As Introduced

134th General Assembly Regular Session 2021-2022

H. B. No. 688

4

Representative Lipps

A BILL

| Regarding coronavirus local fiscal recovery and | 1 |
|---|---|
| prescription digital therapeutics, and to make | 2 |
| appropriations. | 3 |

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. All items in this act are hereby appropriated

| as designated out of any moneys in the state treasury to the | 5 |
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| credit of the designated fund. For all operating appropriations | 6 |
| made in this act, those in the first column are for fiscal year | 7 |
| 2022 and those in the second column are for fiscal year 2023. | 8 |
| The operating appropriations made in this act are in addition to | 9 |
| any other operating appropriations made for the FY 2022-FY 2023 | 10 |
| biennium. | 11 |
| | |
| Section 2. (A) As used in this section, "prescription | 12 |
| digital therapeutic approved for the treatment of substance use | 13 |
| disorders" and "prescription digital therapeutic" means a class | 14 |
| II medical device, as that term is described in 21 C.F.R. 860.3, | 15 |
| that has been approved by the United States Food and Drug | 16 |
| Administration to deliver therapeutic interventions for the | 17 |
| treatment of substance use disorders, including opioid use | 18 |
| disorders. | 19 |

| (B) The Department of Medicaid shall acquire prescription | 20 |
|--|----|
| digital therapeutics approved for the treatment of substance use | 21 |
| disorders for the purpose of operating a pilot program to | 22 |
| explore the effectiveness of prescription digital therapeutics. | 23 |
| Under the pilot program, patients who have been diagnosed with a | 24 |
| substance use disorder, including an opioid use disorder, and | 25 |
| have been prescribed a digital therapeutic as part of treatment | 26 |
| shall be provided the prescription digital therapeutic at no | 27 |
| cost to the patient. | 28 |
| | |

3.5

(C) Each treatment provider that participates in the pilot program shall identify patients who have been diagnosed with a substance use disorder, including an opioid use disorder, and who have been prescribed a digital therapeutic as part of treatment. Patients who elect to use the prescribed digital therapeutic shall be provided access to it by activating an access code through a smart phone application.

The Department and treatment providers shall make best efforts to include patient participants with varied demographic backgrounds and experiences with substance use and opioid use disorders. The use of prescription digital therapeutics by participating patients may be in addition to any other treatment for substance use and opioid use disorders, including medication-assisted treatment and other behavioral health services.

- (D) The pilot program shall begin as soon as practicable after the effective date of this section and shall be operated until December 31, 2023, or until funds appropriated for the program are expended, whichever occurs first.
- (E) Not later than March 31, 2024, the Department shall

 prepare a report, using data supplied by vendors of prescription

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| digital therapeutics and aggregated claims data, describing its | 50 |
| findings regarding the impact of the pilot program and submit it | 51 |
| to the chairpersons and ranking minority members of the standing | 52 |
| committees that consider health and human services issues in the | 53 |
| House of Representatives and the Senate. The report shall | 54 |
| describe all of the following: | 55 |
| (1) The population included in the pilot program; | 56 |
| (2) The successes and challenges of the program; | 57 |
| (3) Treatment access for pilot program participants; | 58 |
| (4) Participant satisfaction; | 59 |
| (5) Participant treatment goals and whether those goals | 60 |
| were achieved; | 61 |
| (6) Impacts related to health equity; | 62 |
| (7) A comparison of hospitalization for program | 63 |
| participants as compared to other patients of participating | 64 |
| treatment providers who are being treated for substance use and | 65 |
| opioid use disorders; | 66 |
| (8) Any recommendations for future coverage of | 67 |
| prescription digital therapeutics. | 68 |
| Section 3. | 69 |
| | |
| | 70 |
| 1 2 3 4 | 5 |
| A MCD DEPARTMENT OF MEDICAID | |

В

| C 5CV3 651692 Digital Therapeut | ics-ARPA | \$0 | \$7,500,000 | |
|---|--------------------|---------|-------------|----|
| D TOTAL DPF Dedicated Purpose Fund | Group | \$0 | \$7,500,000 | |
| E TOTAL ALL BUDGET FUND GROUPS | | \$0 | \$7,500,000 | |
| DIGITAL THERAPEUTICS-ARPA | | | | 71 |
| The foregoing appropriation item (| 551692, Digital | | | 72 |
| Therapeutics-ARPA, shall be used for th | e pilot program | | | 73 |
| established by Section 2 of this act in | order to address | an | | 74 |
| increase in substance use and overdose | deaths due to the | COVID- | | 75 |
| 19 pandemic. An amount equal to the une | xpended, unencumbe | ered | | 76 |
| portion of the foregoing appropriation | item 651692, Digit | al | | 77 |
| Therapeutics-ARPA, at the end of fiscal | year 2023 is here | eby | | 78 |
| reappropriated to the same appropriatio | n item for the sam | ne | | 79 |
| purpose in fiscal year 2024. | | | | 80 |
| Section 4. (A) As used in this sec | ction, "prescripti | on | | 81 |
| digital therapeutic approved for the tr | eatment of substar | ice use | | 82 |
| disorders" and "prescription digital th | erapeutic" means a | class | | 83 |
| II medical device, as that term is desc | ribed in 21 C.F.R. | 860.3 | , | 84 |
| that has been approved by the United St | ates Food and Drug | ſ | | 85 |
| Administration to deliver therapeutic i | nterventions for t | he | | 86 |
| treatment of substance use disorders, i | ncluding opioid us | e | | 87 |
| disorders. | | | | 88 |
| (B) The Department of Mental Healt | ch and Addiction S | ervices | 5 | 89 |
| shall acquire prescription digital ther | apeutics approved | for th | е | 90 |
| treatment of substance use disorders fo | r the purpose of | | | 91 |
| operating a pilot program to explore th | e effectiveness of | : | | 92 |
| prescription digital therapeutics. Unde | r the pilot progra | ım, | | 93 |
| patients who have been diagnosed with a | substance use dis | order, | | 94 |
| including an opioid use disorder, and h | ave been prescribe | ed a | | 95 |

| digital | therapeution | c as | part (| of | tre | eatm | nent s | shal | l be | provided | the | 96 |
|----------|--------------|------|--------|----|-----|------|--------|------|------|----------|-----|----|
| prescrib | oed digital | thei | rapeut | ic | at | no | cost | to | the | patient. | | 97 |

(C) Each treatment provider that participates in the pilot 98 program shall identify patients who have been diagnosed with a 99 substance use disorder, including an opioid use disorder, and 100 who have been prescribed a digital therapeutic as part of 101 treatment. Patients who elect to use the prescribed digital 102 therapeutic shall be provided access to it by activating an 103 access code through a smart phone application. 104

The Department and treatment providers shall make best efforts to include patient participants with varied demographic backgrounds and experiences with substance use and opioid use disorders. The use of prescription digital therapeutics by participating patients may be in addition to any other treatment for substance use and opioid use disorders, including medication-assisted treatment and other behavioral health services.

- (D) The pilot program shall begin as soon as practicable

 after the effective date of this section and shall be operated

 until December 31, 2023, or until funds appropriated for the

 program are expended, whichever occurs first.

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- (E) Not later than March 31, 2024, the Department shall prepare a report, using data supplied by vendors of prescription digital therapeutics and aggregated claims data, describing its findings regarding the impact of the pilot program and submit it to the chairpersons and ranking minority members of the standing committees that consider health and human services issues in the House of Representatives and the Senate. The report shall describe all of the following:

| H. B. N As Intr | lo. 688 oduced | | | | | | Page 6 | |
|--------------------|-------------------|-------------|--------------|------------------------------|-----------|--------|-------------|------------|
| | (1) The po | opulation i | ncluded in | the pilot p | rogram; | | | 125 |
| | (2) The si | uccesses an | d challenge | es of the pro | ogram; | | | 126 |
| | (3) Treati | ment access | for pilot | program par | ticipants | 5; | | 127 |
| | (4) Partio | cipant sati | sfaction; | | | | | 128 |
| were | (5) Partic | cipant trea | tment goals | and whethe | r those o | goals | | 129 130 |
| | (6) Impact | ts related | to health e | quity; | | | | 131 |
| | | | | tion for pro | | | | 132 |
| | | | | cients of pa eated for su | | | ~ d | 133 134 |
| | id use diso | | e being tre | eated for su | DStance | use al | Πα | 134 |
| Opioi | id use diso | ruers, | | | | | | 133 |
| | (8) Any re | ecommendati | ons for fut | ure coverage | e of | | | 136 |
| presc | cription di | gital thera | peutics. | | | | | 137 |
| | Section 5 | | | | | | | 138 |
| | | | | | | | | |
| | | | | | | | | 139 |
| | 1 | 2 | | 3 | 4 | | 5 | |
| A | МН | A DEPARTMEN | IT OF MENTAI | L HEALTH AND | ADDICTIO | ON SEI | RVICES | |
| В | Dedicated | d Purpose F | und Group | | | | | |
| С | 5CV3 | 336652 | Digital Tl | nerapeutics- | | \$0 | \$7,500,000 | |
| D | TOTAL DPI | F Dedicated | Purpose Fu | nd Group | | \$0 | \$7,500,000 | |
| E | TOTAL ALI | L BUDGET FU | ND GROUPS | | | \$0 | \$7,500,000 | |

| DIGITAL THERAPEUTICS-ARPA | 140 |
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| The foregoing appropriation item 336652, Digital | 141 |
| Therapeutics-ARPA, shall be used for the pilot program | 142 |
| established by Section 4 of this act in order to address an | 143 |
| increase in substance use and overdose deaths due to the COVID- | 144 |
| 19 pandemic. An amount equal to the unexpended, unencumbered | 145 |
| portion of the foregoing appropriation item 336652, Digital | 146 |
| Therapeutics-ARPA, at the end of fiscal year 2023 is hereby | 147 |
| reappropriated to the same appropriation item for the same | 148 |
| purpose in fiscal year 2024. | 149 |
| Section 6. Within the limits set forth in this act, the | 150 |
| Director of Budget and Management shall establish accounts | 151 |
| indicating the source and amount of funds for each appropriation | 152 |
| made in this act, and shall determine the form and manner in | 153 |
| which appropriation accounts shall be maintained. Expenditures | 154 |
| from operating appropriations contained in this act shall be | 155 |
| accounted for as though made in H.B. 110 of the 134th General | 156 |
| Assembly. The operating appropriations made in this act are | |
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| subject to all provisions of H.B. 110 of the 134th General | 157 |