

The changing US healthcare climate:

What does it mean for wound care?

The recent transition to a new Presidential administration in the US - and the ongoing health policy debates that have ensued - put the healthcare landscape into a state of flux, leaving many stakeholders in the wound care space wondering what is coming next.

What impacts could the US's new political landscape have on wound care patients and providers? What challenges will the US's new value-based-care payment system create for wound care? How could policy changes impact reimbursement pathways for wound care products?

As Executive Director of the Alliance of Wound Care Stakeholders, I addressed these issues at the May 2017 European Wound Management Association's plenary session "Change, opportunities and challenges - wound management in changing healthcare systems." As part of this panel of international experts, I had the opportunity to share a US perspective on the current healthcare climate and its impact on wound care.

SHARED TRENDS & CHALLENGES

The US and Europe have significantly different healthcare systems; however, there are important global marketplace trends that impact the sector:

- An **aging population** creates an increasing demand for medical products and services.
- This increase is good for the industry and providers; however, it is coupled with increasingly **cost conscious government and insurance payers**. **Cost-containment initiatives** often lead to **unfavourable payment rates and/or discretionary coverage policies**.

- Therefore, we as physicians, clinicians and manufacturers need to **demonstrate value** to patients, payers and the health care system overall.

- Currently, we need to focus on generating **new types of data** - especially for the wound care space - that demonstrate value using **real-world evidence**.

- Similarly, we need to **advocate effectively** to ensure wound care issues are fairly addressed as policies are implemented and evolve. Having a united voice has never been more important. Advocacy is how we ensure patient access to quality care, ultimately leading to better outcomes.

NEW ADMINISTRATION = NEW OPPORTUNITIES FOR ADVOCACY

In the US, health policies are affected by many levels of government: the White House, Congress, and federal regulatory agencies. These regulatory agencies include the Department of Health and Human Services (HHS), which is the umbrella organisation that covers the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration (FDA). The initiatives of these regulatory agencies have the largest impact on wound care practices in the US.

While our current Presidential Administration and its healthcare efforts have dominated headlines, the reality is that wound care practices in the US are not under any significant threat from the new Administration. In fact, the new heads of HHS, CMS and FDA bring extensive experience to the table, and their leadership could present new opportunities to advance and potentially fix



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some of the regulatory challenges we have faced in the wound-care space (*HCPCS-coding process, local coverage determinations, etc.*).

The new HHS Secretary, Tom Price, MD, is a retired surgeon and former Congressman. Who has a reputation for eliminating superfluous regulations and limiting federal involvement. We believe Sec. Price may be receptive to our concerns and advocacy. Seema Verma, the new CMS Administrator, is highly regarded and best known for her work on Medicaid-related issues. Scott Gottlieb, MD, the new FDA Commissioner, has a track record of favouring the industry and supporting faster drug approvals. Overall, these individuals could be good for the wound care sector.

UNIQUE US TRENDS & CHANGES

The seismic shifts in the US health sector are being driven by two recent pieces of legislation:

- **Medicare Access and CHIP Reauthorization Act (MACRA):**

Enacted in 2015, MACRA is a driving force in the US's shift to value-based care. This transformative law changes how US physicians and other clinicians are reimbursed. It creates a new framework for Medicare incentive payments that rewards clinicians for better care and consolidates quality reporting. This law would move reimbursement away from the "fee-for-service" model and toward a quality-measure-based coordinated-care model. However, this innovative new

system could create unique challenges for wound care providers as it evolves and is implemented through the CMS's two Quality Payment Program reimbursement pathways: the Merit-Based Incentive Payment System and Alternative Payment Models. Currently, none of the obligatory quality, resource-use and clinical-performance reporting measures under MACRA are specific to wound care. Ultimately, the lack of reporting measures could impact Medicare reimbursement rates in the wound care space. The Alliance has been proactively engaging CMS policy makers and advocating for the addition of more wound care-specific measures as these payment programs evolve.

- **21st Century Cures Act:**

The goal of this act is to "bring our healthcare innovation infrastructure into the 21st century." The Act advances personalized medicine and emphasises patient-centred outcomes and data. Importantly, it allows the FDA to streamline clinical trials, expands trial-design frameworks, and opens the door for the application of real-world evidence (RWE)—which could be particularly impactful in wound care space. Under the Act, the FDA has a mandate to issue guidance on the use of "complex adaptive and other novel trial design" frameworks and must consider the types of patient-driven quantitative and qualitative data that can be submitted for review. Many countries look to FDA paradigms to



set their own guidance, so implementation of this Act could have global ramifications on trial designs moving forward.

ADVOCACY FOCUS TODAY

Our association of multi-disciplinary clinical organisations, the Alliance of Wound Care Stakeholders, is focused on promoting quality care and access to products and services for patients with wounds. We evaluate US health policies that impacts the wound care space. We bring together wound care clinicians, non-clinical entities, and manufacturers to advocate on regulatory, legislative, and public policy issues, such as coding, coverage, and reimbursement. These issues can create barriers to patients' access to treatment or care. Over the years, we have successfully affected policy and legislation, demonstrating that collaborations between clinical associations and industry can work well together.

Building on the trends outlined above, the priority areas for proactive wound care advocacy in the US include:

- **MACRA Quality Measures:**

MACRA creates unique challenges for wound care providers. Quality, resource-use, and clinical-performance measures—the reporting of which are obligatory for Medicare reimbursement under MACRA - may not truly reflect clinical decision making or the resources used

to treat wound patients. CMS's list of quality measures fall into two categories: (a) those that can be used by all clinicians and (b) those that specifically apply to medical specialties. However, wound care is not designated as a medical specialty in the US. Thus, none of the initial measures that affect Medicare payments are wound care specific. The US Wound Registry has defined quality measures for wound care, but currently, these measures are not eligible for MACRA reporting. As such, wound care practitioners have to find a way to work with the available quality and documentation measures. At present, the Alliance is spearheading advocacy initiatives to educate policy makers about the importance of including quality measures that are meaningful in the wound care space.

- **Optimising real-world evidence (RWE):**

Randomized, controlled clinical trials do not always reflect the clinical realities of wound care. The 21st Century Cures Act opens the door to RWE and provides the wound care community with the opportunity to work together with manufacturers and regulatory agencies to establish RWE-driven pathways for FDA-approval of wound products and technologies. Looking ahead, the FDA has a mandate to hold public meetings on novel clinical trial design and RWE frameworks and to issue guidance on these topics. The guidance-development process will include multiple opportunities for stakeholder input, and the Alliance will proactively voice wound care concerns and identify opportunities.

- **Healthcare Common Procedure Coding System (HCPCS) reform:**

The system for obtaining a HCPCS code (which is used for billing a product under Medicare, Medicaid, and private health plans) lacks transparency, timeliness, and predictability. The process has had a chilling effect on innovation, therefore not allowing new technological developments for patients and ultimately compromising access to quality care. This system has created barriers to the coverage of and reimbursement for new products. Reform is needed to develop a meaningful code set that allows for uniform billing, has appropriate coverage and reimbursement policies, and gives patients access to quality care. The Alliance supports initiatives to reform the HCPCS-coding process by establishing greater transparency, and creating more opportunities for stakeholder input in the process.

- **Medicare Local Coverage Determination (LCD) transparency:**

Most coverage policies for wound care in the US are set regionally by Medicare Administrative Contractors

(MACs). An increasing number of restrictive LCDs have impacted access to wound care therapies. The LCD-development process lacks transparency, and the policies regularly cite outdated evidence that not based on current clinical practice standards. The Alliance has actively voiced concerns to CMS. The US Congress recognised that the LCD-development process needs improvement and included provisions in the 21st Century Cures Act to “increase transparency around the LCD process and begin the process of bringing greater accountability.” This provision requires that MACs provide stakeholders with information, including a response to submitted comments, a summary of the evidence considered during LCD development, and an explanation of the rationale supporting coverage determination. Additional legislation to improve MAC transparency and accountability was introduced in the US Senate (S.794) and in the House of Representatives (H.R. 3635). The Alliance is proactively developing strategies to support and strengthen this legislative initiative.

CONCLUSION

There are several unifying elements needed to navigate the changes in both the US and European health systems:

(1) Relationships matter. Knowing decision makers in regulatory agencies and government is critical for successful advocacy.

(2) Quality evidence. Providing high-quality evidence is more important now than ever. It is needed to demonstrate value and for manufacturers to obtain coverage and reimbursement for medical products.

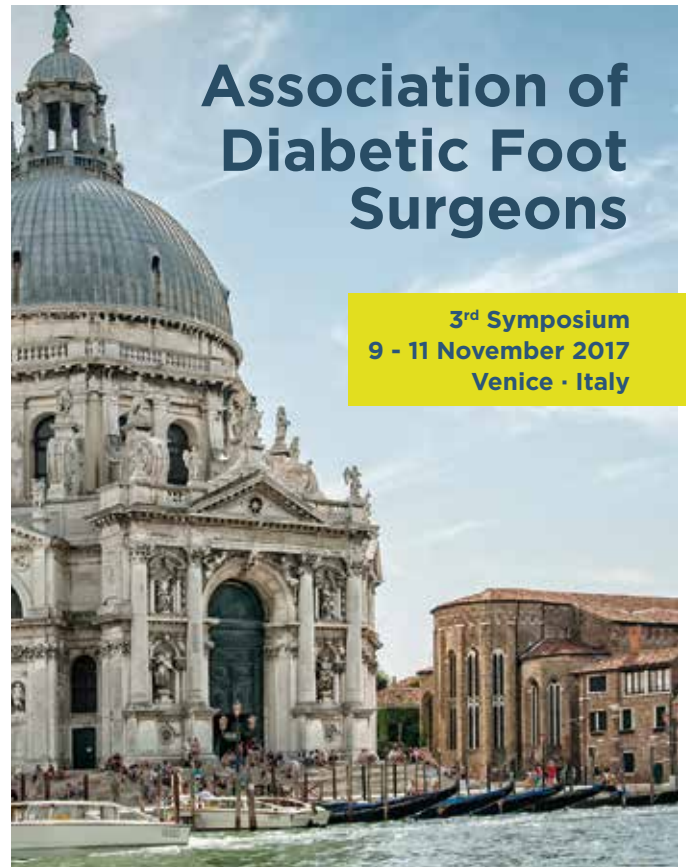
The Alliance unifies the voice of the wound care clinician community and helps navigate and proactively address prospective policy issues. We leverage our collective power to ensure that wound care has visibility and a seat at the regulatory table during healthcare policy development and decision making. Looking to the future, we and our members are ready to tackle the issues of importance to the wound care community. We look forward to keeping EWMA and its members informed of our progress. Keep up to date on our ongoing US wound care advocacy issues and the Alliance’s initiatives at www.woundcarestakeholders.org.

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