Policy Keeping Pace with Innovation

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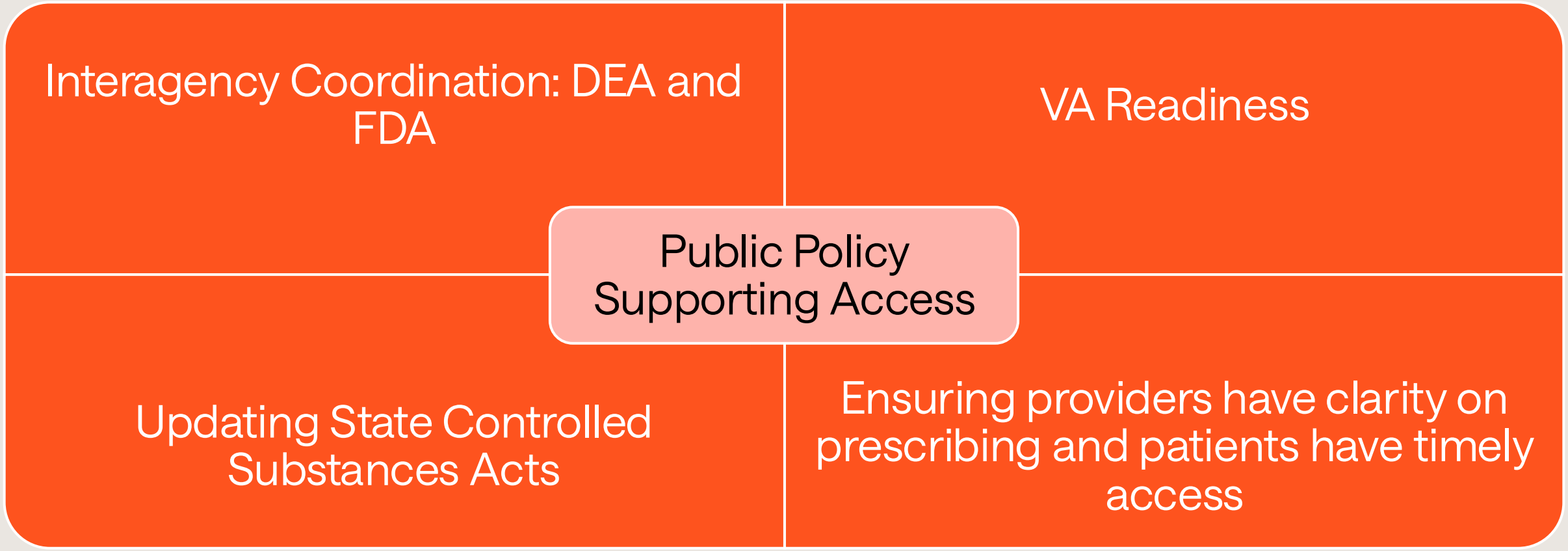
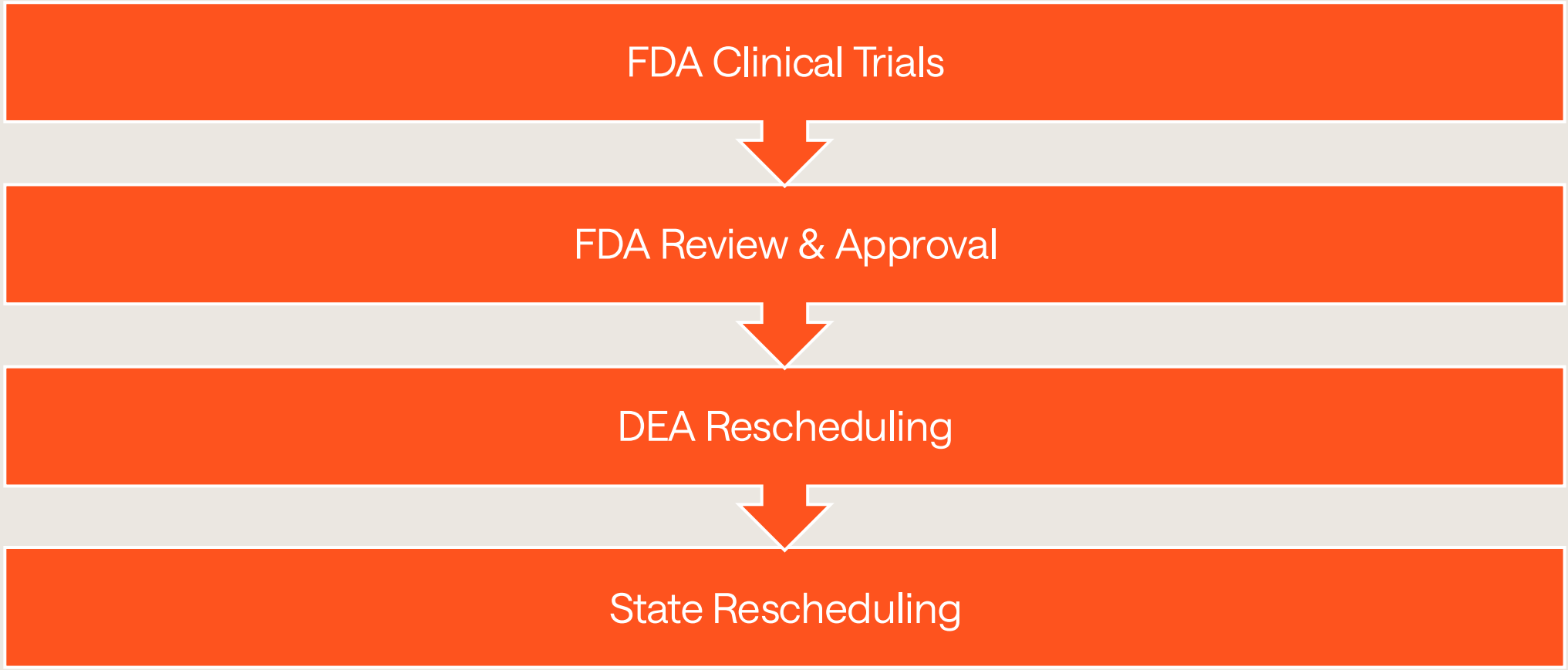
Updating Federal and State Laws to Remove Barriers to Care



Where Science Meets Policy: Ensuring Timely Access to New Treatments



Federal Policy Supporting Access

Administration

- Executive Order (EO) *Accelerating Medical Treatments for Serious Mental Illness* issued April 18, 2026
- The FDA issued psychedelic clinical trial guidance earlier this week with comments due by August 26, 2006
- The FDA also noticed a hearing for September 14, 2026 and will be focused on: provider training/credentialing, patient safety (not product specific), access and best practices for data collection
- Health Resources and Services Administration (HRSA) issued an RFI, comments due by August 14, 2026

Congress

- Congressman Luttrell (R-TX) introduced a bill to codify the EO
- Appropriations bill includes language directing the DEA to work in parallel with the FDA on analysis for rescheduling
- Psychedelics Advancing Therapies Caucus holding quarterly briefings discussing infrastructural readiness

Modernization of Patient Access: Proactive State Policy Chance

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Model Legislation: Controlled Substances Rescheduling for FDA-Approved Medications

ANY COMPOUND, MIXTURE OR PREPARATION THAT IS APPROVED BY THE 13 UNITED STATES FOOD AND DRUG ADMINISTRATION AND THAT IS SCHEDULED OR 14 RESCHEDULED BY THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION TO A 15 SCHEDULE OTHER THAN SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT 16 (P.L. 91-513; 84 STAT. 1242; 21 UNITED STATES CODE SECTIONS 801 THROUGH 17 904) IS A CONTROLLED SUBSTANCE FOR THE PURPOSES OF THIS CHAPTER AND MAY BE 18 PRESCRIBED IN THIS STATE.

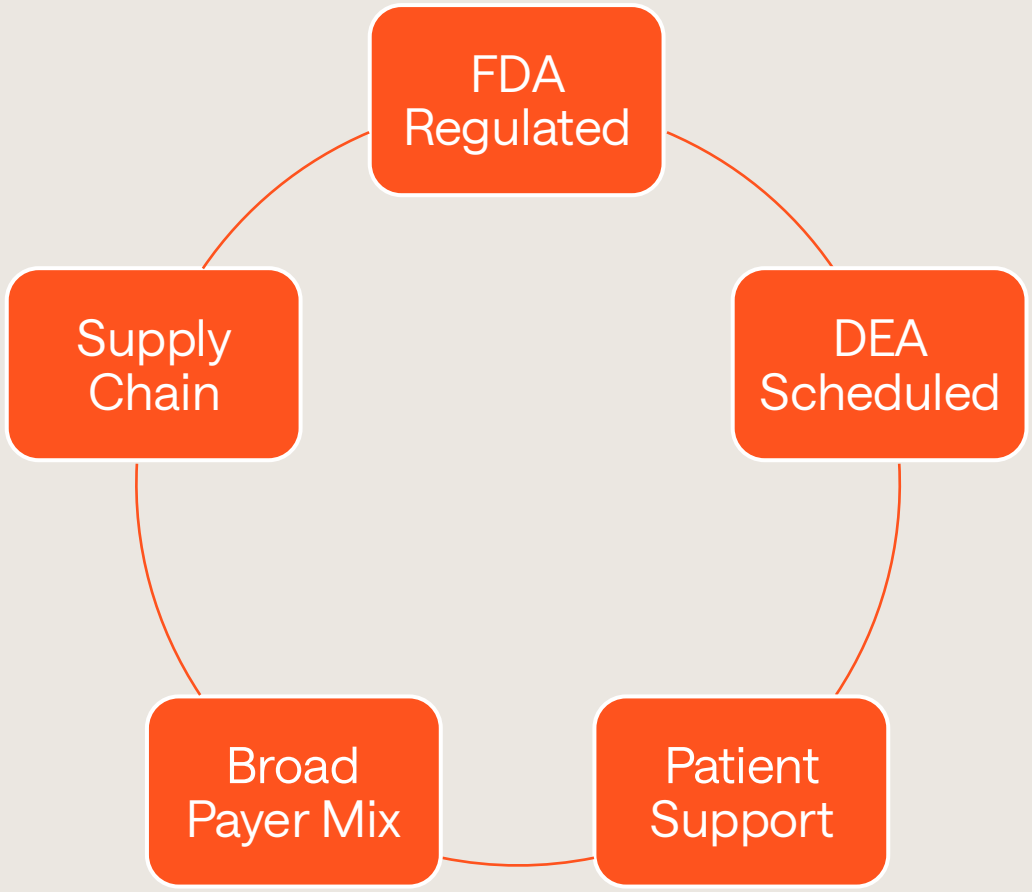
Why This Matters:

- Controlled Substances (CS) statutes were written in the early 1970s with illicit drug use in mind and remains unchanged today
- Advancements in science and technology have accelerated medical innovations with controlled substances
- Timely action is critical for supply chain and treatment administration
- Delays in rescheduling due to regulatory alignment create unintentional access barriers

States Leading the Way :

- Arizona
- Colorado
- Georgia
- Illinois
- Tennessee
- Utah

Key Considerations for Patient Access



- Access to innovation in mental health is important given unmet need and lack of innovation
- FDA REMS requirements will be in place
- DEA will reschedule medicines once approved by FDA
- DEA registration requirements for manufacturer, distributor, clinics, and prescribers

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