JUNE 2024

DTx Integration & Workflow

Grant Funded to:

Digital Therapeutics Alliance

NCPDP Integration:

WG19 | NCPDP Standards Coordination
- Digital Therapeutics Task Group

This grant was made possible through the NCPDP Foundation's Operating Fund and GoodRx's Founder Donation to support increased patient access to care.

Direct inquiries, comments, and questions to ncpdpfoundation@ncpdp.org

Background

Digital therapeutics (DTx) represents a groundbreaking category of medical interventions that leverage technology to improve patient outcomes. These evidence-based interventions aim to prevent, manage, or treat various health conditions. However, integrating DTx into the traditional healthcare system presents opportunities and challenges.

In January 2023 NCPDP, in collaboration with Digital Therapeutics Alliance, hosted a stakeholder action group to discuss the barriers to integration of DTx and coverage through health plans. During this meeting, a critical barrier was identified: understanding the payment pathways as they impact stakeholders downstream. A project was identified as a way to mitigate this barrier resulting in creation, and subsequent funding approval, of a research study to Digital Therapeutics Alliance.

Research Objective

Research how reimbursement pathways impact the work streams and identify where standardization already exists and opportunities for new standards.

While the span of DTx technologies is vast, this research focuses on digital therapeutics, defined as: "*Health software intended to treat or alleviate a disease by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact*"[1]. Three purpose statements were identified:

1. Outline the workflow to integrate digital therapeutic products into the standard practice of care in the U.S.
2. Identify gaps or pain points in the workflow.
3. Propose the next steps to address the pain points to optimize the experience for clinicians and patients.

Research Findings

Within this report are abridged findings that relate to NCPDP Standards and where NCPDP can make an impact on improving payment pathways for DTx products based on the full research report by Digital Therapeutics Alliance. A link to the full report is in the references section.

Key Assumptions

Assumptions in research refer to the fundamental beliefs and values that shape the research process. The following assumptions have been established based on the awareness of DTx product adoption challenges including evaluation criteria, and provider awareness and understanding of the product.

- The product has appropriate clinical evidence
- The product has been approved by your institution
- Clinicians are aware of DTx products and their place in care

Payment Pathways

The reimbursement or payment pathway significantly influences the workflow for the DTx product. Three payor system categories were identified which categorize each DTx product and identify their payment pathway:

Prescription Pathway	Non-Prescription Pathway
Prescription Medical Benefit	Other/Wellness Benefit
Pharmacy Benefit	

Prescription Workflow Pain Points Identified

The prescription workflow begins with a diagnosis from a provider and follows pathways to payment and 'dispensing' the DTx product to the patient. This workflow utilizes NCPDP standards in various points to provide the pathway needed for data exchange. NCPDP standards that may be utilized include Telecom, SCRIPT, Formulary & Benefit, and Real-Time Prescription Benefit.

Research concluded the following pain points within the prescription workflow model, which is included within this report. These pain points are being researched further through various task groups within the Digital Therapeutics Alliance and can be

discussed by NCPDP members within WG19, NCPDP Standards Coordination, or by non-members within the Digital Therapeutics Task Group.

1. The scope of professionals who are involved is not clearly defined.
2. Distribution networks are not standardized.
3. There is a lack of, and inconsistency in, coverage by Medicare, Medicaid, and commercial health plans.
4. No automation exists in the medical benefit pathway.
5. A data feedback loop to provide DTx product data back to payors and providers is needed.

Non-Prescription Workflow Pain Points Identified

Non-prescription DTx products are increasing among patients through the use of apps, over-the-counter purchases, and online platforms. Stakeholders for this pathway is often the patient's employer through a health benefit, the patient themselves, or the patient's provider.

Research concluded the following pain points within the non-prescription workflow model, which is included within this report.

1. Manufacturers are not easily able to identify the key decision maker in the payor's organization.
2. Contracting alignment.
3. Patient engagement expectations are inconsistent.
4. DTx solutions are inconsistent in how they market to patients.
5. Poor or no integration with other payor solutions.
6. How the DTx product/solution is integrated with payor needs/efforts.Recommendations for DTx Integration

Stakeholder Collaboration

DTx developers, healthcare providers, payors, and regulators must collaborate. Regular dialogues foster understanding and drive progress to adoption of important DTx services and products. Together, stakeholders can establish robust data governance frameworks to protect patient privacy while enabling data exchange.

Education and Training

Healthcare Workforce: Train providers and pharmacists on DTx products, benefits, and payment pathways.

Patient Education: Educate patients about DTx options, costs, and benefits to empower informed choices.

Conclusion

Pain points have been identified along two payment pathways for DTx products: Prescription Payment Model and Non-Prescription Payment Model. Within the Prescription Payment Model, four NCPDP Standards were identified as utilized within the payment workflow: F&B, RTPB, Telecom, and SCRIPT. Within this model, next steps include additional research with stakeholders to standardize the exchange of data, distribution networks and feedback loops, medical/prescription benefit coverages, and the scope of professionals.

NCPDP Integration

WG19 NCPDP Standards Coordination

- **Digital Therapeutics Task Group**
  This task group will support prescription digital therapeutic (PDT) products that have been FDA cleared, designated as either 510k, DeNovo or Premarket Approval (PMA) status, and listed on the FDA's GUDID database.

Appendix

Prescription Workflow

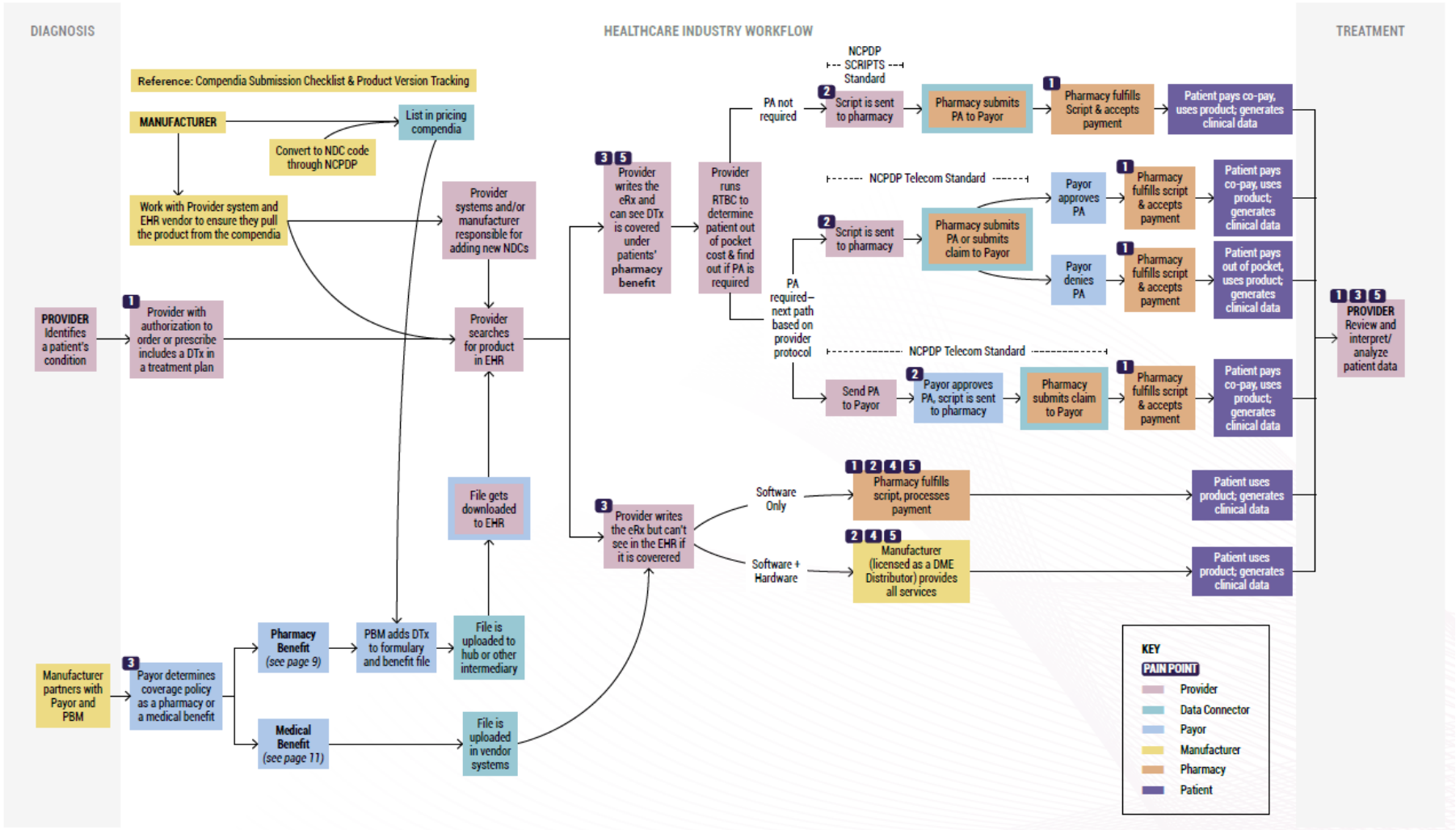

Image source: Digital Therapeutics Alliance, March 2024

Prescription Workflow | Pharmacy Benefit Model

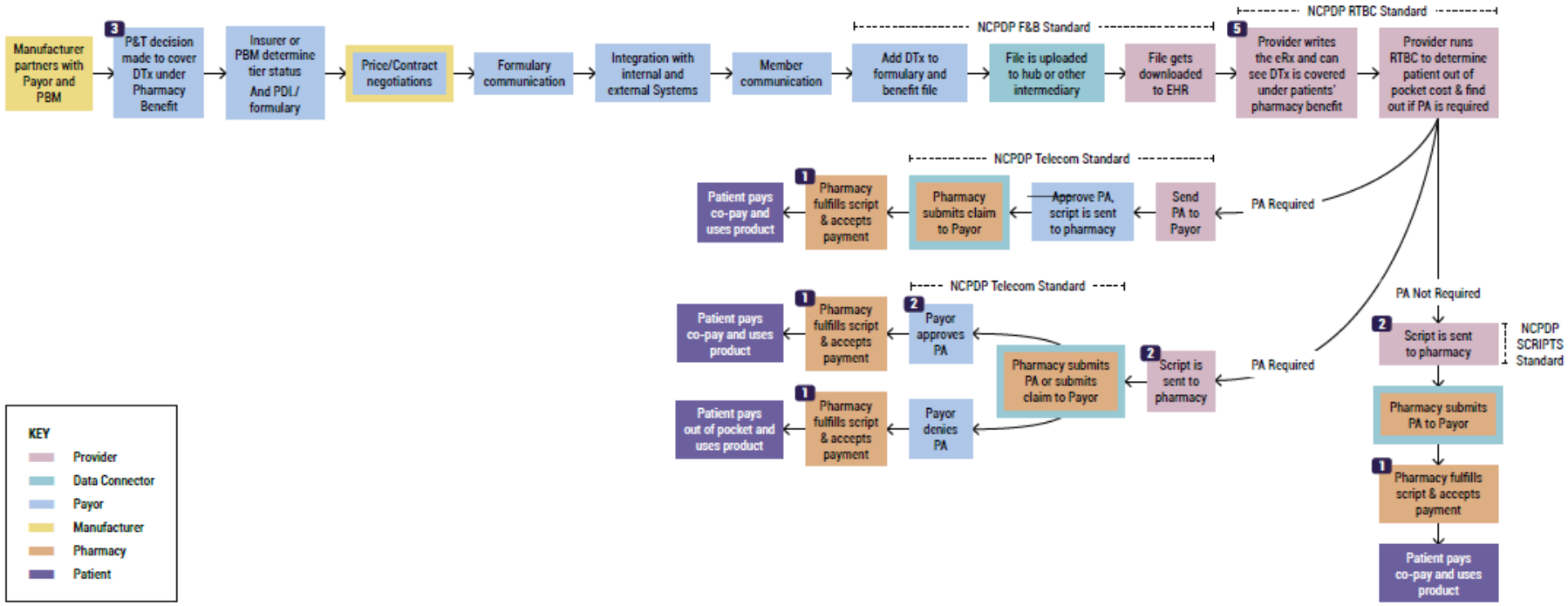

Image source: Digital Therapeutics Alliance, March 2024

Prescription Workflow | Medical Benefit Model

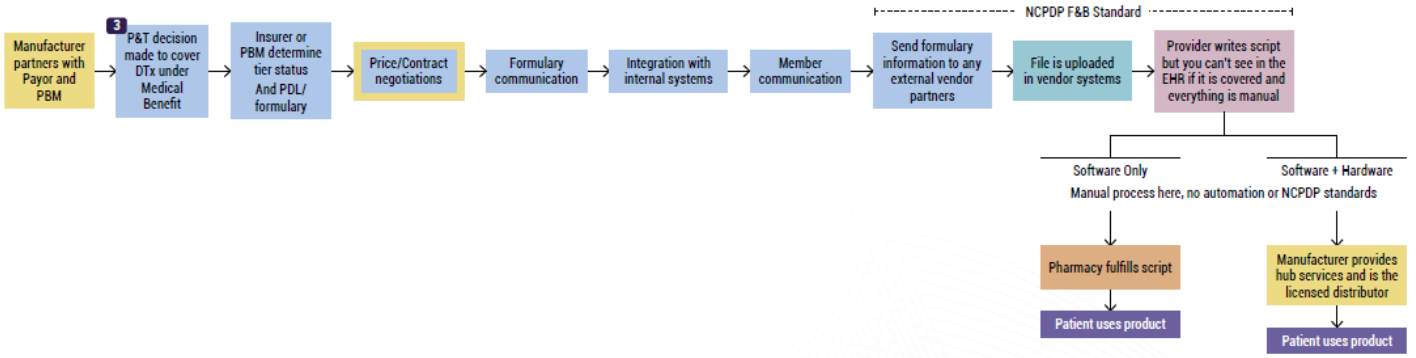

Image source: Digital Therapeutics Alliance, March 2024

Non-Prescription Workflow

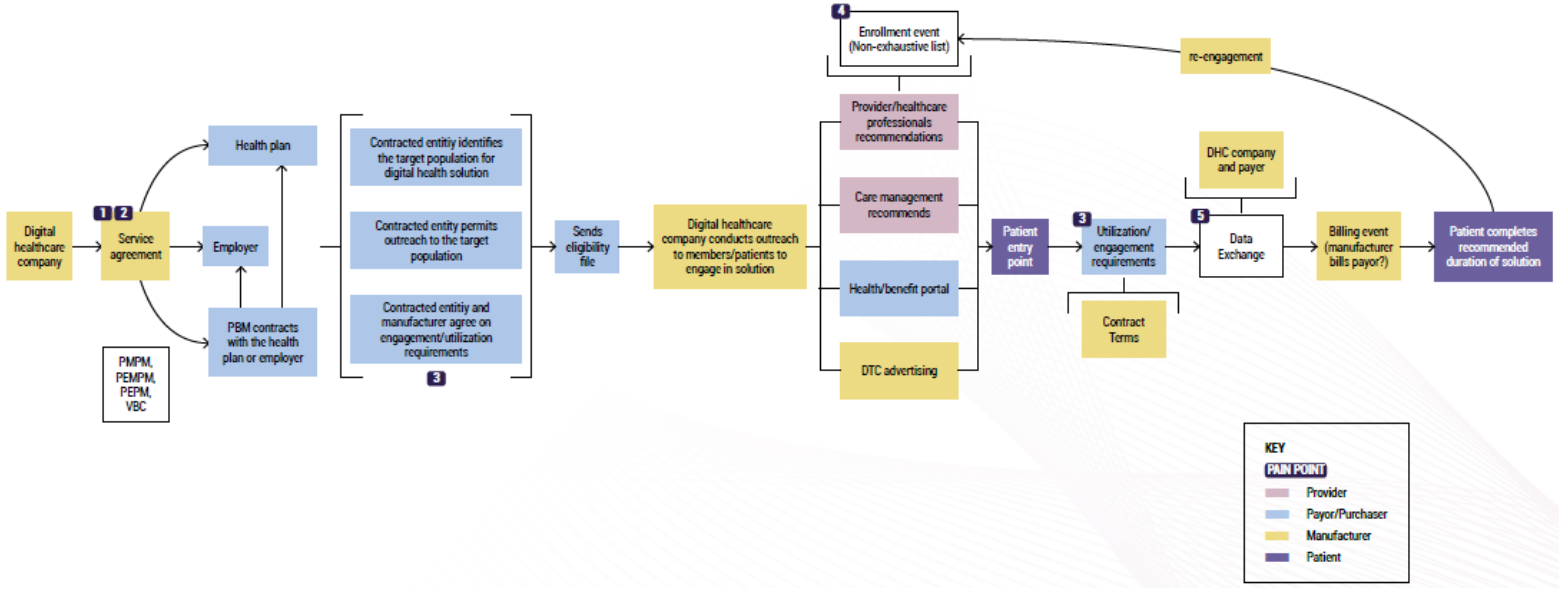

Image source: Digital Therapeutics Alliance, March 2024

References

1. Digital Therapeutics Alliance. March 2024. DTx Integration & Workflow Report. Retrieved from: https://dtxalliance.org/wp-content/uploads/2024/03/March-2024-DTx-Integration-and-Workflow-Report_FINAL-1.pdf