

Prescription Digital Therapeutics: Measuring and Incentivizing Clinical Impact *Agenda*

1:00 p.m. ET Welcome & Overview

1:10 p.m. ET Session 1: Addressing Challenges to Better Evidence Generation for PDTs

Objectives: This session will focus on identifying the key gaps in the current evidence generation infrastructure for PDTs, and how policy and collaborations may be able to help address these gaps. Participants will identify and review challenges with generating evidence that is sufficient to support development, access, and uptake, including trial design and the use of real-world evidence to capture clinical impact. Participants will then discuss evidence generation approaches to address these concerns, and how stakeholders including manufacturers, payers, health systems, and trade associations can collaborate on these efforts.

2:10 p.m. ET Break

2:20 p.m. ET Session 2: Identifying a Novel Value-Based Approach to PDT Reimbursement

Objectives: This session will focus on what a value-based payment structure for PDTs could look like if a statutory amendment is needed to broadly reimburse for PDT use within Medicare. Participants will discuss how Medicare, Medicaid and private payers could approach policies and infrastructure to facilitate value-based payments for PDTs given the freedom to expand outside of the current reimbursement structure and newly proposed Medicare physician fee schedule codes. Participants will discuss key elements to building such a policy, including how it might utilize existing coding and payment frameworks and where new infrastructure might be required.

3:20 p.m. ET Session 3: Integrating PDTs into the Existing Reimbursement Structure

Objectives: This session will focus on solutions to incentivizing high-quality PDTs through coverage within the existing reimbursement system. Participants will review the prospect of reimbursing digital therapeutics like physician-administered drugs under the medical benefit, and how this approach could promote payment for value and the ability to differentiate PDT products based on evidence of their effectiveness. Participants will discuss the appropriateness of this reimbursement approach versus reimbursement of PDTs under the pharmaceutical benefit. Participants will also discuss how elements of these reimbursement systems might be combined to draw out the positives aspects of each approach while reducing the challenges, as well as logistical infrastructure requirements for any proposed approaches.

4:20 p.m. ET Closing Remarks & Next-Steps

4:30 p.m. ET Adjournment