By: Delegate Beitzel

Introduced and read first time: February 10, 2017 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

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Public Health - Ibogaine Treatment Pilot Program

3 FOR the purpose of establishing the Ibogaine Treatment Pilot Program; requiring the 4 Program to begin on or before a certain date and to continue for a certain number of $\mathbf{5}$ years; providing for the purposes of the Program; establishing the Ibogaine 6 Treatment Pilot Program Advisory Board; providing for the purposes and membership of the Advisory Board; providing for the terms of the members of the 7 8 Advisory Board; requiring the Secretary of Health and Mental Hygiene to designate 9 the chair of the Advisory Board; providing that a member of the Advisory Board may not receive certain compensation, but is entitled to certain reimbursement; requiring 1011 the Department of Health and Mental Hygiene to provide staff support for the 12Advisory Board; requiring a certain health care facility to submit a certain proposal 13to participate in the Program; requiring the Advisory Board to review certain 14proposals; requiring the Advisory Board, within a certain time period after receiving 15a certain proposal, to approve a health care facility for participation in the Program 16under certain circumstances or to deny the request to participate in the Program in 17a certain manner; requiring a health care facility that participates in the Program 18 to conduct certain research, adopt certain guidelines and protocols, and take certain 19measures to develop and implement the Program; authorizing certain persons to 20provide and receive certain treatment, notwithstanding certain provisions of law; 21 prohibiting the provision or receipt of certain treatment from being a basis for a 22certain seizure or forfeiture, notwithstanding certain provisions of law; prohibiting 23the imposition of certain penalties on certain persons based solely on the provision 24or receipt of certain treatment, notwithstanding certain provisions of law; 25authorizing certain providers to collect or attempt to collect certain fees and certain 26reimbursement, notwithstanding certain provisions of law; authorizing recipients of 27services under the Program to remit payment for certain fees, notwithstanding 28certain provisions of law; authorizing certain health insurance carriers to reimburse 29certain providers for certain fees, notwithstanding certain provisions of law; 30 providing that certain health care practitioners may not be subject to certain 31disciplinary action under certain circumstances; authorizing certain providers to

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law.



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fund the costs of providing certain treatment under the Program with certain appropriations, certain revenue, certain grants and assistance, and certain money; requiring certain health care facilities to submit certain reports to the Department and Advisory Board on or before certain dates; requiring the Department to submit certain compilations of certain reports to the Governor and to the General Assembly on or before certain dates; defining certain terms; providing for the termination of this Act; and generally relating to the Ibogaine Treatment Pilot Program.

8 BY adding to

- 9 Article Health General
- Section 8–1101 through 8–1108 to be under the new subtitle "Subtitle 11.
 Ibogaine Treatment Pilot Program"
- 12 Annotated Code of Maryland
- 13 (2015 Replacement Volume and 2016 Supplement)
- 14 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, 15 That the Laws of Maryland read as follows:
- 15 That the Laws of Maryland read as follows:
- 16

- Article Health General
- 17 SUBTITLE 11. IBOGAINE TREATMENT PILOT PROGRAM.
- 18 **8–1101.**

19 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 20 INDICATED.

21 (B) "ADVISORY BOARD" MEANS THE IBOGAINE TREATMENT PILOT 22 PROGRAM ADVISORY BOARD ESTABLISHED UNDER THIS SUBTITLE.

23 (C) "HEALTH CARE FACILITY" MEANS A FACILITY OR OFFICE WHERE 24 HEALTH OR MEDICAL CARE IS PROVIDED TO PATIENTS BY A HEALTH CARE 25 PRACTITIONER.

26 (D) "HEALTH CARE PRACTITIONER" MEANS A PERSON WHO IS:

(1) LICENSED, CERTIFIED, OR OTHERWISE AUTHORIZED UNDER THE
 HEALTH OCCUPATIONS ARTICLE TO PROVIDE HEALTH CARE SERVICES IN THE
 ORDINARY COURSE OF BUSINESS OR PRACTICE OF A PROFESSION; AND

30 (2) AUTHORIZED TO PRESCRIBE DRUGS UNDER THE HEALTH 31 OCCUPATIONS ARTICLE.

32 (E) "IBOGAINE" MEANS THE NATURALLY OCCURRING PSYCHOACTIVE 33 SUBSTANCE FOUND IN THE ROOT BARK OF THE IBOGA PLANT.

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1 (F) "IBOGAINE TREATMENT" MEANS THE ADMINISTERING OR DISPENSING 2 OF IBOGAINE BY A HEALTH CARE PRACTITIONER IN A HEALTH CARE FACILITY TO 3 SELECT OPIOID-DEPENDENT INDIVIDUALS.

4 (G) (1) "OPIOID DEPENDENCE" HAS THE MEANING STATED IN THE 5 DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS, 4TH EDITION, 6 PUBLISHED BY THE AMERICAN PSYCHIATRIC ASSOCIATION.

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(2) "OPIOID DEPENDENCE" INCLUDES:

8 (I) A MALADAPTIVE PATTERN OF SUBSTANCE USE LEADING TO 9 CLINICALLY SIGNIFICANT IMPAIRMENT OR DISTRESS; AND

10(II)A COMBINATION OF SEVERAL OF THE FOLLOWING SIGNS11AND SYMPTOMS:

- 12 **1.** INCREASING DRUG TOLERANCE;
- 13 **2.** WITHDRAWAL SIGNS AND SYMPTOMS;
- 143.A DESIRE OR UNSUCCESSFUL EFFORT TO CUT DOWN15OR CONTROL SUBSTANCE USE;
- 164.Loss of social, occupational, or recreational17ACTIVITIES BECAUSE OF SUBSTANCE USE; AND

185. CONTINUINGSUBSTANCEUSEDESPITE19CONSEQUENCES.

20 (H) "OPIOID-DEPENDENT INDIVIDUAL" MEANS AN INDIVIDUAL WHO HAS AN 21 OPIOID DEPENDENCE.

22 (I) "PROGRAM" MEANS THE IBOGAINE TREATMENT PILOT PROGRAM 23 ESTABLISHED UNDER THIS SUBTITLE.

(J) "PROGRAM PROVIDER" MEANS A HEALTH CARE FACILITY OR HEALTH
 CARE PRACTITIONER THAT HAS RECEIVED APPROVAL FROM THE ADVISORY BOARD
 TO PROVIDE IBOGAINE TREATMENT.

27 (K) "PROGRAM RECIPIENT" MEANS AN INDIVIDUAL SELECTED TO RECEIVE 28 IBOGAINE TREATMENT PROVIDED UNDER THE PROGRAM.

| | 4 | HOUSE BILL 1372 |
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| 1 | 8–1102. | |
| 2 | (A) | THERE IS AN IBOGAINE TREATMENT PILOT PROGRAM. |
| $\frac{3}{4}$ | (B) CONTINUE | THE PROGRAM SHALL BEGIN ON OR BEFORE JANUARY 1, 2019, AND FOR A PERIOD OF 4 YEARS. |
| 5 | (C) | THE PURPOSES OF THE PROGRAM ARE TO: |
| 6 7 8 9 | CONVENTI | (1) PROVIDE IBOGAINE TREATMENT AT PARTICIPATING HEALTH LITIES TO OPIOID-DEPENDENT INDIVIDUALS WHO DO NOT BENEFIT FROM ONAL TREATMENT METHODS AND INTERVENTIONS FOR PENDENCE, INCLUDING OPIOID REPLACEMENT THERAPY; AND |
| $10 \\ 11 \\ 12$ | | (2) EVALUATE THE EFFECTIVENESS OF IBOGAINE TREATMENT WHEN TO CONVENTIONAL TREATMENT METHODS AND INTERVENTIONS, OPIOID REPLACEMENT THERAPY. |
| 13 | 8–1103. | |
| $\begin{array}{c} 14 \\ 15 \end{array}$ | (A) BOARD. | THERE IS AN IBOGAINE TREATMENT PILOT PROGRAM ADVISORY |
| 16 | (B) | THE ADVISORY BOARD CONSISTS OF: |
| 17 | | (1) THE SECRETARY, OR THE SECRETARY'S DESIGNEE; AND |
| 18 | | (2) THE FOLLOWING MEMBERS, APPOINTED BY THE SECRETARY: |
| 19 | | (I) ONE PHYSICIAN WITH EXPERTISE IN ADDICTION MEDICINE; |
| 20 | | (II) ONE NURSE WITH EXPERTISE IN ADDICTION TREATMENT; |
| 21 | | (III) ONE SOCIAL WORKER; |
| 22 | | (IV) ONE ADDICTION COUNSELOR; |
| 23 | | (V) ONE REPRESENTATIVE OF LAW ENFORCEMENT; AND |
| $\frac{24}{25}$ | WITH EXPE | (VI) ONE REPRESENTATIVE FROM A SCHOOL OF PUBLIC HEALTH RTISE IN ADDICTION TREATMENT. |
| 26 | (C) | (1) (I) THE TERM OF AN APPOINTED MEMBER IS 3 YEARS. |

THE TERMS OF THE APPOINTED MEMBERS ARE STAGGERED 1 **(II)** $\mathbf{2}$ AS REQUIRED BY THE TERMS PROVIDED ON OCTOBER 1, 2017. 3 (III) AT THE END OF A TERM, AN APPOINTED MEMBER CONTINUES TO SERVE UNTIL A SUCCESSOR IS APPOINTED AND QUALIFIES. 4 $\mathbf{5}$ (IV) AN APPOINTED MEMBER MAY NOT SERVE MORE THAN TWO 6 CONSECUTIVE FULL TERMS. 7 AN APPOINTED MEMBER WHO IS APPOINTED AFTER A TERM (V) 8 HAS BEGUN SERVES ONLY FOR THE REST OF THE TERM AND UNTIL A SUCCESSOR IS 9 **APPOINTED AND QUALIFIES.** 10 (2) THE SECRETARY SHALL DESIGNATE THE CHAIR FROM AMONG 11 THE MEMBERS OF THE ADVISORY BOARD. 12(3) A MAJORITY OF THE MEMBERS PRESENT AT A MEETING IS A QUORUM. 13 14(4) A MEMBER OF THE ADVISORY BOARD: 15**(I)** MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE **ADVISORY BOARD; BUT** 16 17IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER **(II)** 18 THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET. 19 THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE SHALL 20(5) PROVIDE STAFF SUPPORT FOR THE ADVISORY BOARD. 2122**(**D**)** THE PURPOSES OF THE ADVISORY BOARD ARE TO: 23(1) **REVIEW PROPOSALS SUBMITTED BY HEALTH CARE FACILITIES REQUESTING PARTICIPATION IN THE PROGRAM; AND** 2425(2) APPROVE HEALTH CARE FACILITIES THAT DEMONSTRATE AN 26ABILITY TO CARRY OUT THE REQUIREMENTS FOR PROGRAM PROVIDERS ESTABLISHED UNDER § 8-1105 OF THIS SUBTITLE AND HEALTH CARE 2728PRACTITIONERS FOR PARTICIPATION IN THE PROGRAM.

29 **8–1104.**

1 (A) TO PARTICIPATE IN THE PROGRAM, A HEALTH CARE FACILITY SHALL 2 SUBMIT A PROPOSAL TO THE DEPARTMENT REQUESTING APPROVAL TO 3 PARTICIPATE IN THE PROGRAM.

4 (B) THE ADVISORY BOARD SHALL REVIEW EACH PROPOSAL SUBMITTED 5 UNDER SUBSECTION (A) OF THIS SECTION.

6 (C) WITHIN 30 DAYS AFTER RECEIVING A PROPOSAL SUBMITTED UNDER 7 SUBSECTION (A) OF THIS SECTION, THE ADVISORY BOARD SHALL:

8 (1) APPROVE A HEALTH CARE FACILITY FOR PARTICIPATION IN THE 9 PROGRAM IF THE FACILITY DEMONSTRATES IN THE PROPOSAL THE FACILITY'S 10 ABILITY TO CARRY OUT THE REQUIREMENTS FOR PROGRAM PROVIDERS UNDER § 11 8–1105 OF THIS SUBTITLE; OR

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(2) DENY THE REQUEST TO PARTICIPATE IN THE PROGRAM, STATING:

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(I) THE ADVISORY BOARD'S REASONS FOR THE DENIAL; AND

14(II) THE MODIFICATIONS THAT MAY BE MADE TO THE15PROPOSAL TO OBTAIN APPROVAL FROM THE ADVISORY BOARD TO PARTICIPATE IN16THE PROGRAM.

17 **8–1105.**

18 A HEALTH CARE FACILITY THAT PARTICIPATES IN THE PROGRAM SHALL 19 CONDUCT RESEARCH, ADOPT GUIDELINES AND PROTOCOLS, AND TAKE MEASURES 20 NECESSARY TO DEVELOP AND IMPLEMENT THE PROGRAM, INCLUDING:

21 (1) DEVELOPING CRITERIA FOR SELECTING THE HEALTH CARE 22 FACILITIES AND HEALTH CARE PRACTITIONERS WHO WILL PARTICIPATE IN THE 23 PROGRAM;

24 (2) ESTABLISHING SCREENING AND ELIGIBILITY CRITERIA FOR 25 INDIVIDUALS WHO WILL RECEIVE TREATMENT PROVIDED UNDER THE PROGRAM;

26 (3) DEVELOPING AN EFFECTIVE RECRUITMENT STRATEGY FOR 27 INDIVIDUALS WHO WILL RECEIVE TREATMENT IN THE PROGRAM;

28 (4) ESTABLISHING ASSESSMENT AND TREATMENT PROTOCOLS;

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1 (5) ESTABLISHING BEST CLINICAL PRACTICES FOR CONTINUITY OF 2 CARE AND ACUTE CARE FOR UNMET OR URGENT MEDICAL AND PSYCHIATRIC NEEDS 3 OF PROGRAM RECIPIENTS;

4 (6) (I) COORDINATING WITH THE FEDERAL GOVERNMENT TO 5 OBTAIN QUANTITIES OF IBOGAINE REQUIRED FOR USE IN THE PROGRAM; OR

6 (II) IF UNABLE TO OBTAIN QUANTITIES OF IBOGAINE IN 7 COORDINATION WITH THE FEDERAL GOVERNMENT, CONDUCTING AN INVENTORY OF 8 AVAILABLE SOURCES OF IBOGAINE AND CONTRACTING WITH THE BEST AVAILABLE 9 SOURCE FOR THE RECEIPT OF QUANTITIES OF IBOGAINE REQUIRED FOR USE IN THE 10 PROGRAM;

11 (7) DEVELOPING A BROAD-BASED EVALUATION OF THE PROGRAM 12 THAT:

- 13(I) MEASURES OUTCOMES FOR PROGRAM RECIPIENTS,14INCLUDING:
- 15 **1. RETENTION IN TREATMENT;**
- 16 **2. MORBIDITY AND MORTALITY;**
- 17 **3.** CONTINUING OR NEW ILLICIT DRUG USE; AND
- 18 **4. THE COST OF TREATMENT;**
- 19(II) INCLUDES A COMPARISON TO OTHER TREATMENT20METHODS AND INTERVENTIONS; AND
- 21

(III) ESTABLISHES PROCEDURES FOR DATA COLLECTION; AND

22 (8) ESTABLISHING A PLAN FOR THE STORAGE AND ADMINISTRATION 23 OF IBOGAINE PROVIDED UNDER THE PROGRAM.

24 **8–1106.**

25 (A) NOTWITHSTANDING ANY OTHER PROVISION OF STATE OR LOCAL LAW:

26 (1) A PROGRAM PROVIDER MAY PROVIDE IBOGAINE TREATMENT TO 27 PROGRAM RECIPIENTS;

1 (2) A PROGRAM RECIPIENT MAY RECEIVE IBOGAINE TREATMENT 2 FROM A PROGRAM PROVIDER;

3 (3) THE PROVISION OR RECEIPT OF IBOGAINE TREATMENT 4 AUTHORIZED UNDER THE PROGRAM MAY NOT BE A BASIS FOR THE SEIZURE OR 5 FORFEITURE OF ANY PRODUCTS, MATERIALS, EQUIPMENT, PROPERTY, OR ASSETS;

6 (4) A STATE OR LOCAL CRIMINAL, CIVIL, OR ADMINISTRATIVE 7 PENALTY MAY NOT BE IMPOSED ON ANY PERSON PARTICIPATING IN THE PROGRAM 8 BASED SOLELY ON THE PROVISION OR RECEIPT OF IBOGAINE TREATMENT 9 PROVIDED UNDER THE PROGRAM;

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(5) A PROGRAM PROVIDER MAY:

11(I)COLLECT OR ATTEMPT TO COLLECT FEES FROM A12PROGRAM RECIPIENT FOR IBOGAINE TREATMENT AND OTHER HEALTH CARE13SERVICES; AND

14(II) OBTAIN OR ATTEMPT TO OBTAIN REIMBURSEMENT FOR15IBOGAINE TREATMENT AND OTHER HEALTH CARE SERVICES PROVIDED TO A16PROGRAM RECIPIENT FROM A HEALTH INSURANCE CARRIER THAT PROVIDES17COVERAGE FOR SERVICES PROVIDED TO THE PROGRAM RECIPIENT;

18 (6) A PROGRAM RECIPIENT MAY REMIT PAYMENT FOR FEES 19 CHARGED BY A PROGRAM PROVIDER FOR IBOGAINE TREATMENT AND OTHER 20 HEALTH CARE SERVICES PROVIDED TO THE PROGRAM RECIPIENT; AND

(7) A HEALTH INSURANCE CARRIER THAT PROVIDES COVERAGE FOR
SERVICES PROVIDED TO A PROGRAM RECIPIENT MAY REIMBURSE A PROGRAM
PROVIDER FOR FEES CHARGED BY THE PROGRAM PROVIDER FOR IBOGAINE
TREATMENT AND OTHER HEALTH CARE SERVICES PROVIDED TO THE PROGRAM
RECIPIENT.

(B) A HEALTH CARE PRACTITIONER WHO PARTICIPATES IN THE PROGRAM
MAY NOT BE SUBJECT TO ANY DISCIPLINARY ACTION UNDER THE HEALTH
OCCUPATIONS ARTICLE SOLELY FOR THE ACT OF PROVIDING IBOGAINE
TREATMENT THAT IS IN ACCORDANCE WITH PROTOCOLS AND GUIDELINES
CONTAINED IN A PROPOSAL APPROVED BY THE ADVISORY BOARD UNDER § 8–1104
OF THIS SUBTITLE.

32 **8–1107.**

1 A PROGRAM PROVIDER MAY FUND THE COSTS OF PROVIDING 2 IBOGAINE TREATMENT UNDER THE PROGRAM WITH:

3 (1) APPROPRIATIONS PROVIDED IN THE STATE BUDGET;

4 (2) REVENUE FROM FEES CHARGED FOR IBOGAINE TREATMENT AND 5 OTHER HEALTH CARE SERVICES PROVIDED TO PROGRAM RECIPIENTS;

6 (3) GRANTS OR OTHER ASSISTANCE FROM FEDERAL, STATE, OR 7 LOCAL GOVERNMENT; AND

8 (4) ANY OTHER MONEY MADE AVAILABLE TO THE PROGRAM 9 PROVIDER FROM ANY PUBLIC OR PRIVATE SOURCE.

10 **8–1108.**

11 (A) (1) ON OR BEFORE NOVEMBER 30, 2019, AND ON OR BEFORE 12 NOVEMBER 1 EACH YEAR THEREAFTER, A HEALTH CARE FACILITY THAT 13 PARTICIPATES IN THE PROGRAM SHALL SUBMIT A REPORT ON THE STATUS OF 14 IMPLEMENTING THE PROGRAM TO THE DEPARTMENT AND THE ADVISORY BOARD.

15 (2) THE REPORT REQUIRED ON OR BEFORE NOVEMBER 1, 2022, 16 SHALL INCLUDE:

17 (I) AN ANALYSIS OF THE PROGRAM EVALUATION DATA;

18(II)A DETERMINATION OF WHETHER THE PROGRAM DIRECTLY19RESULTS IN:

201.HEALTH RISKS THAT OUTWEIGH THE BENEFITS TO21PROGRAM RECIPIENTS; AND

22 **2. S**IGNIFICANT SAFETY CONSEQUENCES TO THE 23 PUBLIC;

24 (III) AN ASSESSMENT OF THE NEED FOR IBOGAINE TREATMENT;

(IV) ANY RECOMMENDATIONS AND CONCLUSIONS CONCERNING
 THE DESIRABILITY OF TRANSITIONING THE PROGRAM INTO A PERMANENT
 IBOGAINE TREATMENT PROGRAM;

28 (V) AN EVALUATION OF THE NEED TO EXPAND THE PROGRAM 29 TO INCLUDE ADDITIONAL LOCATIONS AND PARTICIPANTS; 1 (VI) A DETERMINATION OF WHETHER ANY MODIFICATIONS OR 2 ADDITIONS TO THE GUIDELINES OR PROTOCOLS GOVERNING THE PROGRAM ARE 3 NECESSARY TO TRANSITION THE PROGRAM TO A PERMANENT IBOGAINE 4 TREATMENT PROGRAM; AND

5 (VII) A RECOMMENDATION AS TO WHETHER PROGRAM 6 RECIPIENTS WHO HAVE BENEFITED FROM PARTICIPATION IN THE PROGRAM, AS 7 MEDICALLY DETERMINED BY A PHYSICIAN, SHOULD HAVE ACCESS TO IBOGAINE 8 TREATMENT FOLLOWING THE CONCLUSION OF THE PROGRAM.

9 (B) ON OR BEFORE DECEMBER 30, 2019, AND ON OR BEFORE DECEMBER 1 10 EACH YEAR THEREAFTER, THE DEPARTMENT SHALL SUBMIT A COMPILATION OF 11 THE REPORTS REQUIRED UNDER SUBSECTION (A)(1) OF THIS SECTION TO THE 12 GOVERNOR AND, IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT 13 ARTICLE, THE GENERAL ASSEMBLY.

14 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 15 October 1, 2017. It shall remain effective for a period of 5 years and 9 months and, at the 16 end of June 30, 2023, with no further action required by the General Assembly, this Act 17 shall be abrogated and of no further force and effect.