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How Medical Device Companies Can Play in Big Data and Remote Patient Monitoring

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Orthopedics and other device companies are exploring the newly invigorated remote patient monitoring opportunity as a way to adapt to increasingly rigid CMS reimbursement. This gives them an important role in the fast-moving world of healthcare big data, but leaves other key components of that world like aggregation, analytics, and systemic perspectives up for grabs. A Q&A with Health Advances' Paula Ness Speers and Greg Chittim.

by
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Digital health and consumerism, backed by positive regulatory and reimbursement changes, are having a notable impact on medical device company strategies, and the interrelated rise of systemic telehealth. New CMS codes with attractive fees for providers, introduced in 2018 and implemented early in 2019, are now driving this impact home. A case in point is the a noticeable rising corporate and provider interest in remote patient monitoring (RPM), which, among various digital approaches to healthcare, has particular resonance for the device industry, since it is based on sensors and information capture technologies that are routinely used in medical devices and familiar to the companies.

Paula Ness Speers, a co-founder and managing director of Health Advances, and Greg Chittim, VP of digital health and leader of the health IT practice at the firm, draw a clear distinction between the near-term opportunity afforded by favorable changes in reimbursement of RPM, which they categorize as a digital tool, and the broader, more complex issues surrounding aggregation and clinical utilization of the data from RPM and other digital sources. The former puts medical device companies at the center of data collection which is so urgently needed in this field, while the latter raises thorny questions about commercial models and the broader role of medical device companies in data aggregation and utilization, including corporate concerns about privacy and liability responsibilities. (*See "As Digital Data Hits a Tipping Point, New Medical Device Models Emerge,"* and *"New Rules and Regs Push Telehealth into the Mainstream," both in* MedTech Strategist, *October 4, 2019*.) They cite examples in the orthopedics world, since it has been an early adoptor of RPM, but their takeaways resonate across the medical device sectors.

Greg Chittim: Device companies absolutely must define telehealth correctly because consumers and executives tend to think about it narrowly, as real-time video consultation with healthcare providers. From a device company perspective, this definition must broaden to consider full remote patient monitoring (RPM), which includes device-to-device, device-to-patient, and device-to-care team communications. These connections, taken together, build a set of robust patient engagement opportunities and valuable data assets.

For this reason, the device companies and their healthcare-provider customers should be very interested in the new set of codes that CMS has just issued covering this broader definition of RPM. These technologies have existed for a long time and are a sensible way to remove costs from the system. A basic at-home monitoring program is better than having patient sit in hospital for days to be monitored. The problem was, the incentives previously were not aligned because if a patient sat at home and got monitored, the physician was not paid to support that program. With these new codes, the device companies have a much clearer path to develop reimbursable software, services and remote monitoring devices for which their buyers will get paid. The codes do not reimburse at exorbitant rates, but they do build in reasonable incentives for physicians and care teams.

Device companies are trying to figure out how to interpret these codes and assess their value. This is important because the previous code, CPT 99091, which covered RPM [indirectly] was old fashioned and required a physician to spend at least 30 minutes reviewing data or communicating remotely with a patient in order to get reimbursed. If the physician wanted to be paid for looking at data generated by a connected device like a CPAP, for example, he or she had to spend that time looking at data, developing a care plan, and then emailing/calling the patient. That was often incompatible with how doctors work today, and the reimbursement was low for 30 full minutes of physician time.

The three new codes work better with the modern healthcare system. CPT code 99453 pays doctors or a care team member to help patients order, set up, and get educated on the use of a new device. Previously, this was not reimbursed through a specific code. There were other codes that could be used for reimbursement if a patient came in for an office visit, but guidance on setting up monitoring devices remotely in the home lacked reimbursement.

Another code, CPT 99454, reimburses providers for re-ordering 30-day supplies and consumables for patients. The burden is not solely on patients to re-order—now, the care team gets reimbursed for supporting that effort.

MedTech Strategist: ***Before that, the burden was on the patient to re-order?***

GC: Correct. Another interesting code, CPT 99457, is around the interactive communication with a patient. This code is less restrictive and a more realistic code than 99091. The interactivity part is key. It may involve chatting via text or email with a doctor through an app or device and allows the physician to bill for that service in 20-minute increments. This code is important beyond the medical device world because it supports new virtual-care model primary care organizations like Iora Health and OneMedical. [*See "The Shift to Digital Primary Care: What Medtech Needs to Know," this issue*.] Jonathan Bush, the ex-CEO of athenahealth is now chair of FireFly Health–all of these are built around virtual care services through text and video interfaces between patients and flexible care teams.

How do traditional medical device companies look at these developments?

Paula Ness Speers: The musculoskeletal segment has been particularly active in digital health in the last few years. Since CMS rolled out CJR [comprehensive care for joint replacement model for reimbursement] for primary hip and knee replacements to be reimbursed under mandatory bundled payments for participating hospitals, the incentive has been for providers to look across the entire episode of care when planning treatment, as opposed to a la carte or fee-for-service care reimbursement for each covered activity. Therefore the provider(s) must know how to control the total episode of care for 90 days so that they don't spend all their money, for example, on the front end (surgical procedure and hospital stay) and leave no money for covering the care and treatment post-discharge (e.g. in-patient rehab or SNF [skilled

nursing facilities] stay, physical therapy [PT], or additional procedures like MUAs [manipulation under anesthesia], if required within the 90 days). (*See "US Hospitals Shift Cost Containment Priorities as Bundled Payment Programs Ramp Up,"* MedTech Strategist, *June 2016 and "The Orthopedics Industry Faces CMS' New Bundled Payment Program,"* MedTech Strategist, *December 2015*.)

If you are managing the $25,000 bundle holistically and want one entity controlling how that payment is best used, you want to capture the data through all the steps—from pre-op PT, to surgical approach and implant selection and other in-hospital care, to post-discharge rehab, and accurately measure improvements in patient outcomes. You need to look for and find correlations with any of the steps employed throughout each episode of care to help inform future decisions on patient care that will lead to the best outcomes. That is one massive, continuous dataset that needs to be collected, linked and analyzed.

Companies have come at this from various perspectives—whether they are a pure technology-software or traditional healthcare company, and one of the earliest places they looked to save money was applying digital health technologies to physical therapy. With virtual PT, a patient does not need to go to a facility for every session. She/he can log in and stand in front of an avatar on a computer screen or video monitor while doing exercises and go through the repetitions on her/his own–the avatar can track the gross motor movements to ensure compliance., These virtual PT solutions can document the date/time, number, and quality of repetitions that the patient performed. Then the provider (physical therapist and/or surgeon) receives the digital file and can monitor/assess compliance. Using virtual PT as a tool to help manage costs of that bundle could save money on the PT portion of costs in that episode, but more importantly ensure the therapy compliance helps drive faster and/or more successful recovery, which means improved outcomes for less cost.

The other way data and devices interact relates to sensors. In orthopedics, for example, one could wear a sensor(s) near your knee to monitor pain, gait, extension/flexion or other valued metric either pre- and/or post-surgery. These sensors could be used to validate the need for a total knee replacement (TKR as part of the pre-authorization process), or to follow the patient post-surgery to identify any potential concerns more quickly so the provider can intervene before more expensive care must be given. Some companies are looking at implantable sensors to monitor post-surgical outcomes and identify any need for early intervention as well.

Components of Successful Remote Patient Monitoring

The technology is not the problem–gathering data and even analyzing is solved/solvable, says Paula Ness Spears
The real questions are:

1. Deciding what data is important to collect
2. Determining how to get permissions to access (gather, retain and use) those data
3. Understanding how the data collection and use fit into the workflow
4. Ensuring compliance from any person or entity that needs to provide inputs to the dataset (e.g. patients reporting outcomes, care providers entering any additional data into the EHR, etc.)
5. Determining how not to overwhelm the care team with the data collected
6. Understanding/determining the implications flowing from those data collected–who should do what with which data?
7. Minimizing the medical liability that may be associated with acting on, or not acting on, data provided
8. Deciding who gets what value from which dataset collected and what they are willing to pay for it

Companies continue to evaluate the most important value propositions in the musculoskeletal sector and where it makes sense to implant or wear sensors, as well as other opportunities to employ remote monitoring or digital health solutions to help improve outcomes and reduce costs.

GC: To put this in a broad context, the new RPM codes deal with the reality of how physicians get paid for doing remote work in a fee for service payment model, which is where we are today. The reason orthopedics and cardiovascular companies have capabilities here is because of the bundled payments, which have hit those service lines. The service line-specific efforts around RPM are very tied to service-line bundled payments.

The next phase of this process will be risk-based contracts, which are starting to focus on the total cost of care for an entire patient or panel, versus a single joint replacement episode. That is where these systems come together, and you need to think about RPM holistically, not just for one aspect of therapy. That is still a way off. We are just now having software, devices, and analytics to really understand the total cost of care. That is where we need to get to if we think about healthcare reform broadly.

What are the bottlenecks to making this happen–is it the technology?

GC: The technology problem is theoretically solved but is overwhelming. The bigger questions are: How does data fit into workflow? And how do you get paid to use this data? Those are the pillars of why this has not happened—and the new codes and attention on physician and patient adoption are an encouraging trend to drive progress in remote patient monitoring. (*See Box, "Components of Successful Remote Patient Monitoring."*)

PNS: This raises one of the key challenges: if you think of all the data that is generated and the way the alert systems are set up, if a caregiver does not respond to an alert based on that data, the company could be liable for any patient harm that occurs. Of course the device companies do not want to incur any liability associated with an "alert" that isn't sent or isn't received by the care provider any more than the care provider wants to miss an alert they should have responded to, or an alert they responded to in a manner that was unnecessary or inappropriate. So determining which data variables/combinations should drive "alerts" and which data are not important is a complex decision algorithm which requires careful clinical expertise to determine, and, even then, there are likely always exceptions to the rules and key drivers/correlations/combinations of data not yet known that should be considered in such algorithms. So the clinical staff has been pushing back on receiving masses of data generated by remote patient monitoring devices, and the device companies have been pushing back on incurring any liability for developing/applying algorithms to reduce and prioritize data collected from these RPM devices before it is sent to the care providers.

As Greg pointed out, the discussion invariably leads to a broader question, that goes way deeper than RPM, which is just one piece of the digital ecosystem. The bigger questions are: What happens to data collected by these device technologies? Who aggregates that data and who controls or owns it? Medicare has set up conveners to aggregate the data collected from broad populations, but where do the medical device companies fit into this new world and how do they address ownership of valuable data?

PNS: There are Medicare-selected conveners, and most often these conveners are pure tech companies that collect and analyze data and offer it as a valuable asset to a variety of stakeholders. Third-party conveners include distributors like Cardinal Health and Owens & Minor; the former acquired Navihealth in 2015 and sold a majority stake in that acute care management company to the PE firm Clayton Dubilier & Rice three years later. Owens & Minor invested in a start-up in 2018, fusion5, which manages bundled payments and has among its executives former Smith & Nephew executives. Premier, the GPO and hospital services organization, is also tackling the space, and some standalone companies like Remedy Health Partners, are also involved. IDNs like the Cleveland Clinic and Kaiser Permanente want to control and capture all the data too. But no one has sorted out who pays for it all and how to measure and capture the full value proposition.

GC: There is an interesting opportunity for patient-mediated, real-time device data to influence many clinical interventions. As you think about conveners–health IT and software analytics technologies have the data. Large public companies like Health Catalyst and Optum, private companies like Arcadia.io and Forward Health have the

EHR, claims data, social determinants of health data. The big piece they are missing is device data (Fitbits, acute holter monitors, implanted defibs, etc).

How are the orthopedics companies positioned to aggregate data and extract value from it? Do you really believe that ortho companies have the capacity to pull this data together and figure out the business proposition?

PNS: Some bigger orthopedics companies have taken that approach and backed off. Orthopedics is not the only area where these data capture and analysis solutions have been introduced across an episode of care. While in every clinical area the value proposition is different, the platforms on which these are built have similarities and some generalizations are possible.

Orthopedics was an early target for bundled payments, however, so some of the larger companies like Zimmer Biomet, Stryker and Smith & Nephew jumped into the big data world early on. Zimmer launched its *Signature Solutions* program in 2016, which was designed as a comprehensive suite of clinical services and technologies to enable streamlining the delivery of care, as well as improving patient outcomes, in a manner consistent with the value-based care environment they saw evolving. Stryker launched its *JointCOACH* platform right after CJR went into effect to help engage and educate patients facing joint replacement surgery. This tool was designed to help providers stay in touch with their patients to better monitor their recovery and flag potential negative responses from patients so that potential post-operative problems could be quickly addressed by providers. SNN focused on developing solutions to help train and qualify surgical technicians in hopes of reducing the requirement for reps in the operating room as one of its objectives in launching its *Syncera* system in 2014, but mention of it seemed to disappear by late 2017, perhaps falling victim to being too radical in its vision to help hospitals go repless and/or not fully appreciating all of the challenges of OR staffing that made that vision hard to achieve.

While some of these company-driven solutions have gotten traction in the market, providers have been concerned about the potential ulterior motives of device companies to try to tie these solutions to their implant usage to drive more implant sales. These concerns have opened the door for the third-party conveners to come in.

If you are an executive sitting at a big manufacturer and watching the rapid evolution of this landscape, how are you organizing to respond to these dynamics?

GC: Every device company we work with is trying to figure out how to build connected capabilities and get paid for that success. All of the big device companies have digital teams. This is a big strategic move for them.

PNS: The companies are typically organized into clinically focused groups, which help define and focus the customizing of the data capture and analysis to meet the key needs within a given clinical application, and these clinically-focused applications groups are matrixed with the platform technology/software developers in the organization. In respiratory, for example, Resmed transformed itself from acquiring other medical products in respiratory to acquiring digital health, EHR, and patient engagement technologies. (*See "Resmed: Using Digital Health to Fuel a MedTech Growth Strategy,"* MedTech Strategist, *June 8, 2018.*)

GC: Even hospital bed companies are concerned about this. For some companies, it is defensive because if they are not incorporating digital solutions into their growth strategies, they will lose, but the majority also realize the opportunity. They want to have solutions–not just products—that get the data to educate the patient, inform/alert the caregiver/provider, confirm compliance with payors, and document all aspects of the care in the EHR—all of those are interconnected.

There is a question in the hospital of where the center of communication should be. In past decade, the assumption has been it should be the EHR. That workstation in the hospital room is where all communication goes to and from but increasingly there are alternatives. The major hospital bed companies—Hill-rom, Stryker—have connected beds, connected nurse call systems, and mobile communication systems—so could those be the center? Or should the center be built around the bedside monitor companies, which have physical systems at the bedside and software solutions? If you think of a company like Philips in particular, but also GE and others, which have scale and have bought into the concept of interoperability and device-to-device solutions, they will want to be the gateway. Phillips pulls in data from other devices and sends it to the EHR. That is a great defense strategy for them. If 10 years from now their vitals monitor goes out of vogue and is not the market leader, they could still be entrenched in hospitals.