## Reaction to CMS final rule on DMEPOS Competitive Bidding Program

On November 28, 2025 the Centers for Medicare and Medicaid Services (CMS) in the US announced a final rule<sup>1)</sup>, which among other, updates the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP).

The final rule confirms that ostomy, tracheostomy and urological supplies, including catheters and related items, will be included in the next round of the nationwide Remote Item Delivery (RID) CBP. It also establishes a separate product category for hydrophilic urinary catheters, aligned with the new HCPCS codes effective January 1, 2026, and requires contract suppliers to furnish the brand specified on the prescribing physician's order in accordance with supplier standards.

Contracts under the nationwide RID CBP will take effect no later than January 1, 2028. Beginning on that date, CMS will allow a six-month transition period for suppliers to move beneficiaries from non-contract suppliers to contract suppliers. CMS will announce lead items and contract numbers in late Spring/early Summer 2026, open bid registration and submission in late Summer/early Fall 2026, and award contracts with published payment amounts in late Summer/early Fall 2027.

Coloplast is mostly present as a manufacturer in the US but has a smaller direct-to-consumer business, Comfort Medical, with a market share of 5-10%. Coloplast expects to participate in the CBP through Comfort Medical.

Once the contracts under CBP enters into effect for our categories no later than January 1, 2028, we expect an impact on the entire supply chain. However, until contracts have been awarded and single payment amounts published, we are unable to provide an estimate of the financial impact on Coloplast.

Coloplast supports the efforts by the US authorities to ensure cost efficiency in healthcare expenditure and welcomes the decision to create a separate product category for hydrophilic urinary catheters, as well as the decision to honour the brand specification on the prescribing physician's order. However, we remain concerned that applying competitive bidding to categories requiring customisation and patient support could limit patient choice and access to high-quality products and innovation.

Coloplast will continue to work with industry associations and other relevant stakeholders to advocate for continued patient choice and product access.

Chronic Care in the US accounted for around 12% of Group sales in FY 2024/25 and we estimate that around 50% of sales are related to Medicare.

<sup>1)</sup> DMEPOS Competitive Bidding Program Final Rule

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Coloplast was founded on passion, ambition, and commitment. We were born from a nurse's wish to help her sister and the skills of an engineer. Guided by empathy, our mission is to make life easier for people with intimate healthcare needs. Over decades, we have helped millions of people to live a more independent life and we continue to do so through innovative products and services. Globally, our business areas include Ostomy Care, Continence Care, Voice and Respiratory Care, Wound and Tissue Repair and Interventional Urology.

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