Digital Health Industry Regulatory Case Study

AppliedVR

Improving access to novel virtual reality (VR) therapies for chronic lower back pain

About AppliedVR

AppliedVR offers scientifically proven, comprehensive prescription virtual reality-based therapeutics for chronic pain management. The RelieVRx® program is the **first FDA-authorized in-home virtual reality (VR) treatment** clinically proven to significantly reduce chronic lower back pain (CLBP).

The opportunity

- Chronic pain affects more than 100 million Americans, costing an estimated $635 billion annually.
- Treating chronic pain with opioids can lead to possible misuse and addiction.
- VR treatment is a safe and effective non-pharmacologic treatment to reduce pain and pain intensity without the risks associated with opioids and other interventions.

The challenge

- Cognitive behavioral therapy (CBT) can reduce the burden of chronic pain and increase function through an emotional, cognitive, and behavioral approach.
- AppliedVR set out to build a prescription-only, CBT-based, home-delivered VR therapy that reduces pain and the impact of pain on function through non-pharmacological mechanisms.
- Public and private payers in the US do not cover prescription CBT products without FDA authorization of safety and effectiveness.

The approach

- As they set out to develop an optimized product that meets patient, clinician, payer, and public health needs, AppliedVR requested a series of **pre-submission meetings with the FDA.**
- These meetings enabled AppliedVR to leverage existing and new research to push the boundaries on how they could build a **VR-based product that delivered clinical impact** that clinicians could legally prescribe, payers could cover, and patients could use within their home environment.
- As AppliedVR continues to diversify its portfolio to meet patient needs and provide safe and effective non-pharmacologic management of conditions such as CLBP, fibromyalgia, and post-surgical pain, they continue to **work with federal agencies such as the FDA and Veterans Affairs Administration (VA)** to push the boundaries of innovation.

The success

- ✔ RelieVRx received **Breakthrough Device designation** and market authorization under FDA's De Novo pathway.
- ✔ Patients can **access therapy with VA benefits**, incurring no out-of-pocket expenses.
- ✔ CMS established a **VR-specific billing code** – HCPCS level II code (E1905) and included it in the Durable Medical Equipment (DME) medical benefit category for reimbursement.

> "It is important to do as many pre-submission meetings with the FDA as you can, even if it is with an 'out-of-the box' idea. They want to work with manufacturers to ensure that we develop products that meet patient needs and address critical public health issues."

— Michael Chibbaro

VP Regulatory Affairs & Quality Assurance, AppliedVR

DME