

AMCP 2018 | Boston, MA

# Operationalizing the First FDA-Cleared Prescription Digital Therapeutic, reSET®, for Real World Implementation: Initial Pilot Methodology

C. Grevenitz<sup>1</sup>, A. Kangethe<sup>1</sup>, M. Polson<sup>1</sup>, T.C. Lord<sup>1</sup>, T. Evangelatos<sup>1</sup>, C.S. Lento<sup>2</sup>, J. Nichols<sup>2</sup>, E. Crosland<sup>2</sup>, D. Zuckerman<sup>2</sup>, M. Smith<sup>2</sup>

# **Problem Description**

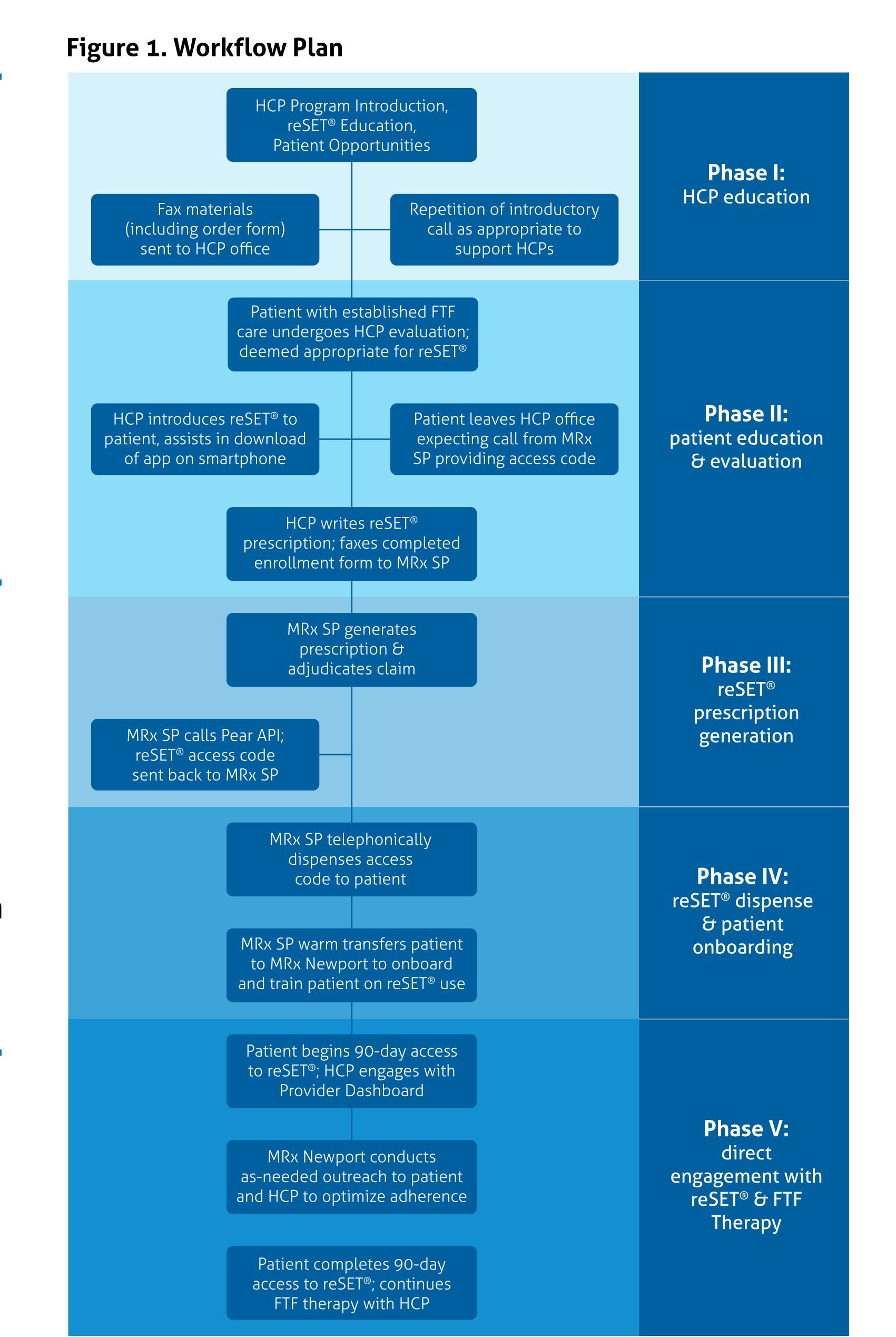
- Healthcare resource utilization and costs are higher for patients living with substance use disorder (SUD) than those without SUD, but <50% of patients receive the recommended minimum of 12 weekly face-to-face (FTF) cognitive behavior therapy sessions<sup>1</sup>
- The first FDA-cleared prescription digital therapeutic, reSET®, is now available for adjunctive therapy with outpatient FTF SUD treatment
- Digitalizing SUD treatment stands to improve the state of access and care; however, further elucidation of optimal strategies for delivering reSET® at the point-of-care and evaluating its effectiveness are needed

#### Goal

- To implement a pilot program with processes for procurement, billing, and dispensing of reSET®
- Pilot strategies to incorporate reSET® into patient treatment plans include:
  - A patient identification algorithm
  - o Physician education, outreach, training and support
  - o Therapy adherence tracking
- The pilot will assess clinical and economic impact using medical/pharmacy administrative claims data

## **Program Description**

- A 6-12 month pilot program seeking to enroll 250 patients with SUD began January 2018 to assess the clinical utility of reSET® on patient abstinence and program retention through engagement and adherence to FTF counseling and reSET® therapies
- Advanced data analytics and clinician dashboards generated through the reSET® mobile application, intended to provide clinical support, and pharmacist-led outreach to providers and their patients will be operationalized and evaluated



#### Observations

- To facilitate a successful approach to treating SUD patients, this pilot established an interdisciplinary clinical and analytical team, developed a detailed workflow plan (Figure 1), and identified and addressed operational needs including:
  - Specialty Pharmacy integration and reimbursement
  - o HUB coordination (support services, for select products)
  - Patient identification criteria
  - o Data management and information privacy
  - Development of an HEOR analysis plan inclusive of outcome metrics to assess medium and long-term program impact on the cost of care

## Findings

- Introduction of FDA-cleared prescription digital therapeutics, such as reSET®, creates new managed care
  and patient support opportunities and challenges
- A well-developed plan is essential for successful integration and assessment of such clinically-validated therapies, including those used in combination with currently available treatment regimens, into payer operations

### Disclosures

 This study was conducted by Magellan Rx Management, Middletown, RI, and sponsored by Pear Therapeutics.

#### References

1. Kangethe A, et al. Real-world health care cost of substance abuse for patients receiving FTF therapy vs. without therapy, AMCP Nexus 2017. Dallas, Texas.