A BILL TO BE ENTITLED
AN ACT ESTABLISHING A PILOT PROGRAM TO ASSESS THE EFFECTIVENESS OF
PRESCRIPTION DIGITAL THERAPEUTICS AUTHORIZED BY THE FEDERAL FOOD
AND DRUG ADMINISTRATION FOR THE TREATMENT OF OPIOID USE
DISORDER; AND APPROPRIATING FUNDS FOR THAT PURPOSE.

The General Assembly of North Carolina enacts:

SECTION 1. It is the intent of the General Assembly to combat the opioid epidemic
in this State by expanding access to innovative evidence-based treatments for individuals with
opioid use disorder. To that end, the State Controller shall transfer the sum of one million eight
hundred fifty thousand dollars ($1,850,000) in nonrecurring funds for the 2022-2023 fiscal year
from funds available in the Opioid Abatement Reserve established in Section 9F.1 of S.L.
2021-180 to the Opioid Abatement Fund in the Department of Health and Human Services. Funds
transferred under this section are appropriated to the Department of Health and Human Services,
Division of Mental Health, Developmental Disabilities, and Substance Abuse Services
(DMH/DD/SAS), to develop and administer a two-year pilot program to gauge the effectiveness
of prescription digital therapeutics (PDTs) authorized by the federal Food and Drug
Administration for the treatment of opioid use disorder. The funds appropriated in this section
shall not revert at the end of the 2022-2023 fiscal year but shall remain available to expend until
December 1, 2024, or upon the termination of the pilot program, whichever is sooner.

SECTION 2. The pilot program authorized by this act shall be subject to all of the
following requirements and limitations:

(1) The pilot program shall commence no later than December 1, 2022, and
terminate no later than December 1, 2024.

(2) The DMH/DD/SAS shall determine all of the following:
   a. The number of sites at which the pilot program will be conducted; provided, however, that the sites shall include regions that are
geographically diverse.
   b. Eligibility requirements for pilot program participants.
   c. The specific types of PDTs that will be prescribed and evaluated under
      the pilot program; provided, however, that the selected PDTs must be
      authorized by the federal Food and Drug Administration for the
      treatment of opioid use disorder.

(3) The DMH/DD/SAS may use up to one hundred fifty thousand dollars
($150,000) of these allocated funds for administrative purposes.

SECTION 3. Within six months after the termination of the pilot program authorized
by this act, the DMH/DD/SAS shall submit a report to the Joint Legislative Oversight Committee
on Health and Human Services on the impact of the pilot program. The report shall include at least all of the following components:

1. A breakdown of all expenditures from the funds appropriated to the DMH/DD/SAS for the pilot program authorized by this act.
2. The number and location of pilot program sites.
3. The number of pilot program participants selected to participate at each site and a description of their individual opioid use disorder treatment plans prior to and upon entering the pilot program.
4. Identification of the specific PDTs prescribed to treat pilot program participants and an evaluation of their effectiveness, as measured by successful completion of their individual treatment goals.
5. An explanation of whether and how the PDTs prescribed to pilot program participants improved their access to treatment.
6. A review of how satisfied program participants were with the PDTs prescribed for their treatment.
7. The impact of the pilot program on issues related to health equity and the hospitalization of pilot program participants, as compared to the patient population at large.
8. An explanation of the successes and challenges of the pilot program.
9. Any recommendations for future coverage of PDTs by State-funded healthcare programs, along with a cost-benefit analysis for such coverage.
10. Any other information the DMH/DD/SAS deems relevant in examining the effectiveness of using PDTs to treat opioid use disorder.

SECTION 4. This act becomes effective July 1, 2022.