ONC | HealthIT ADVISORY COMMITTEE

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Meeting #12

Hans Buitendijk, Co-Chair

Shelly Spiro, Co-Chair

September 27, 2023

Call to Order/Roll Call

Mike Berry, Designated Federal Officer, ONC

Pharmacy Interoperability and Emerging Therapeutics Task Force 2023 Roster

Name	Organization	Name	Organization
Hans Buitendijk* (Co-Chair)	**Oracle Health**	**Shelly Spiro (Co-Chair)**	Pharmacy HIT Collaborative
Pooja Babbrah	Point-of-Care Partners	Deven McGraw*	Invitae Corporation
Chris Blackley	Prescryptive	Ketan Mehta	Micro Merchant Systems
Shila Blend*	North Dakota Health Information Network	Justin Neal	Noble Health Services
David Butler	Curatro, LLC	Eliel Oliveira*	Dell Medical School, University of Texas at Austin
Steven Eichner*	Texas Department of State Health Services	Naresh Sundar Rajan*	CyncHealth
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Scott Robertson	Bear Health Tech Consulting
Adi V. Gundlapalli**	Centers for Disease Control and Prevention	Alexis Snyder*	Individual
Jim Jirjis*	HCA Healthcare	Fillipe Southerland*	Yardi Systems, Inc.
Summerpal Kahlon	Rocket Health Care	Christian Tadrus	Community Pharmacy Owner
Steven Lane*	Health Gorilla	Sheryl Turney*	Elevance Health
Meg Marshall**	Department of Veterans Health Affairs	Afton Wagner	Walgreens
Anna McCollister*	Individual		

* HITAC Member ** HITAC Federal Representative

Agenda

10:30 AM **Call to Order/Roll Call**

- Mike Berry, Designated Federal Officer, ONC

10:35 AM **Opening Remarks**

- Hans Buitendijk, Co-Chair
- Shelly Spiro, Co-Chair

10:40 AM **Task 3 Guest Presentations on Digital Therapeutics**

- Ibrar Ahmed, Software and Enterprise Architecture Manager, ZS

11:00 AM **Topic 1 and 2: Review of Recommendations**

- Hans Buitendijk, Co-Chair
- Shelly Spiro, Co-Chair

11:50 AM **Public Comment**

- Mike Berry, Designated Federal Officer, ONC

11:55 AM **Task Force Work Planning**

- Hans Buitendijk, Co-Chair
- Shelly Spiro, Co-Chair

12:00 PM **Adjourn**

Opening Remarks

Hans Buitendijk, Co-Chair

Shelly Spiro, Co-Chair

Digital Therapeutics & Needs from Manufacturers

Prepared for HITAC Committee

September 27, 2023

Evanston +1 847 492 3600

Impact where it matters.

Agenda

- About ZS
- Digital Therapeutics (DTx) Introduction
- Considerations for Standards
- PDT Ecosystem-A Generalized View
- Needs from Manufacturers

ABOUT ZS

ZS is a global management consulting firm investing in and leading DTx growth for its clients with a team of experts

Ibrar Ahmed
Software & Enterprise Architecture Manager
Ibrar.ahmed@zs.com

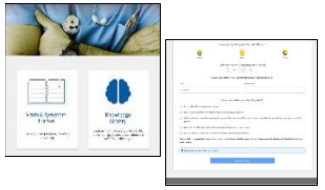
I am a healthcare technologist and has more than 15 years of experience as Architect and Development Manager for digital solutions (incl. SaMDs, HIT) in the healthcare sector.

Some of our work

Prescription Digital Therapeutic (PDT)

Regulated PDT product management best practices by creating POVs, providing expertise & utilizing product leads in each go to market.

4	6	10
Go to Market Workstreams with product oversight	POVs Created on Product Features	Consultant / Product Managers on project



SaMD COVID-19 Solution

Designed, built and deployed solution under ZS SaMD Factory's ISO 13485 QMS to rigor of Class 1 medical device to allow better management of COVID-19 patients post-discharge

ZS Expertise

Business Consulting + **Business Technology**

Greater depth of expertise than general IT consulting firms

30+
Markets covered for Digital Health innovation, incl GTM, localization, data compliance, solution maintenance

60+
TAs across apps, sites, connected devices, algos, EHR etc.

130+
Clients including Biopharma, MedTech, HealthTech, Payer, Provider, Retail Health Clients

210%
Increase in Digital Patient Engagement in chronic and behavioral programs

500+
Digital Health Projects, Programs, & Solutions delivered over last 10 years across therapeutic areas

5M+
Managed Lives in largest launched, scaled, and supported Digital Health Program

Digital therapeutics (DTx) is a SW product that delivers evidence based intervention

	Digital Health	Digital Medicine	Digital Therapeutics
DEFINITION	Digital health includes technologies platforms, and systems that engage consumers for lifestyle, wellness and health-related purposes; capture, store or transmit health data..	Digital medicine includes evidence-based software and/or hardware products that measure and/or intervene in the service of human health.[1]	Digital therapeutic (DTx) products deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.[2]
CLINICAL EVIDENCE	Typically do not require clinical evidence.	Clinical evidence is required for all digital medicine products.	Clinical evidence and real world outcomes are required for all DTx products.
REGULATORY OVERSIGHT	Do not meet the regulatory definition of a medical device and do not require regulatory oversight.	Products that are classified as medical devices require clearance or approval.	DTx products must be reviewed and cleared or certified by regulatory bodies/
PRODUCT EXAMPLES	**Data & information capture, storage, and display** • User-facing technologies • Health Information Technology (HIT) • Consumer health information • Telehealth	**Measurement Product** • Digital diagnostics • Digital biomarkers • Electronic clinical outcome assessments • Remote patient monitoring • Decision support software	**Software that delivers a therapeutic intervention. *Medical claims include:*** • Treat a disease • Manage a disease • Improve a health function

Software as a Medical Device




1 https://www.dimesociety.org/index.php/defining-digital-medicine
2 https://www.dtxalliance.org/dtxproducts/

The different forms of DTx should be considered while creating standards for workflow and interoperability

DTx can take many forms. Some examples include:

Standalone used as medical intervention

Companion DTx – Used alongside physical therapy or drug

Part of RPMs – Used to deliver interventions and actively collect patient data important for providers

Lead to challenges for standardization of flow and data while selecting treatment, prescribing, fulfilling prescription, and benefits verification.

- Could be **OTC** or **prescribed (PDT)**
- Could be **medical** or **procedural**
- May be **patient-led** or **inclusive of provider**
- Distribution **channels** might **vary**

Current standards don't account for uniqueness of DTx compared to a drug

DTX are software products, their definition of consumption, delivery, refill and adherence have to be standardized, if not redefined and adopted for scale

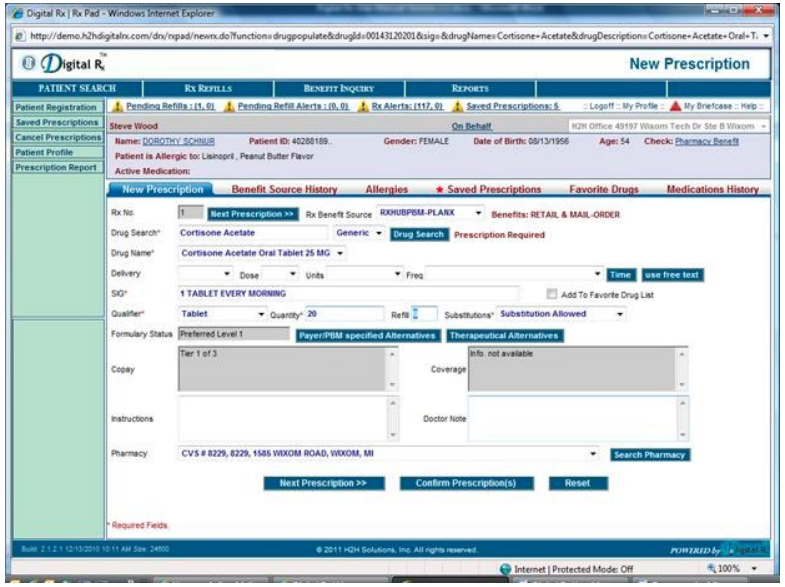


Image of illustrative EHR from public source

Non-Exhaustive

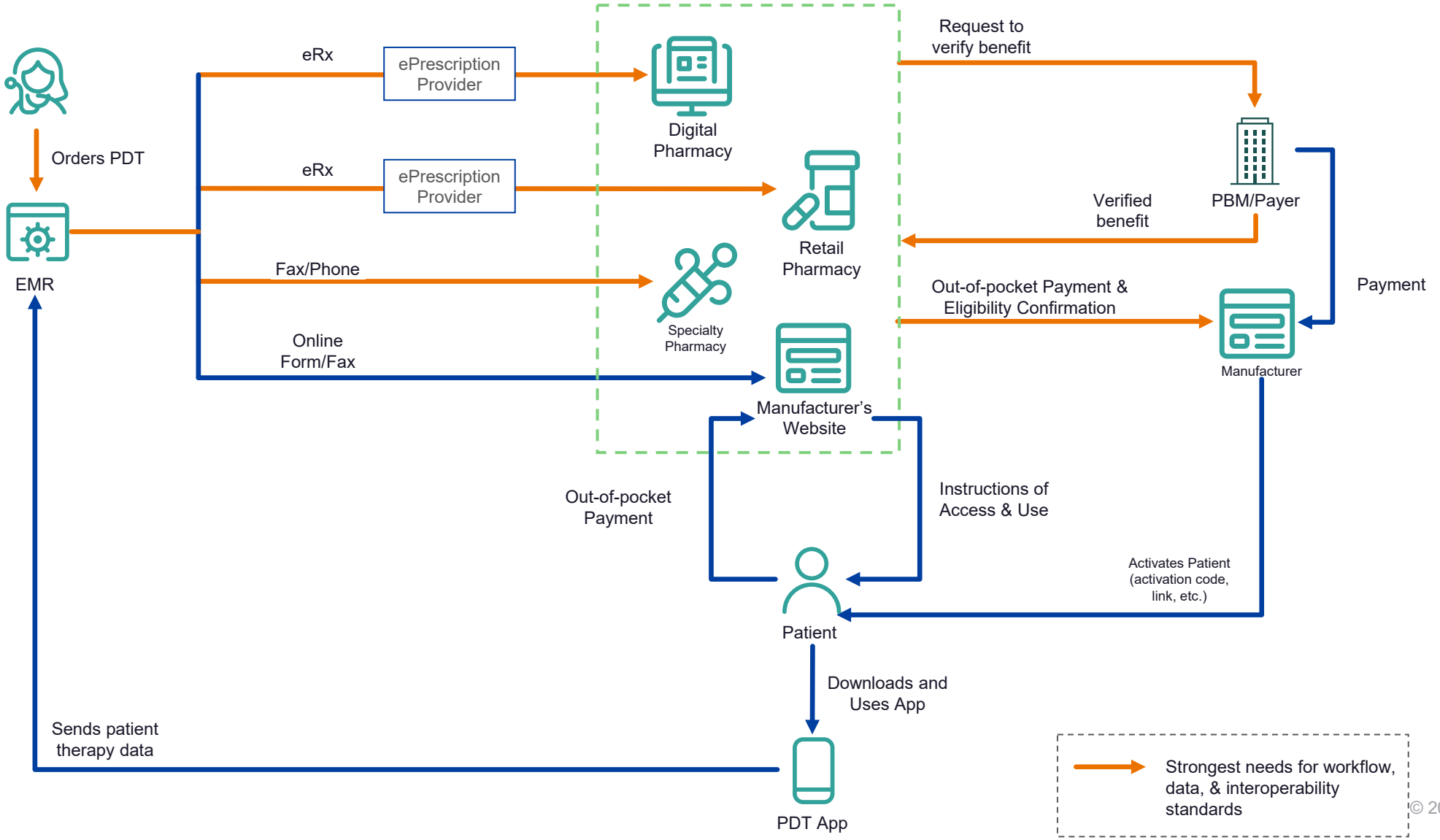
The traditional prescription system needs to adapt for the unique features that PDT has and has to adhere to the changing market

- **Product identifier –**There are a number of options to use for Unique Device Identifier (UDI), Universal Product Code (UPC), Global Trade Identification Number (GTIN), etc.
- **Dosage** – PDTs are typically prescribed for a certain period for a certain number of minutes at a given frequency.
- **Medication Strength, Quantity** – Administration of PDTs are done through the app or digital interface and the strength and quantity may not apply or the fields will need to be repurposed.
- **Substitutions** – Given the early days of DTx, it is unclear if existing fields for substitutions in medication record apply to DTx and if so, how.

UNIQUE DTX Considerations

- Every consumption depends on user's device (different phones, different version). These need to be captured in numerous systems: formularies, pharmacy, manufacturer.
- Most data can be collected in real-time; more data is available than what systems are built for.

While the PDT ecosystem has similarities with drug prescription and fulfillment, there are limited established standards



To summarize, our customers developing DTx solutions need support in standardizing workflow and data for prescribing, adjudicating claims, and fulfilling prescriptions

DTx Data Definition

There is **limited standards or guidelines** for **data describing DTx**. While some existing fields can be leveraged, most fields do not cover all the information required to describe DTx prompting different EHRs, pharmacies, manufacturers, and other systems to have **different ways to describe the same prescription**.

EHR Integration

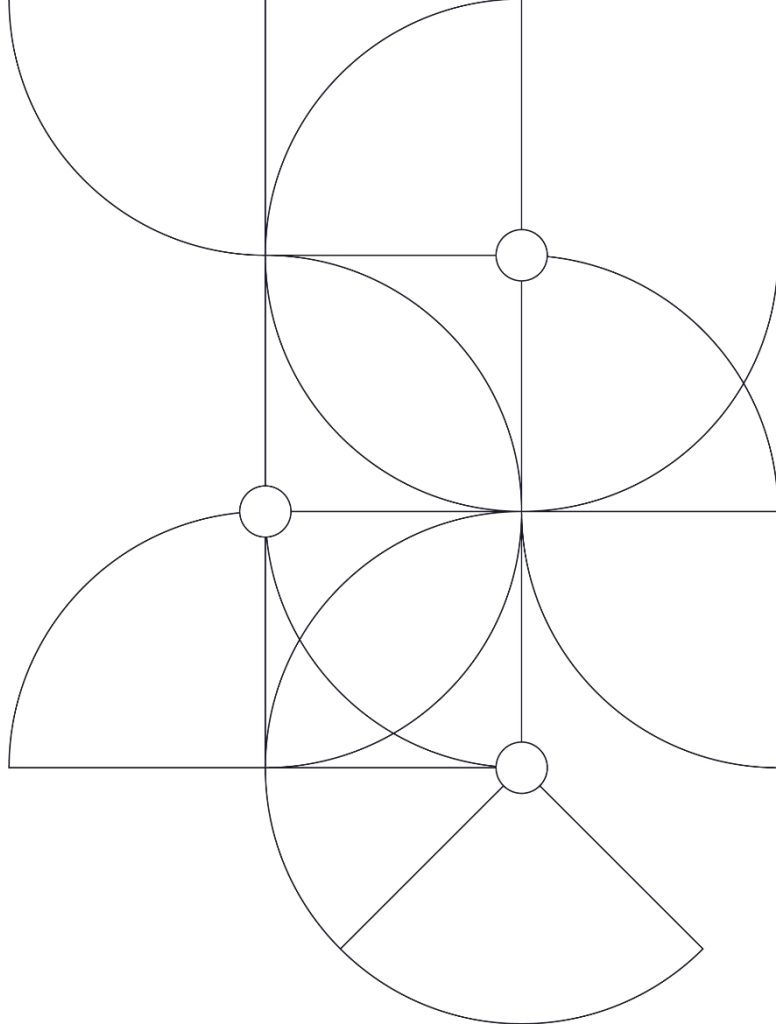
DTx manufacturers recognize **the importance of integrating prescription from within EHRs** but are **challenged** by **limited standards and guideline**s available to facilitate that. We have heard from **clinicians** through our primary research that they need the prescription process to be interoperable within EHR **to reduce their burden**.

Fulfillment of Prescription

Interoperability between **pharmacy** systems and DTx **manufacturers** should be **standardized** to facilitate the **new way of fulfilling** a prescription since **manufacturers** require **key information** such as patient name, date of birth, e-mail, phone numbers, payment confirmation, etc. **to activate patients** on the software. Standards such as **NCPDP** are good places to start.

Claim Adjudication

One ask/suggestion we have heard from manufacturers is to treat DTx claims as **medical benefits** vs **pharmacy benefits** since there is notable difference between DTx and drugs and there is **precedence** in **prescribing devices** with a combination of hardware and software. E.g., Continuous Glucose Monitoring.



Thank you!

Impact where it matters.

Discussion

Topic 1 and 2: Review of Recommendations

Hans Buitendijk, Co-Chair

Shelly Spiro, Co-Chair

Public Comment

To make a comment please

Use the Hand Raise Function

If you are on the phone only, press "*9" to raise your hand

*(Once called upon, press **"*6"** to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

Written comments will not be read at this time,
but they will be delivered to members of the task force and made part of the public record

Task Force Work Planning

Hans Buitendijk, Co-Chair

Shelly Spiro, Co-Chair

Upcoming Meetings

Month	Task Force Meeting Dates	HITAC Meeting Date
October	4, 11, 18, 25	October 19 (TF Update)
November	1	November 9 (Final Recommendation and Vote)

Adjourn