



STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

KODY H. KINSLEY
SECRETARY

December 7, 2023

SENT VIA ELECTRONIC MAIL

The Honorable Jim Burgin, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 620, Legislative Office Building
Raleigh, NC 27603

The Honorable Donny Lambeth, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 303, Legislative Office Building
Raleigh, NC 27603


The Honorable Larry Potts, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 307B1, Legislative Office Building
Raleigh, NC 27603

Dear Chairmen:

Session Law 2022-74, Section 9F.2.(a), required the Department of Health and Human Services (DHHS) 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. In addition, Section (c) required DHHS to report to the Joint Legislative Oversight Committee on Health and Human Services on the impact of the pilot program. Pursuant to the provisions of law, the Department is pleased to submit the attached report.

Should you have any questions regarding this report, please contact Karen Wade, Director of Policy, at Karen.Wade@dhhs.nc.gov.

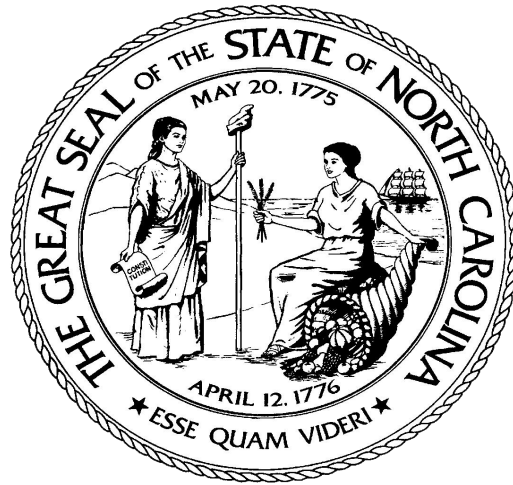
Sincerely,

DocuSigned by:

on behalf of Kody H. Kinsley
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Kody H. Kinsley
Secretary

cc:	Mark Collins	Joyce Jones	Lisa Wilks	Susie Camilleri
	Theresa Matula	Katherine Restrepo	Amy Jo Johnson	Luke MacDonald
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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

**Prescription Digital Therapeutics Pilot Program
For Opioid Use Disorder Treatment
Session Law 2022-74, Section 9F.2(c)**



**Report to the
Joint Legislative Oversight Committee on
Health and Human Services
By
North Carolina Department of Health and Human
Services**

December 7, 2023

Session Law 2022-74, Section 9F.2(a) noted the General Assembly's intent to combat the State's opioid epidemic by increasing access to innovative evidence-based treatments for individuals with opioid use disorder. Consistent with that intent, the session law mandated a transfer of funds from the Opioid Abatement Reserve to the Opioid Abatement Fund and of the funds appropriated to the Department of Health and Human Services, \$1,850,000 was to be allocated to the Division of Mental Health, Developmental Disabilities, and Substance Use Services (DMH/DD/SUS) for the development and implementation of a two-year pilot study to gauge the effectiveness of prescription digital therapeutics authorized by the federal Food and Drug Administration for the treatment of Opioid Use Disorder.

Section 9F.2(b) of the session law imposed the following parameters regarding the pilot study.

1. The pilot was to begin no later than December 1, 2022 and terminate no later than December 1, 2024.
2. DMH/DD/SUS was to make the following determinations.
 - a. *The number of sites at which the pilot would be conducted with the caveat that the sites include geographically diverse regions of the State.*
 - b. *Eligibility requirements for program participants.*
 - c. *The specific types of prescription digital therapeutics (PDTs) that would be prescribed and evaluated under the pilot program provided that the PDTs must be authorized by the Federal Food and Drug Administration for the treatment of opioid use disorder.*
3. DMH/DD/SUS was authorized to use up to \$150,000 of the funds for administrative purposes.

Section 9F.2(c) required that DMH/DD/SUS submit a report to the Joint Legislative Oversight Committee on Health and Human Services on the impact of the pilot program. This report was to address each 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 section.*
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.*

While not specifically named in the legislation, Pear Therapeutics was the only company that had an FDA-approved prescription digital therapeutic for opioid use disorder. The most effective approach to address the requirements of the legislation was determined to provide the funds (\$1,700,000) to MCOs that were interested in participating, as opposed to developing a contract directly with Pear. Pear staff and the DMHDDSUS Addictions and Management Operations Section Chief met with MCOs in November 2022, and allocation letters were written for three MCOs that indicated an interest in implementing the pilot: Eastpointe (\$200,000), Partners (\$300,000) and Vaya (\$200,000). The allocation letters were disseminated November 30, 2022.

Additionally, information about the pilot was shared during the monthly meeting the Addictions and Management Operations Team conducts with all opioid treatment programs (85 programs at the time) on December 6, 2022, to increase their awareness of the opportunity.

After receiving allocation letters, MCO staff worked within their provider networks to identify interested and eligible opioid treatment programs (OTPs) and/or office-based opioid treatment (OBOT) practices to participate. MCO staff worked with representatives assigned by Pear Therapeutics to develop processes for implementation. Training with OTP and OBOT staff were conducted in order for staff to understand the product (as an adjunct to therapy and medication) to increase their comfort level in presenting the opportunity to patients. Once patients were identified, a physician or eligible prescriber would provide the 12-week prescription for the digital therapeutic. The OTP or OBOT practice was responsible for informing the MCO that the digital therapeutic had been prescribed and the MCO was responsible for reimbursing Pear for such.

The three MCOs were at different stages of implementation, either working on their contract with Pear Therapeutics, identifying OTPs and/or OBOTs to participate and providing training and technical assistance to the interested and selected sites on actual implementation when DMHDDSUS learned Pear Therapeutics had filed for Chapter 11 bankruptcy. DMHDDSUS learned of this on April 7, 2023, through several internet articles. Subsequent conversations occurred between the Addiction and Management Operations Section Chief and a Pear Therapeutics representative working on this pilot project that confirmed the media announcements. MCOs were informed of the bankruptcy filing on April 13, 2023, and advised to cease all implementation plans.

Full implementation of this pilot had not been achieved prior to the bankruptcy filing by Pear Therapeutics. Consequently, there is no data or outcomes to report. Finally, no funds for this pilot were utilized by any of the MCOs and none of the funds designated for DMHDDSUS to assist with the evaluation component were expended. The Department will continue to work with the NC General Assembly to redirect the funds for other uses.