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June 22, 2015

The Honorable Orrin Hatch  
Chairman  
Senate Finance Committee  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Ron Wyden  
Ranking Member  
Senate Finance Committee  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Johnny Isakson  
131 Russell Senate Office Building  
Washington, DC 20510

The Honorable Mark Warner  
475 Russell Senate Office Building  
Washington, DC 20510

**Re: Senate Finance Committee Chronic Care Working Group Request for Comments**

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

ConvaTec Inc., a medical device manufacturer with U.S. headquarters in Bridgewater, New Jersey and manufacturing facilities in Greensboro, North Carolina welcomes the opportunity to provide comments to the Senate Finance Committee Chronic Care Working Group. Our company develops and manufactures high-quality, innovative products in the areas of ostomy care, advanced wound dressings, continence and critical care, and infusion devices used in community and hospital settings. We share the Committee's goal of identifying and developing solutions to improve health outcomes for Medicare patients with chronic conditions and lower health care costs, allowing more beneficiaries to remain in the community and out of the hospital.

**Background**

Our company develops technologies that are essential for managing complex and life-changing health conditions. While some of our products are used specifically in the hospital-based setting, we have traditionally focused much of our engineering and research effort in developing cost effective, innovative product solutions that help people with chronic and complex health care needs live healthy and productive lives in their communities. We agree with the importance of empowering more Medicare beneficiaries to play a greater role in managing their health care. Unfortunately, despite routine success in achieving Food and Drug Administration (FDA) clearance for our products, our ability to make such community-focused technologies available through the Medicare program has at times been significantly hampered by current Healthcare Common Procedure Coding System (HCPCS) processes at the Centers for Medicare and Medicaid Services (CMS).



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While CMS has moved to develop more precise coding processes for other areas of the health care system (e.g., ICD-10 coding set for medical procedures with an expansion of thousands of new hospital diagnoses and procedure codes from the previous ICD-9 code set), there has been no such effort within the HCPCS coding set that is utilized for medical devices. The current HCPCS process used by CMS places devices and medical supplies into existing, broad, catch-all generic categories resulting in many devices being provided codes that do not necessarily recognize their clinical function or value compared to other devices/supplies in the same category. Unlike hospital billing codes, CMS historically approves new HCPCS codes for less than 10 percent of the applications it receives for novel technologies.

A poor coding decision can and frequently does result in a manufacturer being unable to make the technology available to Medicare patients in the United States as the cost of manufacturing the technology significantly exceeds what Medicare will pay for it under the code provided. For example, a coding decision made by CMS classified a new first-in-class ostomy device developed by our company into an existing generic code category that, according to outside clinical experts and experienced health care providers, did not appropriately recognize the technology's clinical function. Further, the reimbursement amount associated with the code category would not cover the cost of manufacturing the technology. As a consequence of CMS's decision, we were forced to discontinue marketing the device in the United States, resulting in Medicare beneficiaries, as well as those on Medicaid and private insurance that live with ostomies, not having access to the device.

### **Recommendation**

As part of its legislative framework, ConvaTec urges the Senate Finance Committee to support a formal review and assessment of the HCPCS coding process by the General Accountability Office (GAO). We encourage the Committee to have GAO examine the following:

- Review the current HCPCS application process and the information required for consideration;
- Review the number of HCPCS coding denials and related agency explanations and understand the reason for the high denial rate;
- Review how a HCPCS decision is rendered for first-of-its-kind technologies and the decision making process for code categorization when miscellaneous codes are not utilized;



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- Understand CMS's process for granting miscellaneous code options when a technology does not easily fit any HCPCS coding category;
- Assess whether coverage and pricing decisions are being assessed as part of the HCPCS coding decision process;
- Understand the make up of the review committees/contractors utilized by CMS to ensure the appropriate clinical expertise is available to evaluate different types of technology;
- Understand the CMS reconsideration process and timing for reconsideration for a code that has been appealed and the data required during that review process.

We believe our recommendation fits the Committee's three main bipartisan goals for improving outcomes for Medicare patients with chronic conditions. While we are not yet recommending a formal policy change, we are requesting that the Committee support through legislation a formal evaluation of the HCPCS coding process so that the Committee can consider thoughtful policy reforms going forward.

- **The proposed policy increases care coordination among individual providers across care settings who are treating patients living with chronic diseases.**

An evaluation of the current HCPCS process by the GAO and resulting recommendations could lead to improvement in patient access to new innovative technologies, improving a provider's ability to manage a Medicare patient's care within a given health care setting. For patients with multiple chronic conditions, technology advancements can help manage a patient's quality of care.

- **The proposed policy streamlines Medicare's current payment systems to incentivize the appropriate level of care for patients living with chronic diseases.**

A central goal of our recommendation to evaluate and seek improvements to the current HCPCS decision-making process is to ensure Medicare makes available the right types of technology to improve and manage a patient's health care needs in a cost effective manner. The current process, in our experience, inappropriately considers the upfront cost of the technology when making coding decisions and does so without any cost-benefit analysis of Medicare's overall cost for managing a patient's care.



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- **The proposed policy facilitates the delivery of high quality care, improves care transitions, produces stronger patient outcomes, increases program efficiency, and contributes to an overall effort that will reduce the growth in Medicare spending.**

Our proposed recommendation for GAO to assess the current HCPCS coding process and make recommendations for adjustments is intended to improve the current system so that we can ensure that high quality innovations are made available to enhance patient care. This includes helping to transition patients from the more costly hospital setting into community-based care settings. Innovation can often improve the management of a person's health, reducing overall health care expenditures, and therefore, the growth of Medicare spending.

The current process for obtaining new HCPCS codes for novel technologies is not predictable and discourages investment in research and development. The current HCPCS coding application and appeals process is not efficient and wastes government and private sector resources. Examining and eventually reforming the current HCPCS coding process is essential to increasing Medicare beneficiary access to technology options that can help improve health and reduce the cost of care.

### **Conclusion**

To meet its stated policy goal of ensuring Medicare beneficiaries can more effectively manage their care, Congress should ensure there is a fair and appropriate process for advancing cost effective community-based care and technology solutions for Medicare patients, particularly those with chronic health care needs.

Device manufacturers in the United States invest a significant amount in the research and development of technologies, followed by the process of having such technologies cleared by the FDA for use. This is an investment the U.S. government must support and encourage. To spend years and millions of dollars bringing a product successfully to market, only to receive a HCPCS coding decision that ultimately prohibits a manufacturer from making a product available in the United States, and to have no appropriate recourse in moving such a product forward, is a drain on resources and ultimately impacts a manufacturer's decision to continue investment in new innovations. It also hampers our collective goal of reducing health care costs by making technologies available that help people live healthier and better lives at home.



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ConvaTec is pleased to have the opportunity to provide comments to the Committee, and we thank you for your leadership. We would be pleased to meet with the work group to provide additional insight and answer any questions. For more information, please contact me at 732-412-5451, [Joseph.Rolley@ConvaTec.com](mailto:Joseph.Rolley@ConvaTec.com); or our Washington Representative, Julie Allen at 202-230-5126, [Julie.allen@dbr.com](mailto:Julie.allen@dbr.com).

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph Rolley".

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