Perspectives and Updates on
Health Care Information Technology

HIT Perspectives

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About the Newsletter

HIT Perspectives is published by Point-of-Care Partners. Individuals at the leading management consulting firm assist healthcare organizations in the evaluation, development and implementation of winning health information management strategies in a rapidly evolving electronic world. The team of accomplished healthcare consultants, core services and methodologies are focused on positioning organizations for success in the integrated, data-driven world of value-based care.

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1 Part 1: Four Reasons to Become a FHIRmacy

By Pooja Babbrah, PBM Payer Lead, and Tricia Lee (Wilkins) Rolle, PharmD, MS, PhD, Government Affairs and Health IT Strategist

Heads up, ambulatory and acute care pharmacies. Health Level Seven's (HL7's) novel Fast Healthcare Interoperability Resources (FHIR) standard is rapidly being adopted in the national and global health care marketplaces. Drivers are strong and the changeover is inevitable, which is why we urge pharmacies to act sooner rather than later to remain competitive.

As health care providers and payers are moving to better care coordination and adopting new value-based models of care, interoperable data exchange has become the linchpin for everything from delivering personalized care to managing population health. **FHIR has become the go-to standard to enable streamlined and efficient access to health information and real-time communication.**

To date, ambulatory and acute care pharmacies have operated within two standards-based silos. They typically use standards from the National Council for Prescription Drug Programs (NCPDP) for electronic prescribing and other functions, such as billing, dispensing and inventory control. Pharmacies in large health systems and health maintenance organizations use HL7 standards to handle pharmacy orders and discharge prescriptions. While NCPDP standards will continue to play a vital role for key pharmacy functions, FHIR compatibility will be the path forward for pharmacists to engage as value-based providers in this new era of interoperable health care. However, many pharmacy systems — especially those on the ambulatory side — are slow to recognize the need for FHIR.

Drivers for change. Drivers for the inclusion of FHIR in pharmacy systems are varied and compelling. They include:

1. **Changes in reimbursement.** Value-based contracting (VBC) and other pay-for-performance arrangements are profoundly impacting the need to track medication costs and patient outcomes. VBC relies heavily on clinical data — captured and transmitted electronically — to create metrics for their reimbursement models, which may require clinical content to be sent with the prescription so progress and outcomes can be monitored and quantified. Current standards don't support clinical data exchange whereas FHIR does. FHIR can also be used to document contracting changes involving medications. The data exchanged affects how reimbursement and shared savings are calculated and distributed — among providers as well as participating pharmacies.

2. **Care coordination.** Pharmacy today is evolving into team-based care models driven by value-based payment arrangements. Clinical pharmacists are taking on a larger role in care coordination, often as part of an interdisciplinary team. There, clinical pharmacists provide clinical and therapeutic interventions for individual patients as well as collaborate with providers on medication-related activities and desired patient outcomes. As a result, clinical pharmacists need to have the same tools and electronic platforms as other clinicians to capture and share data on the clinical and medication needs of patients, both as part of the team and in support of other health care providers, patients, caregivers and payers.

   A key tool is the FHIR-based Pharmacist eCare Plan (PeCP), a standardized electronic means to document and exchange information on clinical services and medication management goals delivered and recommended by pharmacists. It is an innovative way to capture clinical documentation by pharmacists as well as an interoperable way to coordinate medication management with other health care providers. This **standards development project** was sponsored by the Office of the National Coordinator for Health Information Technology (ONC) and has been embraced by NCPDP and HL7.

3. **Payer-Provider System Adoption and Coordination.** Provider systems are already on board with FHIR to capture, analyze and share clinical content and patient data. In fact, FHIR is the standard of choice for **electronic health record (EHR) vendors**, with 87% of hospitals and 69% of eligible clinicians having products certified to any FHIR version. On the payer side, FHIR is quickly becoming a necessary tool to capture and exchange clinical data. Claims data — long the mainstay of payer decision making — are not enough anymore. A couple of examples come to mind of how payer systems are being transformed using FHIR. Medicare's **Blue Button 2.0** is set up for FHIR-based application programming interfaces (APIs) to connect to beneficiary data, thus creating new capabilities for providers and patients to share and analyze personal health information.

   Another compelling industry driver is the **HL7 Da Vinci Project**, which has gained traction and public attention for its collaborations, progress and promotion of FHIR. It is a leading example of industry efforts (in this case by payers) that is driving FHIR adoption. Da Vinci's open business model process enables payers, health systems and other industry participants to identify and enumerate use cases that involve managing and sharing clinical and administrative data among industry part-

FHIR is viewed as a game changer, being the go-to building block for clinical information in new and existing clinical workflows in electronic health records and mobile applications.

ners. Such requirements will bleed over to pharmacies, which then will have to use FHIR to provide the needed clinical and administrative information. One of the first Da Vinci use cases is for FHIR-based prior authorization transactions. No doubt, use of FHIR by such large stakeholder groups will drive demand for FHIR adoption in pharmacies.

4. **International Influences and Outcomes Reporting.** Increasing global interoperability of health information technology and continuing foreign innovations in pharmaceuticals means that pharmacies in the United States (US) must have the same tools to monitor and report information on the efficacy, efficiency and safety of drugs. This will become increasingly important as biosimilars and digital therapeutics are developed and approved, especially since pharmacy systems **outside the US** use HL7.

Conclusion. While inclusion of pharmacies in value-based models of care and new reimbursement models may seem far off, it's hard ***not*** to see the obvious implications for specialty medications, specialty medications, which will account for **half of total U.S. drug spend** by 2020. The prescribing process for specialty prescriptions consistently requires clinical and other information to be shared between providers, payers and pharmacies. While the process is largely unautomated, specialty automation is ripe for pharmacy leadership to build the interoperable transactions and platforms to support a streamlined prescribing process and the means for pharmacist-provider coordinated care for these often complex medication therapies. While NCPDP is already working on ways to automate this process, pharmacies should consider efforts to align with industry adoption and use of FHIR for medication management across providers and payers.

Addressing interoperability is top of mind in all sectors of health care, and pharmacy is no exception. FHIR is viewed as a game changer, being the go-to building block for clinical information in new and existing clinical workflows in electronic health records and mobile applications. Including FHIR in pharmacy systems will dovetail with the numerous ongoing efforts in the public and private sectors to improve interoperability.

Key takeaways. Point-of-Care Partners (POCP) has been active for more than a decade in the standards arena and issues related to medication management. Based on our expertise, we see the following takeaways for acute and ambulatory pharmacies:

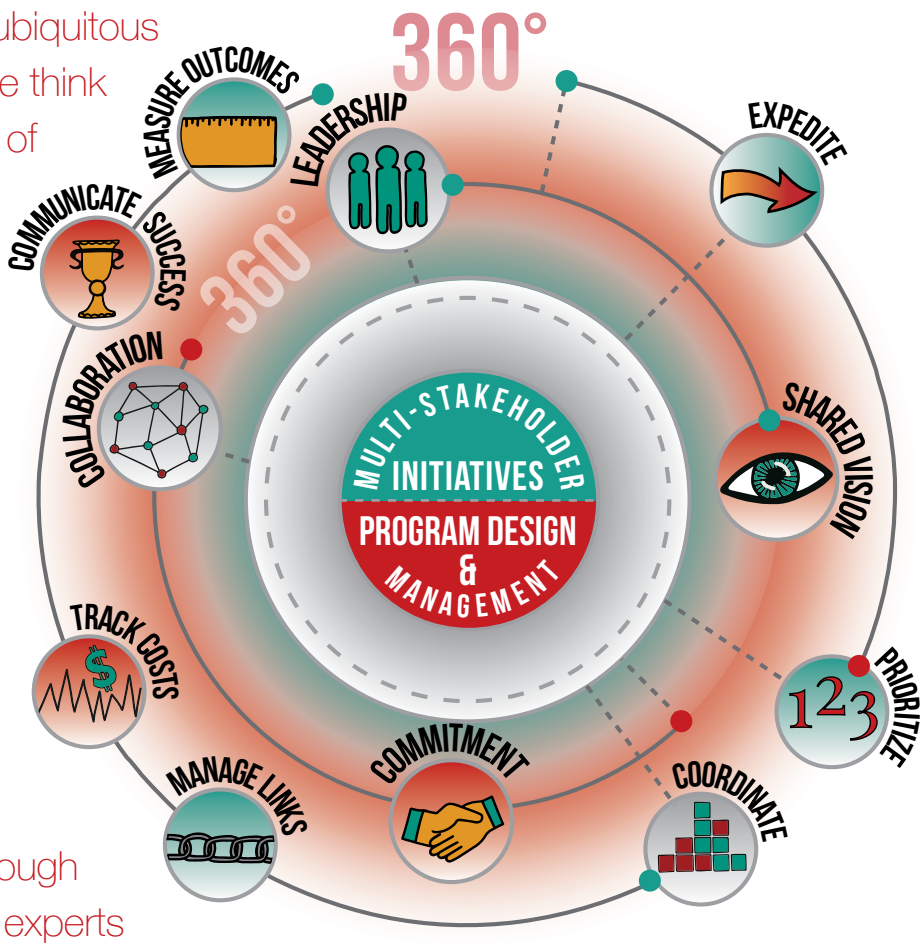
- The use cases for FHIR in pharmacy exist and are ready to be tapped. As FHIR adoption continues to grow among providers and payers, this will drive demand for FHIR in pharmacy systems.
- While FHIR supports a majority of health care use cases, it does not support everything needed by pharmacy. FHIR and NCPDP standards will need to work collaboratively to optimize medication management and meet the requirements of all facets of value-based care.
- Acute and ambulatory pharmacies need to embrace FHIR adoption within their systems. Inaction could have adverse effects on reimbursement or result in exclusion from various value-based care programs.
- Pharmacies may need help in planning and implementing the FHIR changeover in their systems. •

Want to know more? Please feel free to reach out to us: ***tricialee.rolle@pocp.com*** *and* ***pooja.babbrah@pocp.com****. We'd be happy to answer your questions or provide more information on the convergent evolution of FHIR in pharmacy.*

2 Part 2: Five Key Ingredients for Successful Multistakeholder Initiatives

By Tony Schueth, Editor in Chief

There is no "I" in team, and not just in sports. The team approach is nearly ubiquitous in our work lives. Generally, we think of "teams" within the confines of the companies for whom we work. The health information technology (health IT) industry has expanded the idea of teams to include individuals outside the walls of their independent organizations and many times from organizations normally considered competitors. These types of initiatives aim to address widely felt industry challenges and regulatory imperatives through access to a broader group of experts and perspectives.



In fact, multistakeholder initiatives are currently under way to address various issues with standards and technology. Several examples come to mind. The **CARIN Alliance** is working to help consumers understand their out-of-pocket prescription costs with the consumer-facing, real-time pharmacy benefit check. The HL7 **Da Vinci Project**, a collaboration of payers, providers and health IT technical experts, is working to leverage HL7 Fast Healthcare Interoperability Resources in support of value-based care data exchange. Da Vinci Implementation Guides focus on topics like helping payers and providers automate collection of quality data used in Healthcare Effectiveness Data and Information Set from the provider electronic health record (EHR) and improve a payer's ability to share details about patients' benefits to the provider. The **CommonWell Alliance** is one of several groups addressing the need for a unique patient identifier.

Point-of-Care Partners (POCP) is currently the program management organization of Da Vinci and is deeply involved in CARIN. Our firsthand experience with building and **managing multistakeholder initiatives** started back in 2007. A coalition of employers, health plans, pharmacy benefit managers (PBMs) and industry leaders formally committed to working together as the Southeastern Michigan ePrescribing Initiative or SEMI. Over the span of seven years, SEMI delivered on its mission to improve patient safety and reduce prescription drug costs by encouraging the adoption and use of health IT in seven counties comprising nearly half of Michigan's population of nearly 10 million. Through SEMI's efforts, prescribing behavior has changed, patients' lives were saved and an estimated $130 million in reduced costs were achieved.

The challenges facing SEMI are not dissimilar to those facing today's multistakeholder coalitions. As a matter of fact, we've applied what we learned from our work on SEMI to the current initiatives we program manage. The drivers of today's coalitions may be different from those that created SEMI; however, there are some similarities and critical success factors. With that, we offer the following six key ingredients for success.

1. Champion for the cause. Successful coalitions must have a champion at the top. A good champion is passionate about the cause and a strong advocate for the changes that will ensue. In addition to driving the coalition and its work forward, these qualities are essential to weather the bumps in the road that are sure to arise along the way. Successful coalitions develop change and improvement momentum by building around champions who have the standing in the industry and commitment to the cause. This in turn will help bring others on board and drive to success. In the case of SEMI, General Motors initially fulfilled that role and subsequently helped maintain the program's momentum by providing peer-to-peer leadership, hosting steering committee meetings and, by extension, establishing a level of accountability that would have otherwise been unattainable.

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2. Professional program management team. Most coalition members are volunteers who donate personal time or whose time is "donated" by their employers to participate. That is why a professional program management team with relevant skills and a deep understanding of the pain points and perspectives of various stakeholders is needed. Volunteers, frankly, do not have the bandwidth needed to manage the project on a day-to-day basis or with third-party objectivity. The value of program managers is illustrated by the following activities. Program managers can provide the resources and accountability to keep the project on track and on budget by such activities as:

- Providing consistent and accurate communications to the coalition members
- Organizing committee meetings and providing consistent monitoring of milestones and progress

There needs to be an informed balance between strategy and operations to keep the program on target and prepared for the ever-changing health care environment.

- Gathering and analyzing project and budget data
- Providing neutral evaluation and measurement, and suggesting as-needed midcourse adjustments
- Tracking against steering committee-determined objectives

Program managers also need subject matter expertise. Otherwise, the coalition leadership is apt to establish unrealistic timelines, flawed plans for collaboration and unrepresentative pilot projects. There needs to be an informed balance between strategy and operations to keep the program on target and prepared for the ever-changing health care environment.

3. **Coalition membership.** Coalitions must have stakeholder members representing the range of views and business interests. Unfortunately, many multistakeholder initiatives fall short of goals and objectives because the right people aren't consistently in the room or have a say in decision making. Mediocre or unsuccessful coalitions tend to exclude key stakeholders and end up talking to themselves.

   In the case of SEMI, the coalition membership represented all key stakeholders impacted by the adoption and use of health IT, even in the early days of electronic prescribing (ePrescribing). The health plans held the contracts with the physicians; the PBMs represented the claims processing perspective; and employers were paying for the benefit and represented the interests of member lives (i.e., the automakers' employees and families).

   Similarly, the founding members of Da Vinci realized it was critical to have national leaders who had both the backing of their organizations and the emotional intelligence to bring the project to fruition. Having cross-functional representation from providers, payers, EHRs and their vendor partners at the table to agree to the initial use cases has been critical to the project's success thus far.

4. **Clear goals and objectives.** This is the meat of any coalition's work. What is the group trying to accomplish and how can that be carried out? How will success be measured? These must be clearly articulated, communicated and agreed to by the group. Progress needs to be monitored. Further, coalition members representing competing organizations must set aside those business relationships to work toward a common goal.

5. **Know when to call it quits.** There are many reasons why coalitions continue, even though it is clear they are stuck in neutral, their issue has been overtaken by events or they have accomplished what they wanted. It is heartbreaking to see groups stumble along, even though attrition among the ranks has accelerated and the group's below critical mass. Leadership needs to know when to bite the bullet and call it quits, even if that may not be popular with some of the group's more powerful industry leaders. As the song goes, you need to know when to hold 'em and know when to fold 'em. •

POCP would be happy to provide more insights on critical success factors for industry coalitions. Let us put our expertise to work for you. Visit our multistakeholder page for additional insights or drop me a line: ***tonys@pocp.com.***

3 Part 3: Digital Therapeutics: Transforming Care Through Technology

By Tricia Lee (Wilkins) Rolle, PharmD, MS, PhD Government Affairs and Health IT Strategist

Experts expect digital therapeutics (DTx), a new category of medication, to revolutionize how specific conditions are prevented, treated and managed using evidenced-based software applications, primarily through mobile applications (apps). As **one industry analysis** summed it up: DTx are disruptively poised to shift medicine's emphasis from physically dosed treatment regimens to end-to-end disease management by leveraging mobile technology. DTx—also known as digiceuticals and software as a drug—are gaining momentum and a trend to watch.

What are DTx? While DTx bear similarities to digital health and wellness programs, they are not synonymous. According to the industry group **Digital Therapeutics Alliance**, DTx products have distinct properties. They must have rigorous quality controls, undergo randomized clinical trials and obtain approvals by a regulatory body, such as the Food and Drug Administration (FDA). DTx must collect, analyze and apply real-world evidence and product performance data, as well as engage end users in product development and usability processes. Unlike many wellness apps and personal health trackers on the market today, DTx must be prescribed for use.

Most DTx target specific conditions that have an unmet need such as limited treatment options, or conditions, where engaging patients outside usual sites of care will impact their adherence and clinical outcomes. These include chronic diseases (whose treatments account for a huge chunk of the health care budget), neurological disorders and mental health conditions. In fact, as this emerging field of digital medicine grows, DTx may replace current treatment options or even supplement them due to their added ability to help modify patient behavior and provide remote monitoring to improve long-term health outcomes.

The following examples are eye opening. **Propeller uses a sensor** placed on an inhaler for asthma or chronic obstructive pulmonary disease that syncs to an app in the patient's smartphone. The battery is active for about a year and sends patients reminders and tracks doses. This improves medication adherence and significantly reduces the patient's need for a rescue inhaler. **reSET® is an FDA-cleared software package** that delivers substance use disorder treatment, teaches new coping skills and reports progress to a clinician. It combines patient-facing interventions and assessments via a mobile device, with clinician-facing dashboards and data analytics on the back end. Then there's **Abilify MyCite**, the first FDA-approved pill with an embedded sensor to track medication adherence. It will be used for treatment of schizophrenia, acute treatment of bipolar I disorder and as an add-on treatment for depression. When the medication is swallowed, a sensor in the pill will send a message to an abdominal patch, which then transmits the information to a mobile app. Patients can then track their compliance on their smartphones. With the consent of the patient, caregivers and doctors can also retrieve the information online.

Benefits. DTx offer numerous potential benefits. For example, digital therapeutics may:

- Deliver treatment more efficiently than traditional therapies by enhancing provider-patient engagement and capturing health data for clinical decision making.
- Address certain access to care issues by making treatments more widely available to patients through mobile devices and technologies.
- Reduce the stigma attached to traditional therapies, such as for mental health conditions.
- Support precision medicine by capturing data for actionable insights and customized therapies.
- Support national health care quality efforts to empower patients with access to their health data and incorporate use of patient-reported outcomes in health care.

The DTx landscape. To be sure, the digital therapeutics market is in its nascent stages and pales in size when compared with other sectors of the health care economy. **According to one estimate**, the global DTx market was $1.7 billion in 2016. It is projected to grow at rate of 21% over the next few years, bringing it to nearly $9.4 billion by 2025. One unnamed source shared that although overall investments in digital health are growing, investments in DTx account for just 2% of venture capital funding in the United States.

Drivers include:

- **Federal oversight.** Several federal oversight activities will drive DTx development and adoption. Paramount for uptake and use by providers and patients is FDA clearance and approval. A growing number of DTx are in the pipeline and several have been FDA cleared or approved. Additional FDA guidance and policy also will fuel development and adoption of DTx. These include promoting **patient-focused drug development**, as required by the **21st Century Cures Act**, and the **FDA's efforts** to develop a framework for regulating software applications disseminated by drug sponsors in relation to prescription drugs.

Payer's decisions to cover DTx under the medical or pharmacy benefit, as well as pharmaceutical manufacturers' distribution channels, all impact how these products are to be folded into physician workflow and electronic billing and prescribing systems.

- **Value-based care (VBC).** DTx will have appeal to providers and organizations delivering value-based care. As mentioned previously, compared with traditional medicine, use of DTx may provide more efficient ways to engage patients, inform decision making and drive quality outcomes for specific patient populations. Additionally, the ability to capture outcomes of care in order to measure quality is central to VBC reimbursement models and provides a new opportunity for organizations pursuing value-based contracts, among other VBC risk arrangements.
- **Consumers.** Consumers also will drive adoption. DTx give consumers the means and opportunities to be more informed and engaged in shared decision making. In addition, the growing reliance on mobile devices as a part of everyday life will make it easier to accept these new therapies as a way treat disease and improve one's health. In fact, **one study found** the majority of consumers are interested in FDA-approved apps or online tools to treat their medical conditions.

Challenges and opportunities. Like any innovation, DTx are facing a number of opportunities and challenges. These include:

- **Pharmaceutical companies aren't techies.** Platforms for DTx require technical expertise and an understanding of such related issues as health information technology standards, usability and human factors research, electronic health record (EHR) interoperability, and privacy and security specifications, not typically found within pharmaceutical manufacturers. Since pharmaceutical companies lack such technical expertise, it is more likely they will partner with technology vendors and DTx startups in the near term than start de novo. According to one analysis, DTx is a way to differentiate pharma products with relatively low capital investment, especially compared to R&D costs normally associated with a traditional drug or medical device. Many companies are shifting research and development (R&D) investment away from core product lines toward transformational innovation. The analysis also pointed out that DTx also offer an opportunity to extend product life cycles, differentiate products in development, and fill gaps in the market that traditional medicine might be unable to address.
- **Reimbursement.** Reimbursement for DTx is an issue with which payers and other stakeholders are grappling. Payers are looking to find value in covering a drug and device. They want to know that products are safe, efficacious and cost effective before they are covered. Convincing them is another issue; DTx are too new and payers have not yet settled on the kinds of clinical, outcomes and cost data on which to base coverage decisions. The availability of real-world data from DTx is a plus; however, the volume of these data is often unavailable at the time of approval or clearance, when payers are faced with coverage decisions. While the Academy of Managed Care Pharmacy is tackling benefit design and reimbursement of DTx for commercial payers, the Centers for Medicare and Medicaid Services is opening the door by including digital therapy tools in its new Medicare Diabetes Prevention Program.
- **Privacy and security.** Privacy and security of health-related data are already hot-button issues. Fears about the privacy and security of DTx products and the data they generate pose a barrier to adoption. According to one study, patients may be afraid to adopt DTx because data might be compromised, information may be sold to third parties or the product may result in unwanted personal surveillance. Other questions and concerns surround who has access to the data, such as DTx vendors and caregivers, and how such data may be securely accessed and managed.

- **Changes to EHRs and workflow integration.** DTx-related changes will be in store for EHR vendors. First, they will have to adapt to various DTx products by making configurations to capture and analyze health data from these products. Turning these data into actionable insights and incorporating this new information within provider workflow for patient care and quality improvement will be next. Those are only pieces of the puzzle because clinicians and payers have not yet decided on what DTx-related data they need and what performance-related information will be required. Standardized billing and product codes will be required for electronic prescribing (ePrescribing) workflows. Payer's decisions to cover DTx under the medical or pharmacy benefit, as well as pharmaceutical manufacturers' distribution channels, all impact how these products are to be folded into physician workflow and electronic billing and prescribing systems.
- **The digital divide.** The digital divide also presents challenges and opportunities. Despite the widespread availability of broadband and Internet access, there still are segments of the population (such as the elderly, low-income and rural populations) with limited access to dependable wi-fi and internet technologies. Use of DTx could exacerbate health disparities among those populations with limited access to technology and or Internet service. On the other hand, DTx offer opportunities to bridge the gap for vulnerable populations outside the traditional touch points of care. For example, certain patient segments may benefit from being provided a smartphone in order to benefit from digital therapies. That was the thought behind an advisory opinion authored by the Office of the Inspector General (OIG) at the Department of Health and Human Services to a pharmaceutical company seeking to provide access to a DTx by working with potential prescribers to give at-risk low-income patients who could benefit from the treatment refurbished mobile phones. For organizations willing to face the digital divide head on with practical solutions, there are ways to work around current legal and statutory barriers such as seeking an OIG opinion.

Recommendations. Many actions are needed to make the DTx landscape evolve in ways that benefit all stakeholders. These include:

1. A standardized, well-understood definition of DTx that differentiates these FDA-approved products from wellness and other health-related interventions, software and apps. While the **Digital Therapeutics Alliance** has created a definition, it still has not been widely adopted. The lack of such a definition is creating confusion in the marketplace. It may also open the door for emergence of ineffective or potentially harmful products/services/software masquerading as DTx. This can pose a harm to patients and can limit the ability to demonstrate value for bona fide DTx. The FDA should seize the opportunity to create a definition that will be used and accepted by all stakeholders.
2. Standards for reliably determining the quality of safety DTx need to be established. **The U.S. Pharmacopeia**, FDA and DTA are working in this space to determine how to provide a level of confidence in products and services of the future. Interested stakeholders should support these efforts.
3. DTx need to be integrated within current electronic prescribing processes and EHR workflows. Standards are needed for products, transactions and billing. Payers, clinicians and others must decide what DTx-related data they need so they can be captured, analyzed and shared in a standardized manner. Consider the standard for real-time prescription benefit check that allows providers to know how much a prescribed drug will cost their patients. No doubt, patients will want to have these cost conversations for DTx also. This capability for DTx will only be possible through standards and codification.
4. Stakeholders need to continue to address the digital divide. DTx are just the beginning of technology- enabled care of the future. A multistakeholder approach is needed to ensure that innovations are accessible for all who can benefit from them.
5. Pharmaceutical companies should get up to speed on DTx, potential R&D, and their ability to fill gaps in the current standard of care using technology. Partnering with organizations with technologic expertise is one way to do so. •

Conclusion. *To be sure, DTx are poised for disruption and rapid expansion in the health care sector. Point-of-Care Partners (POCP) is tracking developments. Let us put our expertise to work for you in assessing the DTx landscape and understanding how DTx impact your organization's portfolio. Drop me an email: tricialee.rolle@pocp.com.*