Digital Health

By Marilyn McGaffin

During one of our Health Section Council meetings, the topic of digital health came up, as it seems to be an area of great interest right now. The Centers for Medicare and Medicaid Services (CMS) has recently expanded the amount of telehealth services that can be paid for with Medicare Advantage rebate dollars. Many administrative services only (ASO) groups want to know the cost-savings component to these types of programs before purchasing. But what is digital health? What does the term encompass? How is it regulated? What lines of business are best suited to digital health products? Is it just an add-on, like SilverSneakers has been for Medicare, or must there be a cost savings component to it? These seem to be the questions that begin any conversation on the subject.

WHAT IS DIGITAL HEALTH?

Digital health is the convergence of digital technologies to enhance the efficiency of health care delivery. It may include hardware and software solutions, information and communication solutions with applications and services. It is ideally a multidisciplinary domain made up of clinicians, researchers, scientists with expertise in health care, engineers, social scientists, public health representatives, and experts in health economics and data management. In reality, many digital health startups may have only a couple of these disciplines working together.

The areas impacted by digital health are quite varied. Clinical trials for digital health involve companies working to improve operations in drug research and development, study design, patient recruitment and adherence and compliance. In the area of genomics, companies are involved in the capture, sequencing and/ or analysis of genetic data. Once the data have been sequenced, it will hopefully provide new knowledge in the area of genomics. In the world of mental health and wellness, companies apply technology to problems of emotional, psychological and social well-being. A couple of examples are Quartet and Talkspace. Quartet hopes to lower costs by aligning payers, behavioral health clinicians, medical providers and patients. Talkspace

is a telebehavioral health company that connects individual users with a network of licensed therapists through a HIPAA-compliant web and mobile platform, allowing text messages, videos, pictures and audio messages. Many startups focus specifically on providing health care products and services to women.

Digital therapeutics is a broad field within digital health. Its focus is on tech-enabled, out-of-hospital solutions that either complement or replace standard medical treatments for a condition. Artificial intelligence (AI) is used to develop products for the health care market, with AI solutions even being sold to health care clients. A prime focus for AI is radiology and pathology. For example, SigTuple uses artificial intelligence to develop hardware and software products to digitize pathology test results for hospitals and clinics. Lifetrack Medical Systems is a teleradiology startup that makes it easy to interpret radiology readings for medical diagnosis by pairing hospital residents with experienced radiologists who help evaluate medical images and send their reports. Many of these products require FDA approval to give digital health credibility, which will be discussed later.

How does digital health affect us in our daily lives? Wearable devices such as the Fitbit or the Apple Watch are just two examples. The field of e-health delivers health information and services to enable data transmission, storage and retrieval for clinical, educational and administrative purposes. Mobile health involves the practice of medicine and public health supported by mobile devices. We can download many apps on our smartphones that can help monitor our happiness levels, heart rate and the number of steps we take. Through our workplaces, we may be familiar with such companies as TelADoc, Livongo, Retrofit and Noom.

Many of these digital health startups have come about by identifying a specific health care problem and are backed by an

entrepreneur who is passionate about that problem. Research ensues, and a digital solution is developed, which is then evaluated and implemented. Once implemented, the solution becomes a commercial product. Products are perfected through regular re-evaluations and improvements. This is called the *innovation cycle*.

DIGITAL HEALTH REGULATION

In 2019 the FDA created a digital health innovation action plan to continually improve the safety and effectiveness of medical devices, especially since there are so many frequent updates and modifications being made to these devices. There are numerous challenges with cybersecurity and interoperability as this technology transcends international boundaries. The FDA's program focuses its oversight on mobile medical apps that present higher risk to patients. The program does *not* focus on technologies that receive, transmit, store or display data from medical devices, or on products that only promote general wellness. However, the program does provide clarity on expectations pertaining to cybersecurity. The FDA has a 510(k) form that must be submitted when there is a software change to an existing device 90 days prior to offering that device for sale. One medical device that has received a 510(k) approval is for heart failure patients. Biovitals Analytics Engines says that its device may be able to reduce hospital readmissions and decrease the need for emergency department visits by monitoring physiological data (vital signs) and a heart failure patient's daily activities, and comparing them to an established baseline for that patient.

HOW AND WHY DIGITAL HEALTH IS USED

As already stated, digital health is an international practice, and the United States is its largest market. Users include insurers (Oscar and Clover), drug shopper discounts (GoodRx), genomics (Grail), imaging (Heartflow), drug delivery (Intarcia), and primary care networks (One Medical). The states of Texas, Illinois, Pennsylvania and North Carolina are emerging as hubs of the digital health field. The United Kingdom, India and China follow the United States in use of digital health technologies, with Japan, South Korea and Sweden among the emerging countries in this area. "Health care unicorns" are startup companies valued at $1 billion or more that are backed by venture capitalists. At one time they were rare, but there are now more than 38 such unicorns worldwide. CB Insights has a superb map showing the locations of these top unicorns.[1]

Health venture capital companies, pharma companies, device makers, imaging manufacturers and insurers may purchase all or part interests in digital startups. One of the top health venture capitalists, Echo Health Ventures, has offices in Portland, Oregon. Since this is city where I work, I will focus on that

company. It has 38 digital health companies in its portfolio, and according to its website, it is "identifying bold, new and original ways to meet the needs of tomorrow's health care consumers in an economically sustainable way." It is common for a health venture capitalist to approach health insurance companies to sell them access to a digital health operation. One of the selling points is that it will save the insurance company money. How this cost savings is calculated depends. In these contracts, penalties may exist if a contracted return on investment (ROI) is not met; others, such as Livongo, also use a net promoter score.

Livongo is a health startup that focuses on diabetes. Glen Tullman founded the company when his 10-year-old son was diagnosed with type 1 diabetes. Livongo sells an FDA-cleared, two-way, interactive glucometer with unlimited supplies for monitoring A1C levels using cloud-based analytics and real-time monitoring. Its personalized insights prompt members to take actions that are most likely to have a clinical impact, including health coaching for weight loss. The goal is to reduce HbA1c levels.

Tullman has also created Zest Health, which is a smartphone app that provides telemedicine wherever you are. Users can upload their insurance card into the Zest app. A Zest concierge can then answer questions about coverage, schedule in-network care (via email, call or chat in the app), and preview the price for the procedure/visit. If there are billing issues, the concierge can help with those and even with filing an appeal.

ONGOING QUESTIONS

As I continue to learn about Zest Health, cybersecurity issues come to mind. I also start to wonder how to calculate an ROI or a net promoter score for this app and what the sales pitch would be. I can see the need for actuaries' analytical skills in the development of digital health solutions, but there is also a need for them to evaluate the true cost of a company using this type of a feature with its health plan. A key question for actuaries is whether digital health will be an add-on to spending or can it actually provide money-saving advantages. ■

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ENDNOTE

1 CB Insights. *Global Healthcare Report Q2 2019*, p. 27. *https://www.cbinsights.com/research/report/healthcare-trends-q2-2019.*