White Paper from United Ostomy Associations of America, Inc.



Authors:

Jeanine Gleba, MEd, UOAA Director of Advocacy

Rebecca McElyea, MSN, RN, CWOCN

Diego Schaps, MD, MPH

UOAA United Ostomy Associations of America, Inc.
ostomy.org

Table of Contents

Pages 2-3 Section 1 — Executive Summary
Pages 4-5 Section 2 — Background and Policy Context
Page 5 Section 3 — Clinical Context: Why Patient Stability Matters
Page 6 Section 4 — Survey Methodology
Pages 7-11 Section 5 — Data Results: Evidence of Patient Stability and Patient Safety Implications
Pages 12-14 Section 6 — Why Competitive Bidding Could Disrupt Stability
Page 15 Section 7 — Conclusion
Pages 15-19 Appendix A — UOAA Policy Recommendations: Ensuring Patient Access, Stability, and Safety
Page 20 Appendix B — CMS Response to UOAA Concerns with Competitive Bidding

SECTION 1

Executive Summary

For a person living with an ostomy, the right supplies are not simply a preference. They ensure ostomates stay healthy, protect their skin, prevent leaks, leave the house, go to work, and sleep through the night. Once someone finds a pouching system that works, maintaining consistency with that system is important. As the nation's leading nonprofit organization dedicated to supporting, educating, and advocating for people living with an ostomy or continent diversion, United Ostomy Associations of America, Inc. (UOAA) routinely evaluates public policy initiatives that may affect beneficiary access to medically necessary ostomy supplies. This publication reflects UOAA's commitment to providing policymakers with objective, patient-centered evidence to inform healthcare policy decisions.

The Centers for Medicare & Medicaid Services (CMS) has finalized a policy to include ostomy supplies in the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program. Unlike many durable medical products such as walkers or knee braces, successful ostomy management depends upon uninterrupted access to individualized prescribed supplies.

Recognizing the significance of this policy change, United Ostomy Associations of America, Inc. (UOAA) conducted a confidential national survey of 2,504 respondents from all 50 states and the District of Columbia. The survey was designed to capture the patient experience before implementation of Competitive Bidding and to establish a pre-implementation baseline for future comparisons of product access and patient stability. The results presented here are based on responses from 935 ostomy supply users enrolled in Original Medicare.

The **primary finding** of this survey is that Original Medicare beneficiaries with ostomies have achieved a high degree of clinical stability under the current Medicare benefit. This stability depends on reliable access to products that meet individual needs, help prevent complications, and support continuity of care. Any policy that disrupts these pillars risks placing otherwise stable patients at risk.

Executive Summary, continued

Other key findings at a glance

1. **Long-term stability on current pouching system. More than three-quarters of respondents reported using their current ostomy system for at least one year, while more than one-quarter had remained with the same system for more than five years. More than 95% rated their current ostomy supplies as good or excellent.**

2. **Product Selection is based on medical necessity. 68% reported that they selected their current products specifically to prevent medical problems.**

3. **Ostomy products are not interchangeable commodities. Among respondents who had used multiple brands, most reported meaningful differences in product performance, and many said alternative products had not worked for them. More than one-third reported currently using products from multiple manufacturers as part of a single individualized ostomy pouching system.**

Importantly, the survey also identified existing vulnerabilities within the current supply system. Respondents reported experiencing delayed shipments, insurance-related barriers, reduced quantities of supplies, supplier changes, and product substitutions. When these disruptions occurred, respondents described leakage, peristomal skin complications, increased supply utilization, clinician visits, emergency department visits, and hospitalizations.

The purpose of this publication is **not** to predict the future effects of Medicare Competitive Bidding. Rather, it is to establish an objective pre-implementation benchmark documenting patient stability, access to individualized products, and patient-reported outcomes before implementation. CMS has emphasized that protecting beneficiary access is paramount under the Competitive Bidding Program. If CMS proceeds with the inclusion of ostomy supplies in the Competitive Bidding Program, this baseline provides an opportunity to evaluate whether implementation preserves the conditions that currently support patient stability, patient safety, and appropriate access to medically necessary ostomy supplies.

Based on these findings, UOAA recommends that CMS evaluate access to ostomy supplies in clinical and functional terms, rather than simply by whether a covered product is available. Beneficiaries who are stable on an established ostomy system should be able to continue receiving the clinically appropriate products and quantities they need without avoidable interruption or non-medical substitution. UOAA further recommends clear standards for timely fulfillment, a practical and expedited process for resolving access problems, and stronger implementation of existing safeguards when a specific product is prescribed to prevent an adverse medical outcome. Supplier capacity should likewise be evaluated at the beneficiary level, including whether individual patients can reliably obtain the specific products required for their established systems.

Just as importantly, CMS should measure what happens to patients after implementation. UOAA recommends ongoing monitoring of supply delays, reduced quantities, non-medical product changes, leakage, peristomal skin complications, increased healthcare utilization, and patient-reported changes in stability and daily life, with results compared publicly against this pre-implementation baseline. Ultimately, Competitive Bidding must foster an environment where meaningful access exists when a beneficiary can obtain the clinically appropriate products and quantities needed to maintain an established, stable ostomy system without avoidable interruption to be considered successful. Competitive Bidding for ostomy supplies should therefore be judged not only by payment amounts, supplier participation, or aggregate product availability, but by whether Medicare beneficiaries remain stable, safe, and independent.

SECTION 2

Background and Policy Context

BY THE NUMBERS



725,000 to 1 million

people living with an ostomy in the U.S.



approximately 100,000

surgeries annually



estimated that fifty percent of the population are Medicare beneficiaries.

There are estimated to be 725,000 to 1 million people living with an ostomy or continent diversion in the United States, and approximately 100,000 surgeries are performed annually. [1] It is estimated that fifty percent of the population are Medicare beneficiaries. An ostomy is a surgically created opening (stoma) on the abdomen for eliminating waste. People living with an ostomy have undergone surgery to divert urine or stool because of conditions such as cancer, inflammatory bowel disease, diverticulitis, trauma, or other serious diseases affecting the bladder or intestine.This surgery impairs their ability to store and eliminate bodily waste, so they continuously wear a 'pouching prosthetic system' over the stoma to contain it. Well-fitting ostomy products allow people to live their lives normally. These products are unique to each individual and replace surgically removed or dysfunctional body systems.

The Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) was established to reduce Medicare expenditures while safeguarding beneficiary access to quality items and services. Under the program, Medicare awards contracts to selected suppliers through a competitive bidding process for designated product categories. CMS has stated that the program is intended to promote competition, reduce costs, and preserve beneficiary access through supplier qualification requirements, quality standards, beneficiary protections, and ongoing program monitoring.

In the Calendar Year 2026 Home Health Prospective Payment System Final Rule, CMS finalized the inclusion of ostomy supplies in the DMEPOS Competitive Bidding Program. This represents one of the most significant policy changes affecting people with Medicare living with an ostomy since the Medicare ostomy benefit was established.

Throughout the rulemaking process, UOAA, clinicians, manufacturers, suppliers, professional organizations, and other stakeholders expressed strong opposition and concerns regarding inclusion of ostomy supplies in the competitive bidding program due to the unique clinical characteristics of ostomy care. Unlike many medical supply categories, ostomy supplies are not interchangeable commodities.

CMS has consistently stated that preserving beneficiary access remains a central objective of the Competitive Bidding Program. The agency has described numerous safeguards intended to protect beneficiaries, including supplier accreditation requirements, quality standards, complaint resolution processes, and oversight mechanisms designed to ensure continued access to medically necessary items and services.

UOAA recognizes the importance of these stated objectives. However, evaluating whether they are achieved requires an objective understanding of beneficiary experiences before implementation. Because relatively little information is available on current patient stability, individualized product utilization, healthcare utilization, and patient-reported outcomes among Original Medicare beneficiaries living with an ostomy, UOAA designed and administered this survey in partnership with researchers at Duke University to establish a pre-implementation baseline.

Background and Policy Context, continued

This publication does not predict the future effects of Medicare Competitive Bidding. Instead, it documents current patient experiences and establishes measurable benchmarks against which future outcomes can be evaluated. *Public policy is most effectively evaluated when conditions are documented before and after implementation.*

By creating a contemporaneous record of conditions before implementation, this publication provides CMS with a best estimate of baseline measures and gives CMS, Congress, and other stakeholders an independent reference point for assessing whether program implementation preserves the conditions that currently support successful ostomy management and, if disruptions occur, measuring their magnitude and consequences.

- References: *Ostomy101.* Accessed September 15, 2026. https://www.ostomy.org/wp-content/uploads/2023/05/ostomy_ infographic_ 20230508.pdf

SECTION 3

Clinical Context: Why Patient Stability Matters



Successful ostomy care means having a pouching system that works reliably for the expected wear time, without leaks or the need for unplanned changes.

Achieving stability requires careful assessment, product trials, and individualized fitting. Patients and clinicians work together to find products, or combinations of products, that provide a secure seal, protect the skin, minimize leakage, and support independence. Selection may depend on stoma size and location, abdominal contours, body habitus, skin characteristics, allergies or sensitivities, underlying disease, dexterity, and vision.

Once an effective system is found, continued access helps maintain stability. Repeated product changes can lead to leakage, skin complications, shorter wear time, reduced confidence, and the need for additional medical care.

Stability also depends on access to necessary accessories, knowledgeable suppliers, timely delivery, and clinicians with ostomy expertise.

Our findings suggest that patient stability is supported by two interrelated components:

- **Individualized Product Selection** – Products are selected to meet each person's clinical needs and cannot be assumed to be interchangeable.
- **Continuity of Access** – Reliable access to medically necessary ostomy supplies supports patient stability, prevents complications, and preserves individualized care.

Policy Significance

These findings show that most surveyed Medicare beneficiaries who rely on ostomy supplies have an established ostomy pouching system that works reliably for them. Any Medicare policy changes should protect that stability.



SECTION 4

Survey Methodology

The survey was developed and administered in partnership with researchers at Duke University. This study was determined to be exempt by the Duke University Health System Institutional Review Board (Pro00120223). It was disseminated through UOAA's website, e-newsletter and social media, and in partnership with ally organizations. Adults aged 18 or over living in the United States, and who rely on ostomy supplies or urological catheters were eligible. In total, there were 2,504 individual survey respondents, of whom 935 were Original Medicare beneficiaries who use ostomy supplies. None of the catheter users were Medicare beneficiaries, so results shown are for people who use ostomy supplies.

2,504
total respondents

935
Original Medicare respondents who use ostomy supplies

SECTION 5

Data Results: Evidence of Patient Stability and Patient Safety Implication

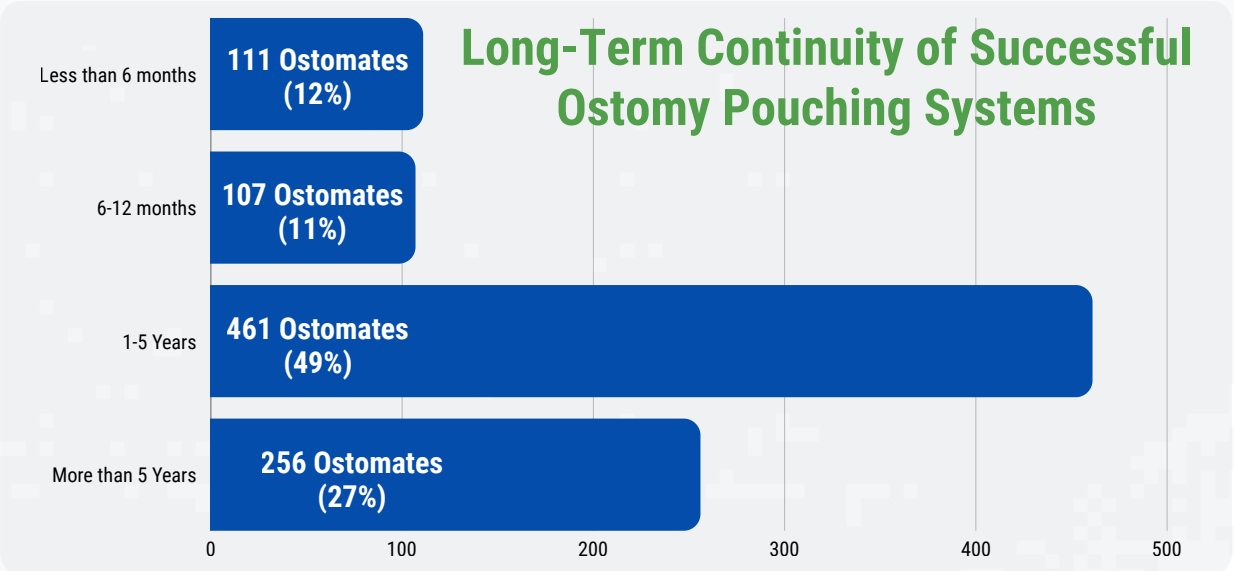
The survey evaluated domains relevant to patient stability before implementation of Medicare Competitive Bidding: continuity of successful ostomy systems, satisfaction with current supplies, individualized product selection, experience with alternative products, use of products from multiple manufacturers, healthcare utilization, and existing supply disruptions.

5.1 Respondent Population and Characteristics

The survey included 935 respondents with Original Medicare. Respondents represented a broad geographic distribution across the United States. The population included 38.8% using colostomy supplies, 39.7% using ileostomy supplies, and 24.4% using urostomy supplies. These categories may overlap for individuals with more than one ostomy. Nearly half (49.3%) had lived with an ostomy for 1 to 5 years, 15.1% for 6 to 10 years, and 20.6% for more than 10 years. Most respondents reported substantial self-management: 77.7% said they take care of their ostomy on their own, while another 13.6% care for it themselves but sometimes receive help.

5.2 Long-Term Continuity of Successful Ostomy Pouching Systems

Nearly half (49.3%) reported using their current ostomy supplies, brand, or setup for 1 to 5 years, and 27.4% for more than 5 years. Thus, 76.7% had maintained their current ostomy supply, brand, or setup for at least one year, including more than one-quarter for more than five years. This finding demonstrates that long-term continuity is a prominent feature of current beneficiary experience.

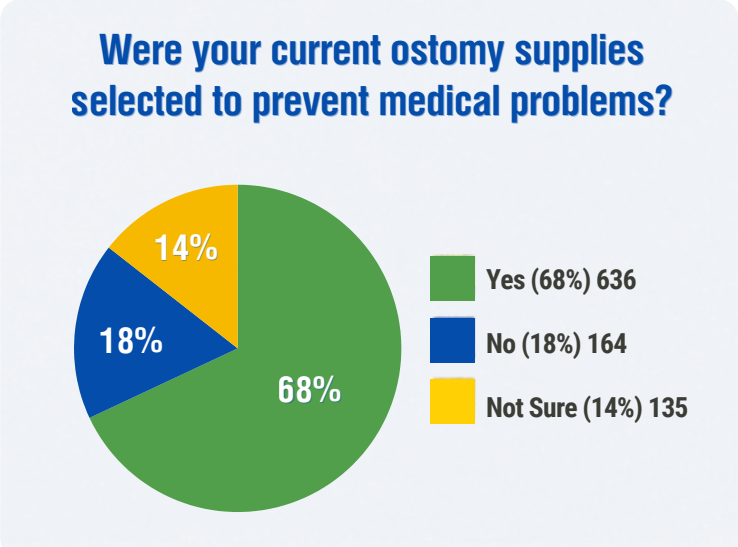


5.3 Satisfaction with Current Ostomy Supplies

Respondents reported satisfaction with their current ostomy supplies. Most respondents (95.6%) rated their supplies as good or excellent. In the context of the long-term continuity described above, these findings demonstrate that the majority of respondents have products that work well for them.

5.4 Individualized Product Selection and Clinical Stability

Of 935 respondents, 71.34% reported skin irritation or breakdown around their stoma in the past six months: 20.43% monthly or more and 50.91% once or twice. These findings establish a baseline for monitoring peristomal skin health as a patient-safety outcome as ostomy supply access changes. More than two-thirds (68%) reported that their current ostomy supplies were chosen specifically to prevent medical problems. This finding reinforces that product selection is based on medical necessity and is not a matter of preference or convenience.



These findings reinforce that:

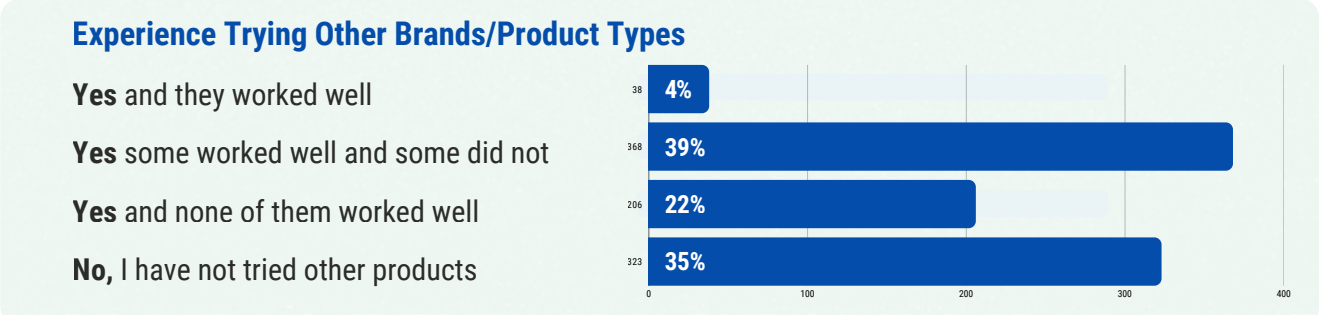
- **skin protection**
- **leakage prevention**
- **wear time**
- **anatomy**
- **underlying medical conditions**

are driving product choice.

Additionally, 66.8% have NOT needed additional healthcare utilization related to ostomy supplies such as emergency department visits or clinician visits demonstrating a population that has achieved a relative degree of clinical stability under the current Medicare benefit.

5.5 Experience with Alternative Brands and Product Types

Among the 65.5% of respondents that had tried other brands or product types, 93.7% reported an experience in which alternative products did not work uniformly well. *This demonstrates that ostomy products are not interchangeable commodities.* It also reflects substantial experience showing that product performance and suitability can vary from one individual to another, a distinction important for patient safety. A policy that changes which products are available to beneficiaries should be evaluated not only on whether another ostomy product is available, but also on whether beneficiaries can continue to obtain products that meet their established clinical needs.



5.6 Use of Products from Multiple Manufacturers

More than one-third of respondents (38.2%) reported that their current ostomy pouching system uses products from multiple manufacturers. A majority (56.8%) reported using one brand. The use of multiple brands within a single current setup is relevant to product interchangeability because some beneficiaries assemble a combination of products that works for their individual circumstances. Future access evaluation should therefore consider whether beneficiaries can continue to obtain the appropriate combination of products.

5.7 Existing Supply Disruptions Before Competitive Bidding

The survey results demonstrate that supply-access disruptions already occur under the current environment. During the previous six months, 18.9% respondents reported delayed supplies, 8.5% a reduced amount, 11% a required product switch, 4.2% a required supplier change, and 9.8% insurance denial of needed products. Among 228 respondents who reported a non-medical supply change, 50.8% reported leakage, 56.6% skin problems, 36.4% needing more supplies than usual, 19.3% needing a doctor or nurse visit, 1.8% an emergency room visit, and 4.4% a hospital stay. These findings document existing supply-access challenges and their reported consequences. They establish a baseline for evaluating whether changes under Competitive Bidding affect beneficiary access, clinical stability, or patient safety.

5.8 Patient Safety as an Outcome of Stable Ostomy Care

For individuals living with an ostomy, patient safety is central to maintaining a clinically appropriate ostomy pouching system. An effective system must function consistently for the individual patient, protect the peristomal skin, minimize leakage, provide adequate wear time, and support the patient's ability to manage the ostomy safely and independently.

The survey findings provide a pre-implementation baseline for several factors relevant to patient safety. These include the frequency of problems with current supplies, clinical purpose of current product selection, experiences with alternative products, healthcare utilization, and reported consequences of supply disruptions.

The findings show that respondents' current ostomy pouching systems are clinically important and that access disruptions can be accompanied by patient-reported problems.

5.9 Clinical Evidence Supporting Patient Safety

The survey findings align with a substantial body of clinical literature showing that ostomy product selection, pouching-system fit, leakage, peristomal skin health, and healthcare utilization are interconnected.

Individualized Product Selection and Product Fit

Clinical literature emphasizes that appropriate barrier fit and product selection are important for achieving a secure seal and maintaining healthy skin around the stoma. A 2024 randomized controlled crossover trial reinforces the importance of matching a pouching system to an individual's body profile. The authors concluded that a pouching system designed for an outward peristomal body profile "achieved a better body fit" and resulted in "fewer leakage incidents and higher [quality of life]" compared with a flat skin barrier (Rolfsen et al., 2024). These findings demonstrate that pouching-system fit directly affects leakage and quality of life. [1]

Similarly, a study using peristomal body-profile assessment found that changing to ostomy products selected to better fit an individual's body profile significantly reduced reported leakage from 5.9 to 1.8 episodes per seven days and improved quality of life. The authors concluded that assessing an individual's peristomal body profile helps guide selection of the best-fitting ostomy products (Vendelbo et al., 2023). [2] These findings reinforce that the clinical suitability of an ostomy product depends on the individual patient's anatomy and circumstances.

Our survey findings are consistent with this evidence. More than two-thirds of respondents (68%) reported that they chose their current ostomy supplies specifically to prevent medical problems. In addition, among the 65.5% of respondents that had tried other brands or product types, 93.7% reported an experience in which alternative products did not work uniformly well.

Leakage and Peristomal Skin Complications

Leakage can expose the peristomal skin to ostomy effluent and contribute to skin irritation and breakdown. Peristomal skin complications are the most common complication experienced by people living with an ostomy. An international consensus publication reported that more than 80% of individuals with an ostomy experience a stomal or peristomal complication within two years of ostomy surgery and noted that complications are associated with clinically relevant impairments in physical function and quality of life, as well as higher costs. [3]

The broader literature also shows that peristomal skin complications are common and can lead to greater healthcare use. In a systematic review, D'Ambrosio et al. (2023) reported peristomal skin complication incidence ranging from 36.3% to 73.4%. The review also found that these complications were associated with longer hospital stays and increased hospital readmissions within 120 days following surgery. [4]

Our survey results provide an important pre-implementation measure of this problem among Original Medicare beneficiaries. One in five respondents (20.4%) reported experiencing skin irritation or breakdown around the stoma monthly or more often, while another 50.9% reported experiencing it once or twice. When considered alongside the literature, *these findings underscore why peristomal skin health should be treated as an important patient-safety outcome when evaluating future policy changes that may impact ostomy product access.*

Healthcare Utilization

The effects of peristomal skin complications extend beyond the skin itself. In a U.S. study of 168 patients undergoing ostomy surgery, Taneja et al. (2019) found that 36.3% developed a peristomal skin complication within 90 days. Patients who developed these complications were more likely to be readmitted to the hospital within 120 days than those who did not (55.7% vs. 35.5%) and had mean total healthcare costs that were approximately $8,000 higher during the 120-day period. [5]

An earlier U.S. study by the same group likewise found substantially higher healthcare utilization and costs among patients who developed peristomal skin complications, including higher hospital readmission rates and substantially higher total healthcare costs. [6]

5.9 Clinical Evidence Supporting Patient Safety, cont'd

These studies establish that PSCs are associated with increased healthcare utilization and cost at the population level.

When considering Medicare policy, if future changes in product or supplier access are accompanied by increases in skin complications, the consequences could extend beyond the immediate supply issue and appear elsewhere in the healthcare system.

Connecting Product Access to Patient Safety

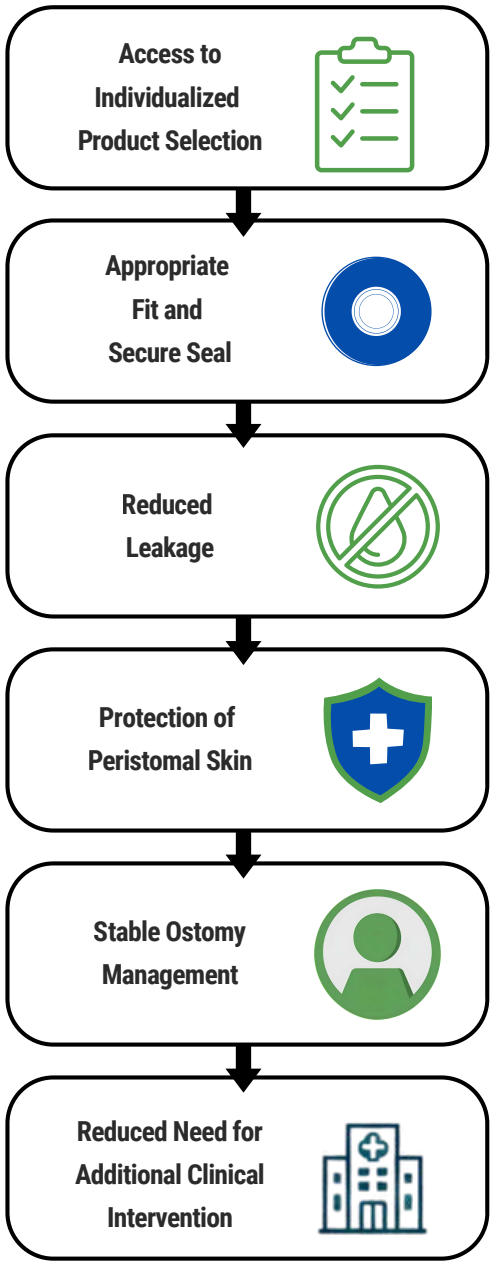
Taken together, the survey findings coupled with the literature support a patient-safety framework in which product access is connected to clinical stability:

Patient-Safety Pathway Linking Product Access to Clinical Stability

Survey findings and prior literature support a patient-safety framework connecting product access to clinical stability.

If Medicare changes how beneficiaries obtain ostomy supplies, this framework identifies the mechanisms and outcomes to monitor.

The survey provides the pre-implementation patient-level baseline. The literature provides evidence that the outcomes of product fit, leakage, skin integrity, healthcare utilization, and patient stability are clinically meaningful.
Together, they provide a stronger foundation for evaluating the effect of changes.



References:

1. Rolfsen T, et al. Body Fit With a Pouching System With Concave Contour for People With an Outward Peristomal Body Profile: Effects on Leakage, Wear Time, and Quality of Life: A Randomized Controlled Cross-Over Trial. Journal of Wound, Ostomy and Continence Nursing. 2024;51(4):303-311.
2. Vendelbo G, Carlsson E, Tøndel LT, et al. Using peristomal body profile assessment to improve leakage-related quality of life for individuals with an ostomy. British Journal of Nursing. 2023;32(4):173–181. doi:10.12968/bjon.2023.32.4.173.
3. LeBlanc K, Whiteley I, McNichol L, et al. Peristomal Medical Adhesive-Related Skin Injury: Results of an International Consensus Meeting. Journal of Wound, Ostomy and Continence Nursing. 2019;46(2):125-136.
4. D'Ambrosio F, Pappalardo C, Scardigno A, Maida A, Ricciardi R, Calabrò GE. Peristomal Skin Complications in Ileostomy and Colostomy Patients: What We Need to Know from a Public Health Perspective. Int J Environ Res Public Health. 2023;20(1):79. doi:10.3390/ijerph20010079.
5. Taneja C, Netsch D, Rolstad BS, et al. Risk and Economic Burden of Peristomal Skin Complications Following Ostomy Surgery. Journal of Wound, Ostomy and Continence Nursing. 2019;46(2):143-149.
6. Taneja C, Netsch D, Rolstad BS, et al. Clinical and Economic Burden of Peristomal Skin Complications in Patients With Recent Ostomies. Journal of Wound, Ostomy and Continence Nursing. 2017;44(4):350-357.

SECTION 6

Why Competitive Bidding Could Disrupt Stability

Competitive Bidding changes the environment in which beneficiaries obtain their ostomy supplies. It changes which suppliers may furnish competitively bid products, establishes contracted suppliers and payment amounts, and creates requirements governing how beneficiaries obtain those products. Though CMS has suggested safeguards intended to preserve access, the concern is whether the beneficiary can continue to obtain the clinically appropriate product or combination of products that has enabled that individual to remain stable.

6.1 Stability Depends on More Than Product Availability

Among respondents, 76.8% had used their current supplies, brand, or pouching system for at least one year, including 27.4% who had used their current setup for more than five years. Overall, 95.6% rated their current supplies as good or excellent which demonstrates that medicare beneficiaries by and large have pouching systems compatible with their needs. The literature supports the importance of this individualized fit. Thus, availability of a similar product is not equivalent to access to a specific prescribed product.

A beneficiary may technically receive a covered ostomy product while simultaneously experiencing a clinically meaningful loss of stability if that product does not perform adequately for the individual's anatomy or needs.

6.2 Product Substitution Can Create Clinical Uncertainty

The survey provides evidence that respondents do not experience all ostomy products as interchangeable. Among the 65.5% of respondents that had tried other brands or product types, 93.7% reported an experience in which alternative products did not work uniformly well. In addition, 38.2% currently use products from more than one brand. These findings establish that individual product performance varies and that beneficiaries may rely on combinations of products to achieve successful ostomy management.

This distinction is important to consider in a competitive bidding purchasing environment. If a beneficiary's established product is no longer available through the beneficiary's current supplier, or if the beneficiary is encouraged or required to transition to another product, the relevant question is not simply:
Is another product available?
It is:

Will the alternative product perform adequately for this individual beneficiary?

The survey suggests that, for a meaningful proportion of beneficiaries, that question cannot be answered solely by assuming product interchangeability.

6.3 Changes in Supplier Access Could Affect Continuity

Competitive Bidding changes the supplier environment by limiting Medicare payment for competitively bid items in the applicable competitive bidding area to contract suppliers, subject to specified exceptions. CMS currently describes Round 2028 as a nationwide Remote Item Delivery competitive bidding program and will award six contracts for ostomy supplies. This structure creates a potential pathway for disruption if a beneficiary's established supplier is not awarded a contract or if the beneficiary has difficulty obtaining needed products or support from a contract supplier.

CMS has suggested safeguards intended to protect beneficiary access. However, CMS removed requirements related to bidders' prior product experience. This raises concern that some contract suppliers may have limited experience with ostomy products and the specialized support needed to safely and effectively meet individual beneficiary needs.

CMS has recognized the importance of this transition and has established a six-month transition period for beneficiaries moving from non-contract to contract suppliers allowing a six-month grace period for in-network suppliers to obtain a written order for patients transitioning to them from non-contract suppliers beginning on or after January 1, 2028. This also raises concerns since legally a supplier cannot dispense without a prescription.

A supplier change may appear administratively straightforward. However, it can lead to issues:

Changing an Ostomy Supplier Can Be Challenging

For a person living with an ostomy, switching suppliers often involves multiple steps, which can create delays and increase the risk of not receiving the needed products.

Establish a new supplier relationship



Patient must enroll with a new supplier and provide personal and insurance information.

Communicate product specifications and quantities



Patient must ensure the new supplier understands their exact product needs, including brand, size, and quantity.

Transfer documentation and obtain a new prescription



Medical records and prescriptions must be sent to the new supplier, which can take time and may require additional steps with the healthcare provider.

Ensure the supplier carries the necessary products



Not all suppliers carry every brand or product, so the needed items may not be available through the new supplier.

Resolve problems when the expected product is not available



If the correct product is delayed, unavailable, or substituted, patients may need to contact the supplier, their provider, and/or Medicare to resolve the issue.

These challenges can lead to delays, product substitutions, and gaps in care, which may put patients at risk.

6.4 The Evidence Supports Thoughtful Implementation Guided by Evaluation

What we know:

- Most beneficiaries have established ostomy systems that meet their individual needs and provide stability.
- Pouching-system fit, leakage, peristomal skin health, and healthcare utilization are interconnected.
- Competitive Bidding will change the way beneficiaries obtain their ostomy supplies.

What we do not yet know is how this policy change will affect beneficiaries in practice: Will beneficiaries continue to have access to the products they need? Will non-medical product substitutions, supply disruptions, leakage, skin complications, or healthcare utilization increase? And will CMS safeguards, such as the Physician or Treating Practitioner Authorization Process, effectively protect access for ostomy beneficiaries?

These questions make a pre-implementation baseline important.

These measures would allow Congress, CMS and other policymakers to evaluate whether the program's stated objective of preserving beneficiary access is also being achieved in a manner that maintains patient stability and safety.



SECTION 7

Conclusion

This pre-implementation baseline documents the experience of 935 Original Medicare beneficiaries living with an ostomy before Medicare Competitive Bidding is implemented for ostomy supplies.

The findings demonstrate that stability, not product substitution, is the hallmark of successful ostomy care. Maintaining access to clinically appropriate products helps protect patient safety, supports independence, and reduces avoidable healthcare utilization. It documents concerns about product changes, supply disruptions, and the potential consequences of losing access to products that work. The literature provides important context. Product fit, leakage, peristomal skin health, and healthcare utilization are clinically connected. Policies that disrupt stability through non-medical product substitutions or supplier restrictions risk compromising patient safety and increasing healthcare utilization.

Competitive Bidding has not yet been implemented for these supplies, and this study establishes a measurable starting point against which post-implementation outcomes can be evaluated.

CMS acknowledges that beneficiary access is a central objective of the competitive bidding program and has safeguards intended to protect that access. UOAA supports meaningful safeguards that protect Medicare beneficiaries from avoidable disruption in access to clinically necessary ostomy supplies. At the same time, a stated safeguard does not ensure a positive outcome. UOAA believes that safeguards must be measurable and accountable. The purpose of this pre-implementation baseline is to establish the beneficiary experience against which the effectiveness of CMS's safeguards can be evaluated. For example, if CMS's Physician or Treating Practitioner Authorization Process is intended to prevent adverse medical outcomes, post-implementation monitoring should determine whether forced product changes, product-related problems, skin problems, urgent clinical visits, emergency department visits, or hospitalizations change after implementation.

Similarly, if CMS's supplier-capacity methodology is intended to ensure that beneficiary demand is met, evaluation should assess whether beneficiaries are actually receiving the products and quantities they need, whether delays or reductions occur, and whether beneficiaries can obtain appropriate products.

Without this defined baseline, it will be difficult to determine whether access, stability, and safety have been preserved after implementation.

Appendix A

UOAA Policy Recommendations: Ensuring Patient Access, Stability, and Safety

UOAA supports CMS's stated objective of ensuring that Medicare beneficiaries maintain access to quality, medically necessary DMEPOS items and services under the Competitive Bidding Program as noted in a CMS response letter to UOAA concerns dated August 19, 2026. CMS has established beneficiary safeguards, including a Physician or Treating Practitioner Authorization Process under which a specific brand or mode of delivery may be prescribed when needed to avoid an adverse medical outcome. Under this process, CMS requires a contract supplier to furnish the prescribed item under specified circumstances, assist the beneficiary in locating another contract supplier that can provide the item, or work with the treating practitioner to identify an appropriate alternative.

UOAA's recommendations are intended to complement—not replace—these safeguards. The survey findings indicate that access to an ostomy supply is meaningful only when the beneficiary can obtain products that meet individual clinical needs and maintain a stable ostomy system. The recommendations below focus on preserving continuity, identifying early signs of disruption, and creating a transparent process for evaluating whether beneficiary access, stability, and safety are maintained after implementation.

Define Beneficiary Access as Clinical Access, Not Merely Product Availability

CMS should define and evaluate beneficiary access to ostomy supplies in functional and clinical terms. A beneficiary should not be considered to have meaningful access simply because some ostomy product is available. Meaningful access should include the ability to obtain clinically appropriate products, in the quantities needed, within the time needed, and with sufficient continuity to maintain the beneficiary's established ostomy pouching system.

UOAA recommends that CMS define successful beneficiary access using both access and outcome measures, including continuity of clinically appropriate products, timely fulfillment, adequate quantities, and patient-reported stability.

Ensure Timely Access and Delivery of Ostomy Supplies

Section I (D)(1) of the DMEPOS Quality Standards requires that suppliers "provide information regarding expected time frames for receipt of delivered items." Further, Section II (B)(1) requires that suppliers "[d]eliver and set-up, or coordinate set-up with another supplier, all equipment and item(s) *in a timely manner* as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician." The DMEPOS Quality Standards must be met by all DMEPOS suppliers, not just contract suppliers in the DMEPOS CBP.

If unable to fulfill and furnish supplies, "timely manner" should be clearly defined.

UOAA recommends that this should happen within 72 hours of beneficiary order placement and that this be added to the Contract Supplier Obligations and the Quality Standards.

Preserve Continuity of Established Products When Clinically Appropriate

CMS should establish a clear continuity-of-care policy for beneficiaries who are clinically stable on an established ostomy product or product system before Competitive Bidding implementation. Beneficiaries should not be required to change products solely because of a change in supplier, contract status, or payment arrangement when the existing product is covered and clinically appropriate.

Appendix A, continued

As detailed in the Contract Supplier Obligations fact sheet, failure to adhere to contract terms, including **failure to furnish prescribed items, unauthorized product substitution, or any other noncompliance, constitutes a breach of contract.**

Where a product change is necessary, CMS should require the transition to be clinically appropriate, documented, and coordinated so that the beneficiary does not experience an avoidable interruption in supply.

UOAA recommends:

1. *Ostomy supplies are patient-specific prosthetic devices. The prescribing clinician's prescription for a specific ostomy product or product feature (including, but not limited to, barrier type, wear time, convexity, adhesive formulation, filter design, pouch configuration, or accessory use) and quantity needed to avoid an adverse outcomes shall be accepted as medically necessary and not require serial appeals. Contract suppliers may not require additional clinical justification, repeated documentation, or product trials once the prescription is issued. According to CMS Article A52487, medical need was already established at the time the item(s) is first ordered, therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. Once initial medical need is established, ongoing need for ostomy supplies is assumed to be met.*
2. *Products sharing the same HCPCS code shall not be presumed clinically interchangeable. Beneficiaries who are stable on a specific ostomy product must be allowed to continue that product without interruption. Substitutions based solely on HCPCS code equivalency, lower cost, or inventory preference are prohibited and should constitute a breach of contract. At no time shall a beneficiary be required to fail a product before getting the product they have been stable on. This should be added to the Contract Supplier Obligations.*

Strengthen and Operationalize the Physician Authorization Safeguard

CMS should ensure the Physician or Treating Practitioner Authorization Process functions as a practical patient-safety safeguard, not a mechanism that becomes useful only after a beneficiary experiences an adverse outcome.

CMS currently permits a physician or treating practitioner to prescribe a specific brand or mode of delivery when necessary to avoid an adverse medical outcome and requires the contract supplier to follow the process established by CMS.

UOAA recommends that CMS should provide clear beneficiary, clinician, and supplier guidance addressing:

- *how the safeguard should be initiated;*
- *what clinical documentation is sufficient;*
- *how quickly requests should be resolved;*
- *what happens when a supplier does not ordinarily furnish the prescribed product;*
- *how beneficiaries can obtain the product while an authorization issue is being resolved; and*
- *how beneficiaries and clinicians can escalate unresolved cases.*

CMS should also monitor authorization requests, denials, delays, and escalations as part of its beneficiary-access oversight.

CMS should make the Physician Authorization Process readily accessible, timely, transparent, and measurable for beneficiaries living with an ostomy. CMS should report on and make public Physician Authorization Process activity.

Appendix A, continued

Monitor Patient Stability, Compare Outcomes, and Establish Triggers for Action

CMS should use the pre-implementation baseline to monitor beneficiary access, stability, and safety after Competitive Bidding implementation and identify emerging problems before they progress to more serious patient-safety events.

Key measures should include:

- supply delays or reduced quantities;
- non-medical product changes or inability to obtain needed products;
- leakage and peristomal skin problems;
- increased supply use;
- additional healthcare encounters, including emergency department visits and hospitalizations; and
- beneficiary complaints and patient-reported changes in stability or daily life.

CMS should publicly compare these measures with the pre-implementation baseline using consistent definitions and establish measurable thresholds that trigger review and corrective action when meaningful deterioration occurs. Published criteria should also identify the actions CMS may take when individual problems indicate a broader pattern.

UOAA recommends that CMS use the pre-implementation baseline to monitor patient stability, publicly report changes, and establish transparent thresholds for corrective action.



Key Domains for Post-Implementation Monitoring

At minimum, monitoring after implementation should assess product access, clinical effects, healthcare use, and patient-reported outcomes.



Product Access and Coverage

- **Access to established and clinically appropriate ostomy products and systems**
- **Frequency of forced or non-medical product changes**
- **Supply delays and reductions in quantities received**
- **Insurance-related inability to obtain needed products**



Ostomy Management and Complications

- **Leakage and peristomal skin problems**
- **Increased use of supplies**



Healthcare Utilization

- **Additional nurse or physician visits**
- **Emergency department visits and hospitalizations**



Patient-Reported Outcomes

- **Patient-reported changes in stability and daily life**

These measures can help determine whether implementation affects safety, stability, and continuity of ostomy care.

Appendix A, continued

Evaluate Supplier Capacity and Product Availability at the Beneficiary Level

CMS should evaluate supplier capacity not only by whether contract suppliers collectively can meet aggregate demand, but also by whether beneficiaries can obtain the specific products and quantities required for their established systems.

CMS currently states that its methodology aims to ensure sufficient contracts to meet beneficiary demand and that it may award additional contracts if demand is not met.

For ostomy supplies, however, aggregate capacity may not fully capture beneficiary-level access. A supplier may have sufficient overall inventory while an individual beneficiary experiences an access problem because the supplier does not stock or reliably furnish the particular product needed by that beneficiary.

UOAA recommends that CMS incorporate beneficiary-level product availability and fulfillment into its monitoring of supplier capacity rather than relying solely on aggregate demand measures.

Provide an Expedited Patient-Safety Escalation Pathway

CMS should provide beneficiaries and clinicians with a clearly identified, expedited pathway for resolving situations in which a beneficiary cannot obtain an established, clinically necessary ostomy product or experiences a clinically significant problem following a product or supplier change.

CMS already maintains a Competitive Acquisition Ombudsman and a formal complaint process through 1-800-Medicare for beneficiaries, caregivers, suppliers, and other stakeholders.

UOAA recommends enhancing this existing infrastructure by distinguishing urgent clinical-access concerns from routine administrative complaints and establishing appropriate response expectations for urgent cases.

An expedited pathway would allow CMS to identify systemic problems while they are still correctable and would provide beneficiaries with a practical mechanism for preventing avoidable deterioration in ostomy management.

Conduct Ongoing Beneficiary-Centered Evaluation

CMS should incorporate direct beneficiary experience into ongoing evaluation of the Competitive Bidding Program for ostomy supplies.

Claims data can identify hospitalizations and other healthcare utilization, but they may not capture earlier changes in product performance, leakage, skin problems, supply adequacy, or loss of confidence and independence.

A recurring beneficiary survey using core questions from this pre-implementation baseline would allow CMS to identify changes that may not yet appear in claims data. It would also complement CMS's existing health-status monitoring, complaint processes, and other oversight mechanisms.

UOAA recommends that CMS conduct recurring beneficiary-centered assessments using a consistent set of measures that can be directly compared with the pre-implementation baseline.

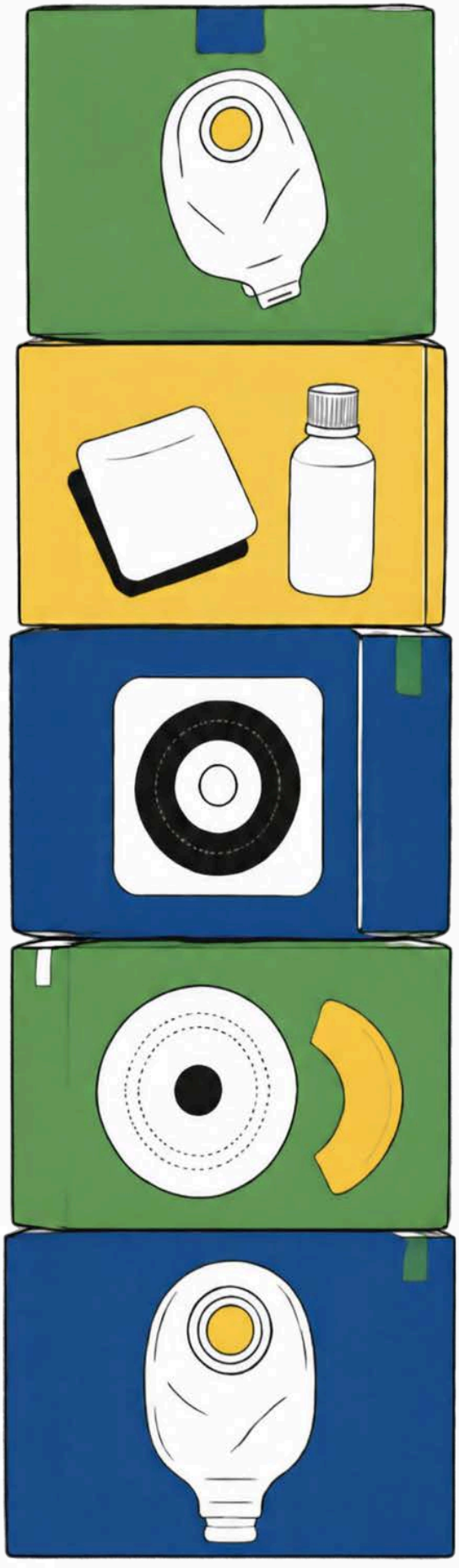
UOAA's Recommended Policy Standard

UOAA recommends that CMS use the following standard when evaluating implementation of Competitive Bidding for ostomy supplies:

> **A beneficiary should be considered to have meaningful access to ostomy supplies only when the beneficiary can obtain the clinically appropriate products and quantities needed to maintain an established, stable ostomy system without avoidable interruption.**

Under this standard, evaluate the success of Competitive Bidding not solely by payment amounts, supplier participation, aggregate fulfillment, or the availability of some covered product.

It should also be evaluated by whether beneficiaries can keep products that work, clinical stability, patient safety, and independence documented in this pre-implementation baseline.



UOAA's overarching recommendation:

Protect patient stability.
Measure the outcomes.

The success of Medicare Competitive Bidding for ostomy supplies should ultimately be judged by whether Medicare beneficiaries continue to have meaningful access to the clinically appropriate supplies they need to remain stable, safe, and independent.

Appendix B

CMS Response to UOAA Concerns with Competitive Bidding

UOAA has met with and corresponded with CMS. UOAA appreciates the work being done by the Administration to reduce healthcare costs, prevent fraud and keep the Medicare program sustainable for years to come. But those savings should never come at the expense of patient safety or access to medically necessary supplies.

Following this page are the official comments from CMS.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-15-12
Baltimore, Maryland 21244-1850

Center for Medicare

August 19, 2026

Jeanine Gleba
Director of Advocacy
United Ostomy Association of America (UOAA)
advocacy@ostomy.org

Dear Ms. Gleba:

Thank you for your continued engagement with the Centers for Medicare & Medicaid Services (CMS) regarding the inclusion of ostomy and urological supplies in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) for Round 2028. We appreciate UOAA's commitment to ensuring that Medicare beneficiaries maintain access to the clinically appropriate, high-quality supplies they need, and we welcome the opportunity to address your questions and recommendations.

The DMEPOS CBP does not diminish existing beneficiary rights or supplier responsibilities; rather, it adds an additional layer of accountability through contract requirements and active monitoring.

Beneficiary Access and Supplier Obligations

DMEPOS CBP contract suppliers will be required to furnish competitively bid items, including ostomy and urological supplies, to all Medicare beneficiaries in the nationwide Remote Item Delivery competitive bidding area. Importantly, the DMEPOS Quality Standards already directly address the concerns UOAA raises regarding timely access and delivery.
Specifically, Section I (D)(1) of the DMEPOS Quality Standards requires that suppliers *"provide information regarding expected time frames for receipt of delivered items*." Further, Section II (B) (1) requires that suppliers *"[d]eliver and set-up, or coordinate set-up with another supplier, all equipment and item(s) in a timely manner as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician."* The DMEPOS Quality Standards must be met by all DMEPOS suppliers, not just contract suppliers in the DMEPOS CBP.

As outlined in the Physician or Treating Practitioner Authorization Process fact sheet, the Physician Authorization Process requires the contract supplier: (1) furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner; (2) consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or (3) assist the beneficiary in locating a contract supplier that can furnish

the particular brand of item or mode of delivery prescribed by the physician or treating practitioner. CMS will ensure this resource is prominently featured across all Round 2028 education channels including bidder instruction communications, beneficiary-facing guidance, and provider and referral agent resources with plain-language explanations of documentation requirements and supplier obligations.

Supplier Capacity Validation

As part of the competitive bidding process, CMS evaluates each supplier's:

- Financial information
- Accreditation and licensure status in the Medicare enrollment system
- Bid surety bond

As described in 42 CFR section 414.414(d), a bidding entity's business credit report with a numerical score or rating will serve as the primary mechanism for evaluating whether a bidder has the financial resources necessary to serve beneficiaries in a competitive bidding area. For additional information on how CMS evaluates a bidder's credit report in determining whether the entity meets the financial substantiality threshold and, therefore, may be considered for a potential contract award, please refer to the Financial Standard Reporting fact sheet.

Enforcement, Compliance, and Performance Management

CMS takes compliance seriously and has robust mechanisms in place to hold contract suppliers accountable. In addition to routine monitoring of claims data, Medicare enrollment data, and supplier performance indicators, Section I (E)(1) of the DMEPOS Quality Standards requires suppliers to *"implement a performance management plan that measures: outcomes of consumer services, billing practices, and adverse events. The data collection may targetcertain aspects of services that have a potential to cause harm or injury . . . ."*

As detailed in the Contract Supplier Obligations fact sheet that was recently published, failure to adhere to contract terms, including failure to furnish prescribed items, unauthorized product substitution, or any other noncompliance, constitutes a breach of contract. Pursuant to 42 C.F.R. section 414.422(g)(2), CMS may take enforcement action, including contract termination and preclusion from participation in future rounds of the DMEPOS CBP. Beneficiaries, caregivers, providers, and referral agents are encouraged to report complaints through 1-800-MEDICARE, which are tracked, incorporated into CMS's oversight processes, and referred to both the Competitive Bidding Implementation Contractor and the CMS Competitive Acquisition Ombudsman. If you are aware of specific instances where our policies are not being adhered to, please bring this to our attention.

Transparency and Education

The DMEPOS CBP provides additional transparency and access to information that is not otherwise available outside of the program, as it requires contract suppliers to submit semi-annual reports (Form C) disclosing the manufacturer and model of specific items offered to customers that then becomes available on Medicare's Supplier Directory. CMS is committed to

ensuring that beneficiaries, providers, and referral agents are aware of this additional transparency and receive robust education on their rights and options under the DMEPOS CBP, including the Physician Authorization Process, ordering options under Remote Item Delivery, and available recourse pathways discussed above.

CMS remains committed to ensuring successful implementation and will continue to engage with UOAA and other stakeholders as Round 2028 moves forward. We share your goal of ensuring that every Medicare beneficiary relying on ostomy and urology care has uninterrupted access to the supplies they need to maintain their health, dignity, and independence.

Sincerely,

James Bailey

James Bailey
Deputy Director
Technology, Coding, and Pricing Group
Center for Medicare
Centers for Medicare & Medicaid Services