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Valuation of Remote Therapeutic Monitoring: Technological Environment

As discussed in the first installment in this five-part series on valuing remote therapeutic monitoring (RTM), such services require the use of a device to collect and report the non-physiologic data. Those devices must be "medical devices" (rather than a general wellness device) as defined by the U.S. Food & Drug Administration (FDA).[1] This final installment in this series will discuss the technological environment in which RTM operates.

The *Food, Drug, and Cosmetics Act* (FD&C Act) requires that a medical device be used in RTM. The FD&C Act defines "device" as:

> "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man...."[2]

Some examples of devices that may be utilized in RTM include:

(1) A sensor that attaches to an inhaler and sends information regarding where the inhaler is used (and links it to weather and air quality in the patient's area) and how often it is utilized (i.e., medication adherence);[3]
(2) A smart pill dispenser, which sends information regarding what drugs are dispensed and when (i.e., medication adherence);
(3) A smart-sensor shoe insole that tracks the temperature, inflammation levels, and pressure being applied to a diabetic patient's ulceration;[4] and,
(4) A digital goniometer that a patient can use at home to measure their range of motion before and after performing exercises recommended by their physical therapist.[5]

Note that wellness devices (e.g., apps that play sounds to reduce anxiety, food journal apps, FitBit and Apple watches, Apple Watch's blood oxygen sensor) are not considered medical devices by the FD&C Act. However, patients may self-report data from these devices provided they are collected and submitted via Software as a Medical Device (SaMD), in addition to the standalone peripheral devices.[6] In the RTM space, SaMD is likely the pathway through which data will be self-reported by patients, e.g., pain levels and medication adherence.[7] SaMD is defined the same as a medical device, except that the software (rather than the physical hardware) is performing that function. Further, that software can be used without being part of a hardware medical device.[8] Some examples of this are "software that allows a smartphone to view images obtained from a magnetic resonance imaging (MRI) medical device for diagnostic purposes" and "Computer-Aided Detection (CAD) software that performs image post-processing to help detect breast cancer."[9]

The market for RTM may experience increasing demand in the coming years, due to an aging U.S. population and the growing prevalence of musculoskeletal and respiratory conditions. These factors may augment the number of individuals that are candidates for RTM. However, RTM's requisite reliance on one or more FDA-approved devices may serve as a ceiling on the swiftness with which providers can adopt and bill for RTM. Nevertheless, RTM may allow providers to streamline care and reduce costs through earlier identification of health issues and improving data-driven clinical decision making, which will prepare them for participation in value-based reimbursement models. Ultimately, this could promote one of the central goals of healthcare reform, i.e., increased efficiency in healthcare and high quality care.

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1 "New Reimbursement for Remote Therapeutic Monitoring in the Final 2022 Medicare Physician Fee Schedule" By Carrie Nixon, Nixon Gwilt Law, November 3, 2021, https://nixongwiltlaw.com/nlg-blog/2021/11/3/new-reimbursement-for-remote-therapeutic-monitoring-in-the-final-2022-medicare-physician-fee-schedule (Accessed 2/15/22).

2 "Definitions; generally" 21 U.S.C. § 321(h).

3 "Propeller" https://propellerhealth.com/ (Accessed 2/23/22).

4 "Orpyx SI Sensory Insoles" https://www.orpyx.com/for-providers?utm_term=remote%20monitoring%20devices%20in%20healthcare&utm_campaign=LI+Orpyx+insoles+Search+2021&utm_source=adwords&utm_medium=ppc&hsa_acc=8265099028&hsa_cam=13828184848&hsa_grp=123345347454&hsa_ad=532410977898&hsa_src=g&hsa_tgt=kwd-743696508938&hsa_kw=remote%20monitoring%20devices%20in%20healthcare&hsa_mt=p&hsa_net=adwords&hsa_ver=3&gclid=EAIaIQobChMI_Y_rzqSb9gIVlQaICR3d8QqLEAAYASAAEgLl8vD_BwE (Accessed 2/25/22).

5 "Digital Goniometer – EasyAngle" https://meloqdevices.com/products/digital-goniometer-easyangle (Accessed 2/25/22).

6 Nixon, Nixon Gwilt Law, November 3, 2021, https://nixongwiltlaw.com/nlg-blog/2021/11/3/new-reimbursement-for-remote-therapeutic-monitoring-in-the-final-2022-medicare-phys.

7 "CMS Finalizes New Remote Therapeutic Monitoring Codes" By Gerald Buggs, MSG, Health Recovery Solutions, https://www.healthrecoverysolutions.com/blog/cms-finalizes-new-remote-therapeutic-monitoring-codes#:~:text=Remote%20Therapeutic%20Monitoring%20(RTM)%20Codes&text=The%20submission%20of%20self%2Dreported,transmitted%20through%20existing%20hardware%20devices. (Accessed 2/23/22).

8 "Software as a Medical Device (SaMD)" U.S. Food & Drug Administration, December 4, 2018, https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd (Accessed 2/23/22).

9 "What are examples of Software as a Medical Device?" U.S. Food & Drug Administration, December 6, 2017, https://www.fda.gov/medical-devices/software-medical-device-samd/what-are-examples-software-medical-device (Accessed 2/23/22).

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