DIGITAL THERAPEUTICS ALLIANCE

JANUARY 2023

DTx Integration & Workflow Report

PURPOSE

Identify gaps and pain points in integrating digital therapeutic (DTx) products into workflows across the U.S. healthcare system and outline necessary next steps to optimize the patient and clinician experience.

IN PARTNERSHIP WITH

NCPDP®

www.ncpdp.org

www.dtxalliance.org

ABOUT DTA

Digital Therapeutics Alliance (DTA) is a trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics (DTx). As the leading international organization on DTx thought leadership and education, DTA provides policymakers, payors, clinicians, and patients with the necessary tools to evaluate and utilize DTx products.

MISSION

Broaden the understanding, adoption, and integration of clinically-evaluated digital therapeutics for patients, clinicians, payors, and policymakers through education, advocacy, and cross-industry collaboration.

ABOUT NCPDP

NCPDP, a 501(c)6 not-for-profit ANSI Accredited Standards Developer (ASD), is a multi-stakeholder forum for developing voluntary consensus standards and business solutions designed by the industry for the industry that improves patient safety and health outcomes, while decreasing costs. The company was incorporated in Arizona in 1977 and copyrights and owns all standards documents created by Work Groups.

NCPDP's primary focus is on information exchange for prescribing, dispensing, monitoring, managing, and paying for medications and pharmacy services crucial to quality healthcare.

Executive Summary

Digital therapeutics (DTx) have the potential to fill gaps in care for people and their families across the world. As a new category of medicine, DTx face numerous barriers in becoming fully integrated into traditional healthcare systems. To enable patients to receive access to DTx products that are convenient and effective, DTA and NCPDP co-hosted a workshop with stakeholders from across the U.S. healthcare system to map existing DTx integration and workflow pathways, while simultaneously identifying areas of improvement.

Workshop participants included patients, policymakers, clinicians, health systems, health plans, pharmacies, and DTx product manufacturers.

Over the course of six months, between August 2022–January 2023, DTA and NCPDP brought together subject matter experts from relevant stakeholder groups to contribute to the development of this report that outlines the integration and workflow of DTx products in the healthcare system, using the patient journey—from diagnosis through treatment—as the primary focal point.

DTA and NCPDP are committed to providing patients with access to healthcare and ensuring that clinicians have the ability to utilize and deliver innovative products like digital therapeutics to patients. We will work with stakeholders on addressing the next steps outlined in this report to optimize the healthcare system to meet the needs of patients and clinicians.

Andy Molnar
Chief Executive Officer
Digital Therapeutics Alliance

Lee Ann Stember
President & CEO
NCPDP

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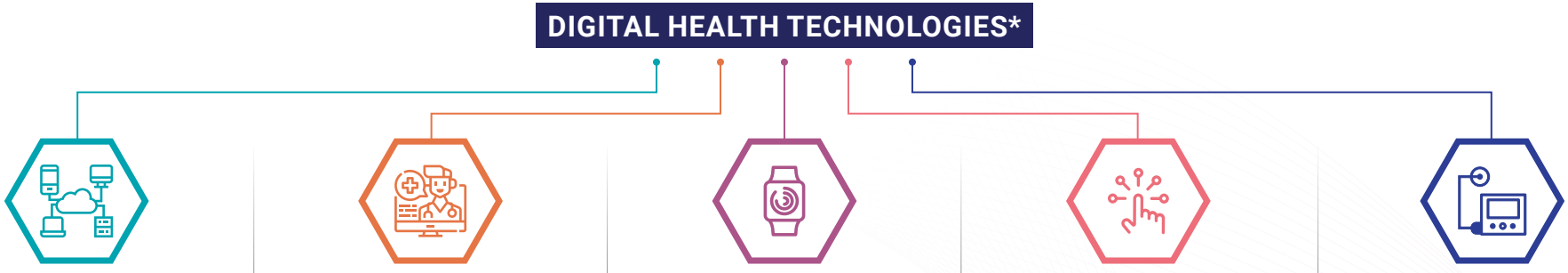
Understanding Digital Therapeutics

Digital Health Technology Ecosystem

Digital health technologies (DHT) include a wide variety of products ranging from Health Information Technology systems to telehealth, monitoring products to diagnostics, and wellness apps to digital therapeutics. Each has a role to play in supporting clinicians, payors, patients, and other healthcare stakeholders to achieve their goals. For the purpose of this report, we are focusing on digital therapeutics, referenced on the far right side of the diagram below.



**Categorizations of the digital health technology ecosystem will continue to evolve. This is a select representation of a broad, diverse ecosystem.*

About Digital Therapeutics

DTx products deliver to patients evidence-based therapeutic interventions that are driven by high quality software programs to treat, manage, or prevent a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

DTx at a Glance

» Evidence-based and clinically validated by peer-reviewed clinical trials

» Use clinical endpoints to measure efficacy

» Make a medical claim to treat, manage, or prevent a disease or disorder

» Deliver an intervention directly to the patient by software

Value in Patient Care

DTx products equip patients, clinicians, and payors with scalable, data-driven tools to address a wide range of diseases and disorders.

DTx products are often:

- Accessible via smartphones, tablets, virtual reality (VR) headsets, or other devices
- Deliver personalized medical interventions to patients in their preferred environments
- Are provided to patients through prescription or non-prescription authorization pathways
- Provide secure, meaningful results and insights on patient goals, engagement, and outcomes
- Extend the reach of clinical care and improve health equity through standardizing therapy and enabling easier access

Approach to Discovery

DTA and NCPDP identified several stakeholder groups that were well positioned to draft initial flowcharts of existing integration and workflow pathways, noting potential gaps and pain points. These groups included:

» DTA clinician, payor, and patient advisors

» DTA commercialization Task Group members

» NCPDP DTx Task Group members

Each group drafted their own flowchart, which were later combined into a master copy.

DTA and NCPDP collaborated to host a workshop with 40 subject matter experts (SME) representing different perspectives of the flowcharts. During this two-day workshop, the SMEs reviewed, debated, and edited the combined flowchart and developed a detailed narrative about relevant pain points, considerations to address each pain point, and actionable next steps to resolve or mitigate the pain points. Stakeholder sub-groups took deeper dives into developing further details. Sub-groups included clinicians, payors, data connectors, and pharmacy representatives.

Workshop participants aligned on the final direction of the report and provided guidance on next steps of this initiative.

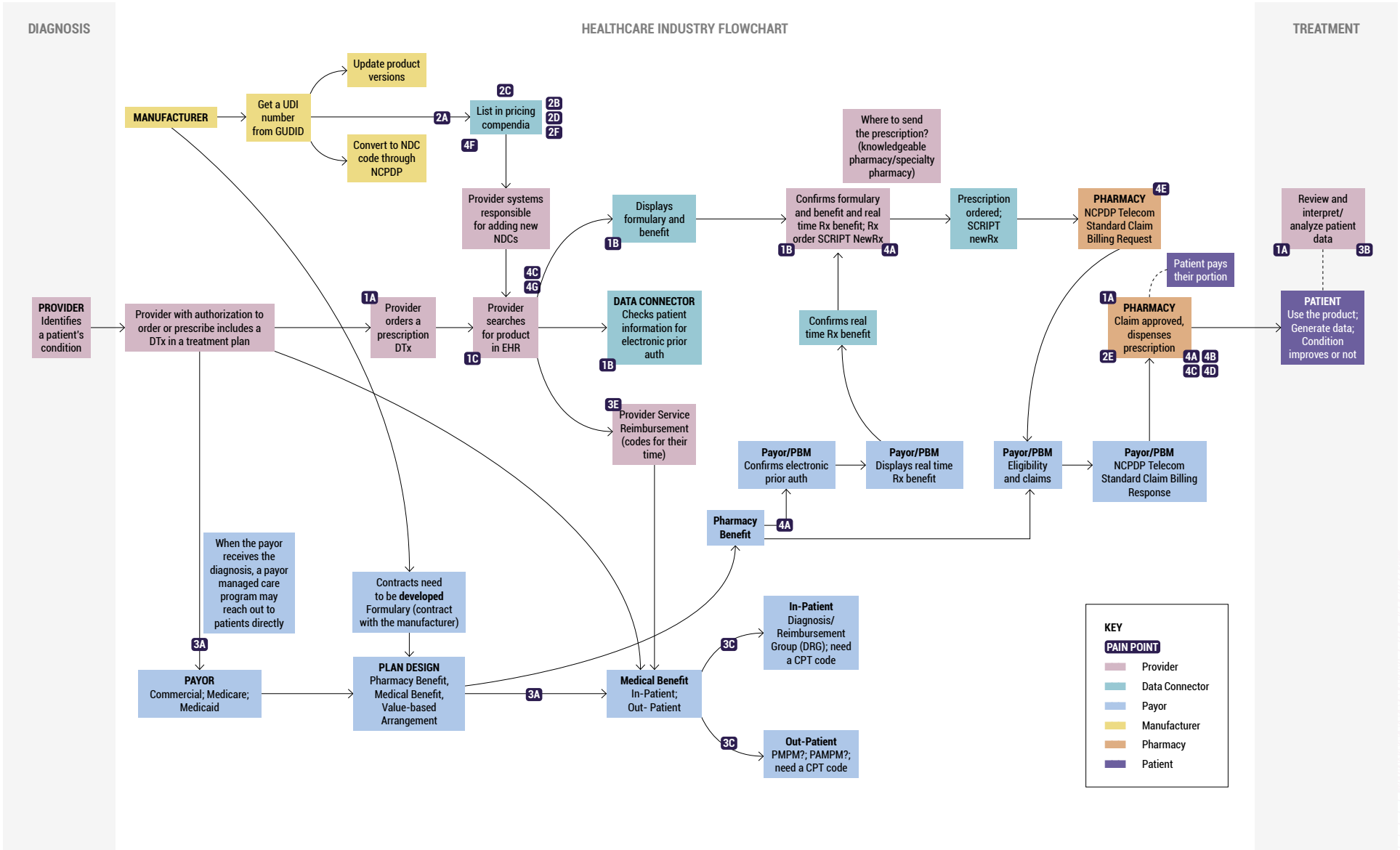
Scope and Key Assumptions

SCOPE: The first phase of this initiative and workshop focuses on pathways for **prescription digital therapeutic products** when they are ordered by a licensed practitioner in a clinical setting.

Key Assumptions	Notes
The product has appropriate clinical evidence.	» Sufficient clinical evidence varies depending on the patient condition, population, regulatory requirements, etc. » For more information, reference DTA's Clinical Evidence whitepaper
The product has been approved for use by the institution.	» Each institution has its own approval process » For support, reference DTA's DTx Value Assessment & Integration Guide
Clinicians are aware of DTx products and their place in care.	» Clinicians require greater awareness and understanding of DTx products' place in care » DTA is undertaking a wide-scale initiative this year related to clinician education
The clinician is using an integrated EHR.	» Not all clinicians have access to a fully integrated Electronic Health Record (EHR) » Next steps should support clinics that do not use integrated EHRs

Note: DTx products that are recommended (not prescribed) by employers, payors, public health professionals, and other counselors will be considered in forthcoming phases of this initiative.

Findings: Pain Points, Considerations, and Next Steps



Workshop participants drafted the following notes related to DTx product integration and workflow pain points, relevant considerations, and next steps:

Pain Point	Considerations	Next Steps
PROVIDER		
1A The scope of professionals who are involved is not clearly defined.	» What scope of professionals can order? This varies by state, varies by submission (label) to FDA » What scope of professionals can sign? » What scope of professionals can release/fulfill? » What is the place order and place of release/fulfillment? In the office in real time or with a pharmacist? Virtual? » What scope of professionals will monitor the treatment?	USP to help create an outline with input from DTA payer ad board and FDA contact
1B The type of reimbursement/ payment model impacts the workflow.	» Patient identification of eligibility » Real time eligibility check, helps with fulfillment	» Review NCPDP paper on Facilitating Access to Specialty Products as the model is similar to limited distribution for drugs » NCPDP to determine if their Real Time Benefit check standard could work for DTx products
1C Provider systems' EHR integrations are not optimized for DTx products.	» Precursors to the order, screening tool in place to determine fit for patient (a nurse or clinic staff member may look at the screener) » Types of orders and when » Data collection will be a challenge—right data delivered in the right way to the right professionals » What types of prescription orders should we have inside of the system? » EHR vendors/provider organization do not load DTx into the prescribing application with drugs from the Compendia	» EHRs may need to code to support renewal requests for DTx » Learn from EHR vendors and provider organizations how DTx are loaded in comparison to drugs

Pain Point	Considerations	Next Steps
DATA CONNECTOR		
2A DTx products need a uniform way to be codified in the Compendias so that it can be used by providers, payors, and pharmacies.	» Pharmacies use the four middle numbers as the product ID number. If the company prefix is too long, using the first numbers, it may take up too many numbers so the pharmacies can easily look them up. » FDA Authorized = DeNovo, 510k designation (GUDID requirements) » Non-FDA Authorized = Does not exist on the GUDID database	» NCPDP to Introduce topic (UDI formatting to 11 digit product code) to solve in Work Group 2 » DTA to update the Product Launch Playbook to include Compendia submission requirements (work with Compendia to create a checklist)
2B Not all Compendia will load DTx products.	Compendia are on the receiving end of DTx submissions and have requested a check-list of requirements and a submission template for the makers of DTx.	NCPDP to work with compendia vendors: » Review with DTA Workflow and Integration Task Group » Discuss with Compendia Partners at NCPDP conference
2C There needs to be a way for Compendia to track product versions.	» Should versions be "linked" in Compendia submissions or old versions become obsolete when a new version is active? » Best Practice: Must not link if there are changes in UDI that is a result of clinical differentiation between different versions that have been determined by the FDA 510k/DeNovo designation of the originator DTx/device. Old versions should convert to new (Hub service provider can notify previous version users). Old version becomes Obsolete in Compendia. » There should be some tracking in case of a product recall.	» DTA and others will share this newly developed Best Practice broadly (DTA Product Launch Playbook, NCPDP documents i.e. FAQ) » For product recalls, identify a process for recall of the digital app. Start by comparing drug and device recall practices.

Pain Point	Considerations	Next Steps
DATA CONNECTOR *(continued)*		
2D There is a gap in Compendia around DUR (clinical data, DDI, Drug Lab, Dosing, Age Range) as it isn't generally part of device products.	» Age range and dose could be included in the product name » How do you determine the therapeutic indication if the products are listed in the device database? » ICD-10 codes can bring back indications and contraindications	NCPDP to inform the compendia of the need to include clinical information, such as age range, contraindications, dose range/duration, will be important content to associate with these products
2E There is no standard way for pharmacies or prescription fulfillers to obtain the authorization code for the DTx product.	Application Programming Interface (API)—DTx APP that connects to HUB/Switch	NCPDP to create a standard message to exchange DTx authorization (message for access codes) between pharmacies and DTx developers. (Work Group ownership TBD; start in the NCPDP DTx Task Group)
2F Unclear how Drug + DTx or Device + DTx combinations products would be handled.	» DTx App to reside in the DTX space for version control so there is minimal impact on the drug product itself » Drug + Device combined as a single unit…how is this handled within the data systems	NCPDP Work Group 2 Product Identification to discuss this issue.

Pain Point	Considerations	Next Steps
PAYOR		
3A There is a lack of and inconsistent coverage by health plans and CMS.	» Workflows will be impacted by whether the product falls into a pharmacy or medical benefit due to billing » Coverage determination will always be inconsistent (based on organization approach to DTx, client requests, and line of business) » The dispensing pharmacies need to be included in the network » Value-based arrangements could influence adoption however would be unique to each institution » Prior Auth process—how does the authorization code get shared/ ingested—unique to DTx » May invoke some other parts, trigger some action by the manufacturer (releasing code to activate software for example) Will the developer need the PA information in order to release the code? » NCPDP ePA could be used by prescriber, however the more common workflow does not have this initiated by the prescriber at this time » How are digital therapeutics incorporated into the sources that the payors use to determine clinical policy and UM criteria (IPD, WK, starts with the FDA, clinical team looks at the way the trials were run) » Some plans may have the opportunity to tie DTx to wellness programs » Formulary inclusion and exclusion decisions may ultimately be made by individual employers	» DTA to drive legislation for CMS to cover DTx products » DTA to work with state Medicaid programs because of their flexibility outside of federal legislation » DTA to work with commercial health plans on evaluation frameworks, challenges, industry expectations, and plan designs » DTA to assess opportunities at the state level with a focus on Mental Health Parity regulations (SPAs, Demonstration Projects, waivers, etc) » DTA to work with payors to understand the workflow in both Pharmacy and Medical Benefit models, as well as, what the non-prescription pathways entail » Potential to develop a template to use as a sample model

Pain Point	Considerations	Next Steps
PAYOR *(continued)*		
3B The data feedback loop is unclear.	» What type of data? Content vs codes. De novo or in/add to existing standards » Value-based arrangement » The professional needs the right data delivered in the right way to the right professionals	» NCPDP and DTA to work with HL7 (clinical), X12 (medical claims, authorizations, and other administrative transactions), and other SDOs » Feedback from DTx to prescriber/ dispenser/ payor with outcomes and usage data. Need participation from DTx to understand the scope of data available. Can look at MedHx messages as a starting point.
3C Insufficient CPT/HCPCS codes.	» There is only one non-reimbursement (through CMS) HCPCS code, and a few CPT codes for providers—important for medical billing; pharmacy benefit billing with use NCPDP Product ID	DTA to work with DMPAG/CMS/Legislators to create a CPT strategy

Pain Point	Considerations	Next Steps
PHARMACY		
4A Payment and reimbursement models are unclear.	» The health plan design will impact reimbursement (Pharmacy benefit or medical benefit) » Medical Benefits – ICD-10, HCPCS, and CPT codes – Only one CPT code for all DTx—how do you bill medical with this single code? – Will need to define specific to DTx services • Define the problem… • Understand the best approach to expand CPT to be more specific to procedures associated with DTx » Pharmacy Benefit – Is there a specific reject code indicating the benefit may be covered under Medical?	» Identify someone to assist (i.e. NCPA) » Is there a reject message to notify the dispenser that it is covered under the medical benefit? » How is the Pharmacy Benefit reject message handled today? Is there guidance already or do we need to address this? » NCPDP to determine if their External Code List for reject codes can be used if the benefit is listed as Medical instead of Pharmacy. Is this list sufficient?
4B Collection of copay is unclear.	» Assume that this is related to any prescription billed under pharmacy benefit » This should follow the same workflow as all other claim-based prescriptions – Script received by pharmacy – Pharmacy submits claim to the PBM/Payer – PBM/Payer adjudicates and approves or denies the claim. PBM/Payor indicates the copay (if any) to collect from the patient and amount the PBM/Payor will pay the pharmacy – Pharmacy collects the copay and sets up a receivable for services paid under the benefit	DTA Task Group, DTA Payor Advisory Board, and NCPDP DTx Task Group to address this pain point

Pain Point	Considerations	Next Steps
PHARMACY *(continued)*		
4C There is a limited distribution network.	» Will there be certification required? What are the clinical expectations for the pharmacy/pharmacist for DTx? Are there parallels to REMS programs? » Will this differ by product/manufacturer? » How does the prescriber know where to prescribe? How to communicate the network to prescribers and payers? » Not all are trained or have time to download the app with the patient and train them » Specialty pharmacies have specific approaches to this issue with drugs	» USP to support and outline of the rules/ regulations and process for dispensing and compliance; NABP discussions on state boards of pharmacy work » Review NCPDP paper on Facilitating Access to Specialty Products as the model is similar to limited distribution for drugs » DTA to connect with specialty pharmacies to seek their input » DTA, NCPDP, and AMCP to assess pharmacy/pharmacist awareness and understanding of DTx products » DTA to work with payors, pharmacies, and manufacturers to ensure network participate at time of product launch to minimize delays in access and/or develop a best practice to communicating the pharmacy network to prescribers » NCPDP to determine if their Real Time Benefits check can support this

Pain Point	Considerations	Next Steps
PHARMACY *(continued)*		
4D Unclear process for how to activate the DTx.	» Is it notified through the approved adjudicated claim, via API on a separate transaction, or are the patients given a physical card? » Pharmacy relies on processor to approve and communicate activation to the pharmacy » Responsibility for pharmacy to activate, educate, follow up, report on progress, receive compensation for services » Responsibility/Expectation for patients to activate, comply with dosing terms, follow up with provider/pharmacy, get help when needed, pay according to health plan » How will refills be handled?	» NCPDP DTx Task group will work with Work Group 1 to determine where the PBM may put the activation code on the approved claim. Note that the PBM may not have an activation code—the DTx developer may have it so there will need to be a transaction between pharmacy and DTx developer to obtain activation code. Another question is if pharmacy systems will need to store activation codes in case the patient loses it » NCPDP to inform if consistency in the size and characteristics of the activation codes is a requirement and, if so, DTA will work with members to ensure activation codes meet the requirements
4E Unclear how Hubs fit or play a role.	» Does pharmacy simply bill and all other services performed by the Hub? » How does the pharmacy know if there is a Hub? Or does the prescriber communicate with the Hub to reach the patient? Or is it part of the DTx?	NCPDP to work within their workgroups to address this pain point

Pain Point	Considerations	Next Steps
PHARMACY *(continued)*		
4F Unclear how the Compendia will represent DTx and the data associated with DTx.	» Is there a better way to filter out the DTx from devices? » Will DTx be listed in a clinical/therapeutic class and not just as a DTx? » Is there the necessary associated clinical decision support for Drug-Drug, Drug-therapy checks? » Is this expected to be done at the pharmacy or also at the point of prescribing? » What if the DTx is dispensed/activated at the provider or Hub?	DTA and NCPDP to host a compendia roundtable discussion to address this pain point
4G We need EHR developers at the table.		DTA and NCPDP to socialize this report with EHR vendors, incorporate them on next steps, and include them in future discussions

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For more information, please
contact **info@dtxalliance.org**

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