TWENTY-SECOND NORTHERN MARIANAS COMMONWEALTH LEGISLATURE

IN THE HOUSE OF REPRESENTATIVES

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| 368 | sion. | - 24 | 12.1 |
| No. of Street, | CARALTE | , | - A |

Н. В. 22- 68

A BILL FOR AN ACT

To establish a Prescription Drug Monitoring Program in the Commonwealth of the Northern Mariana Islands; and for other purposes.

BE IT ENACTED BY THE 22ND NORTHERN MARIANAS COMMONWEALTH LEGISLATURE:

1 Section 1. Findings and Purpose. The Legislature finds that most U.S. states have implemented Prescription Drug Monitoring Programs (PDMPs) for the 2 efficient monitoring and reporting of controlled, and in some cases, non-controlled 3 prescription medications dispensed within the state. The Legislature finds that 4 5 while most U.S. states use data from their PDMPs primarily to detect and deter diversion of controlled substances, identify persons who may have substance use 6 disorder for referral to evidence-based interventions and treatment, and informing 7 public health initiatives by outlining drug trends, the CNMI is positioned to take 8 9 the use of PDMPs a step further by monitoring all prescription drug dispensing to allow prescribers and dispensers to better monitor the care and treatment of their 10 patients. The Legislature finds that access to patient prescription history is essential 11 for patient safety, allows providers to make better informed treatment decisions, 12

| 1 | and improves the quality of health care. Therefore, the Legislature finds that a |
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| 2 | PDMP shall be established in the CNMI to collect information about dispensed |
| 3 | controlled and non-controlled prescription drugs to assist in reducing non- |
| 4 | evidence-based use of those drugs, thereby improving patient safety and quality |
| 5 | of care. |
| 6 | The Legislature further finds that the Commonwealth Healthcare |
| 7 | Corporation (CHCC) is the largest healthcare provider in the CNMI, overseeing the |
| 8 | only hospital and emergency room, and health centers on Tinian and Rota, in |
| 9 | addition to other outpatient, ancillary and public health services. The Legislature |
| 10 | finds that the CHCC, as the largest single organization of prescribers and |
| 11 | dispensers, and as an autonomous agency of the CNMI government, is best suited |
| 12 | to oversee the operation of the CNMI PDMP. Therefore, the purpose of this |
| 13 | legislation is to establish a prescription drug monitoring program in the CNMI, as |
| 14 | a corporate power of the CHCC. |
| 15 | Section 2. Enactment. The following is hereby enacted subject to |
| 16 | codification by the CNMI Law Revision Commission: |
| 17 | "101. Definitions. For the purposes of this Act, the following terms are |
| 18 | defined as follows: |
| 19 | (a) "Commonwealth Healthcare Corporation" means the |
| 20 | corporation established in 3 CMC §2823 and that is responsible for |
| 21 | the implementation of this Act. |

| 1 | (b) "Controlled Substance" means a prescribed drug or substance |
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| 2 | listed in Schedules II, III, IV or V of 6 CMC §2115 to §2122. |
| 3 | (c) "Qualified Delegate" means an individual who is employed by, |
| 4 | and acts as, an agent, pursuant to requirements of the |
| 5 | Commonwealth Healthcare Corporation, to submit, request, or |
| 6 | receive PDMP data on behalf of an individual, health care facility or |
| 7 | other entity who is otherwise authorized to submit, request, or |
| 8 | receive PDMP data. |
| 9 | (d) "Dispense" means the interpretation, preparation, and delivery |
| 0 | of a Prescription Drug to a patient or ultimate user. |
| 1 | (e) "Dispenser" means a person, authorized in the jurisdiction in |
| 2 | which the person is practicing, to dispense a prescription drug to the |
| 3 | ultimate user by or pursuant to the prescription drug order of a |
| 4 | prescriber. |
| 5 | (f) "Drug" means: |
| 6 | (i) Any substance recognized as a drug in the official |
| 7 | compendium, or supplement thereto, designated by the |
| 8 | Federal Food, Drug, and Cosmetic Act for use in the |
| 9 | diagnosis, cure, mitigation, treatment, or prevention of |
| 0 | disease in humans. |

| 1 | (ii) Any substance intended for use in the diagnosis, cure, |
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| 2 | mitigation, treatment, or prevention of disease in humans. |
| 3 | (iii) Any substance other than food intended to affect the |
| 4 | structure or any function of the body of humans. |
| 5 | (g) "Hospice" means a program of palliative and supportive care |
| 6 | for terminally ill persons and their families and/or caregivers. |
| 7 | (h) "Patient" means an individual for whom a prescription is issued |
| 8 | or for whom a prescriber directly dispenses a prescription drug. |
| 9 | (i) "Prescribe" means to direct, designate, or order the use of a drug |
| 10 | and the manner of using the drug. |
| 11 | (j) "Prescriber" means a health care professional authorized in the |
| 12 | jurisdiction in which the professional is practicing to prescribe a |
| 13 | prescription drug to a patient. |
| 14 | (k) "Prescription Drug" means a drug that is required under Federal |
| 15 | law to be labeled with either of the following statements prior to |
| 16 | being Dispensed: (1) "Rx Only"; (2) "Caution: Federal law restricts |
| 17 | this drug to use by, or on the order of, a licensed veterinarian"; or a |
| 18 | drug that is required by any applicable Federal or State law or rule |
| 19 | to be dispensed pursuant only to a Prescription Drug Order. |
| 20 | (l) "Prescription Drug Monitoring Program" or "PDMP" means a |
| 21 | program that collects, manages, analyzes, and provides information |

| 1 | | regarding prescription drugs, including but not limited to the PDMP |
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| 2 | | established by this Act. |
| 3 | | (m) "Prescription Drug Order" means a lawful order from a |
| 4 | | prescriber for a prescription drug for a patient. |
| 5 | | (n) "Ultimate User" means a person who lawfully possesses a |
| 6 | | prescription drug for personal use or for the use of a member of his |
| 7 | | or her household. |
| 8 | 102. | Prescription Drug Monitoring Program Established. |
| 9 | | (a) The Commonwealth Healthcare Corporation shall establish and |
| 0 | | maintain an electronic Prescription Drug Monitoring Program for |
| 1 | | the monitoring of all prescription drugs dispensed in the CNMI or |
| 2 | | dispensed to an address in the CNMI. |
| 3 | | (b) The Commonwealth Healthcare Corporation may contract with |
| 4 | | another government agency or private vendor to establish and |
| 5 | | maintain the electronic monitoring system pursuant to the rules and |
| 6 | | regulations promulgated by the Commonwealth Healthcare |
| 7 | | Corporation. |
| 8 | | (c) The Commonwealth Healthcare Corporation may establish an |
| 9 | | advisory group to provide input and advice regarding the |
| 0 | | establishment, administration, and evaluation of the PDMP. |
| 1 | 103. N | Mandatory Data Reporting. |

| 1 | (a) Each dispenser or qualified delegate shall submit to the CNMI |
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| 2 | Prescription Drug Monitoring Program information regarding each |
| 3 | prescription drug dispensed. |
| 4 | (b) Unless a waiver is granted under subsection (e), each dispenser |
| 5 | required to report under subsection (a) of this section shall submit |
| 6 | by electronic means to the CNMI PDMP information that shall |
| 7 | include, but is not be limited to: |
| 8 | (i) The patient's name, address, and date of birth; |
| 9 | (ii) The name of the ultimate user, if different from the |
| 0 | patient, when reporting a controlled substance; |
| 1 | (iii) The name and address of the pharmacy dispensing the |
| 2 | prescription; |
| 3 | (iv) The date the prescription drug order is issued; |
| 4 | (v) The date the prescription drug order is filled; |
| 5 | (vi) The name of the drug dispensed or the National Drug |
| 6 | Code number of the drug dispensed; |
| 7 | (vii) The strength of the drug dispensed; |
| 8 | (viii) The quantity of the drug dispensed and the number of |
| 9 | days' supply; |
| 0 | (ix) The prescriber's and dispenser's name: |

| 1 | (x) The prescriber's and dispenser's National Provider |
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| 2 | Identifier number; |
| 3 | (xi) The prescriber's and dispenser's Drug Enforcement |
| 4 | Administration number when reporting a controlled |
| 5 | substance; and |
| 6 | (xii) Any other information as determined by CHCC. |
| 7 | (c) Each dispenser shall submit the required information on all |
| 8 | prescription drugs dispensed in the CNMI or dispensed to an address |
| 9 | in the CNMI in accordance with transmission methods and |
| 0 | frequency established by the Commonwealth Healthcare |
| 1 | Corporation. |
| 2 | (d) An individual may be both a dispenser and prescriber for the |
| 3 | purposes of this Act, and in these circumstances, is subject to the |
| 4 | requirements of both dispensers and prescribers. |
| 5 | (e) The Commonwealth Healthcare Corporation may issue a |
| 6 | limited-time waiver to a dispenser, which, due to unforeseen |
| 7 | circumstances which interfere with electronic submission, is unable |
| 8 | to submit prescription information by electronic means. Such waiver |
| 9 | may permit the dispenser to submit prescription information by |
| 0 | paper form or other means, provided all information required in |
| 1 | subsection (a) of this section is submitted in this alternative format |

| 1 | 104. | Registration with the Prescription Drug Monitoring Program. |
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| 2 | | (a) All prescribers and dispensers who issue prescription drug orders |
| 3 | | or dispense prescription drugs in the CNMI shall register with the |
| 4 | | prescription drug monitoring program either upon the initial |
| 5 | | registration or renewal of the individual's CNMI professional |
| 6 | | license or certification. |
| 7 | 105. | Querying the Prescription Drug Monitoring Program. |
| 8 | | (a) A prescriber or prescriber's qualified delegate shall query the |
| 9 | | prescription drug monitoring program prior to initially prescribing |
| 10 | | or personally dispensing a controlled substance to a patient. If the |
| 11 | | patient's course of treatment continues for more than ninety (90) |
| 12 | | days after the date of the initial prescription, the prescriber or |
| 13 | | prescriber's designee shall make periodic requests for prescription |
| 14 | | drug monitoring program information, no less frequently than |
| 15 | | annually or until the course of treatment has ended. |
| 16 | | (b) A dispenser or a dispenser's delegate shall query the prescription |
| 17 | | drug monitoring program prior to dispensing a controlled substance |
| 8 | | to the patient. |
| 19 | | (c) The requirements listed in (a) and (b) of this section shall not |
| 20 | | apply if one of the following conditions is met: |

| 1 | | (i) The prescription drug is a controlled substance which is |
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| 2 | | prescribed or dispensed to a patient currently receiving |
| 3 | | hospice care. |
| 4 | | (ii) If it is not possible to query the prescription drug |
| 5 | | monitoring program in a timely manner due to an emergency |
| 6 | | situation. |
| 7 | | (iii) The PDMP system is not operational at the time the |
| 8 | | query is attempted. |
| 9 | | (d) A prescriber or dispenser may query the Prescription Drug |
| 0 | | Monitoring Program for information on a patient as detailed in rules |
| 1 | | and regulations promulgated pursuant to this Act. |
| 2 | 106. | Confidentiality. |
| 3 | | (a) Information submitted to the PDMP shall be confidential and |
| 4 | | not subject to public or open records laws, except as provided in |
| 5 | | Section 107. |
| 6 | | (b) The Commonwealth Healthcare Corporation shall establish and |
| 7 | | enforce policies and procedures to ensure that the privacy and |
| 8 | | confidentiality of patients are maintained and that patient |
| 9 | | information collected, recorded, transmitted, and stored pursuant to |
| 0 | | the PDMP is protected and not disclosed to persons except as |
| 1 | | provided in Section 107. |

| 1 | | (c) The Commonwealth Healthcare Corporation shall establish and |
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| 2 | | maintain a process for verifying the credentials and authorizing the |
| 3 | | use of data collected by the PDMP by those individuals as allowed |
| 4 | | for in Section 107. |
| 5 | 107. | Access to and Use of Prescription Drug Monitoring Program Data. |
| 6 | | (a) The Commonwealth Healthcare Corporation may use |
| 7 | | prescription monitoring information for statistical analysis, |
| 8 | | research, public policy, PDMP or provider evaluation, or |
| 9 | | educational purposes. |
| 10 | | (b) The Commonwealth Healthcare Corporation is further |
| 1 | | authorized to provide information in the PDMP upon request to the |
| 2 | | following individuals: |
| 3 | | (i) Persons authorized to prescribe or dispense prescription |
| 4 | | drugs, for the purpose of providing medical or |
| 5 | | pharmaceutical care for their patients or for reviewing |
| 6 | | information regarding prescriptions that have been issued or |
| 7 | | dispensed by the requester. |
| 8 | | (ii) A patient who requests the patient's own prescription |
| 9 | | monitoring information, the legal representative of such a |
| .0 | | patient, or the parent of a minor, in accordance with |

| 1 | procedures established by the Commonwealth Healthcare |
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| 2 | Corporation. |
| 3 | (iii) The CNMI Health Care Professions Licensing Board if |
| 4 | the request is pursuant to an investigation or is pursuant to |
| 5 | the agency's official duties and responsibilities. |
| 6 | (iv) Local, state, and federal law enforcement or |
| 7 | prosecutorial officials responsible for the administration, |
| 8 | investigation, or enforcement of the laws governing |
| 9 | controlled substances for criminal cases pursuant to their |
| 0 | official duties. Law enforcement or prosecutorial officials |
| 1 | seeking information from the Prescription Drug Monitoring |
| 2 | Program must include a warrant in any request for |
| 3 | information. |
| 4 | (v) The CNMI Medicaid Agency regarding Medicaid |
| 5 | program recipients and Medicaid program providers for the |
| 6 | purposes of medical provider quality evaluation, drug |
| 7 | utilization review, beneficiary health outcomes |
| 8 | improvement, and investigations of fraud, waste and abuse. |
| 9 | (vi) Public or private entities for the purpose of research or |
| 0 | education as approved by the Commonwealth Healthcare |
| 1 | Corporation in accordance with local and federal rules. |

| 1 | (VII) Other disclosures as permitted in rules and regulations |
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| 2 | promulgated by the Commonwealth Healthcare |
| 3 | Corporation. |
| 4 | (c) The Commonwealth Healthcare Corporation is authorized to |
| 5 | proactively send unsolicited reports to prescribers or dispensers, |
| 6 | which may include flags of potentially harmful prescribing or |
| 7 | dispensing activity, and, for prescribers, may include comparison to |
| 8 | median or average prescribing activity of other prescribers in the |
| 9 | CNMI. |
| 0 | (d) The Commonwealth Healthcare Corporation shall not disclose |
| 1 | PDMP data in response to a subpoena or other method of discovery |
| 2 | or compelled production in a civil proceeding. PDMP data and audit |
| 3 | trail information shall not be admissible as evidence in a civil |
| 4 | proceeding. |
| 5 | (e) The Commonwealth Healthcare Corporation shall review |
| 6 | information submitted to the PDMP. Such reviews, which may link |
| 7 | PDMP data with other data sets, should include, but are not limited |
| 8 | to: |
| 9 | (i) A review to identify information that appears to indicate |
| 0 | if a person may be obtaining prescriptions in a manner that |
| 1 | suggests that the patient may have a substance use disorder. |

| 1 | | When such information is identified, the Commonwealth |
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| 2 | | Healthcare Corporation may confidentially contact the |
| 3 | | patient with information regarding evidence-based treatment |
| 4 | | options and other services which may benefit patients with a |
| 5 | | substance use disorder. |
| 6 | | (ii) A review to identify ways to improve clinical decision- |
| 7 | | making and practices. |
| 8 | | (iii) A review to identify information that appears to indicate |
| 9 | | if a violation of law or breach of professional standards may |
| 10 | | have occurred. Whenever such information is identified, the |
| 11 | | Commonwealth Healthcare Corporation should notify the |
| 12 | | professional who may have violated legal or professional |
| 13 | | standards and may also notify the CNMI Healthcare |
| 14 | | Professionals Licensing Board. |
| 15 | 108. | Information Exchange with Other Prescription Drug Monitoring |
| 16 | Programs. | |
| 17 | | (a) The Commonwealth Healthcare Corporation may provide |
| 8 | | prescription monitoring information to other states' and territories' |
| 9 | | prescription drug monitoring programs, and the information may be |
| 20 | | used by those programs consistent with this subchapter. |

| 1 | (b) The Commonwealth Healthcare Corporation may request and |
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| 2 | receive prescription monitoring information from other states' and |
| 3 | territories' prescription drug monitoring programs and may use the |
| 4 | information as permitted under this subchapter. |
| 5 | (c) The Commonwealth Healthcare Corporation may develop the |
| 6 | capability to transmit information to other prescription drug |
| 7 | monitoring programs and receive information from other |
| 8 | prescription drug monitoring programs. |
| 9 | (d) The Commonwealth Healthcare Corporation may enter into |
| 0 | written agreements with other states' and territories' prescription |
| 1 | drug monitoring programs for the purpose of describing the terms |
| 2 | and conditions for sharing prescription information under this |
| 3 | subchapter. |
| 4 109. | Immunity. |
| 5 | (a) Unless there is a finding of reckless disregard, gross negligence, |
| 6 | malice, or criminal intent, the Commonwealth Healthcare |
| 7 | Corporation shall not be subject to civil liability, administrative |
| 8 | action, or other legal or equitable relief for the: |
| 9 | (i) failure to possess PDMP data that was not reported to the |
| 0 | Commonwealth Healthcare Corporation; |
| 1 | (ii) release or use of PDMP data that was factually incorrect; |

| 1 | (iii) unlawful access to PDMP data by an individual, health |
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| 2 | care facility or entity, or unlawful disclosure or use of PDMP |
| 3 | data by an individual, health care facility, or entity who |
| 4 | requested and received PDMP data pursuant to Section 107. |
| 5 | (b) Unless the CHCC finds a lack of good faith, a dispenser or |
| 6 | qualified delegate is not subject to civil liability, administrative |
| 7 | action, or other legal or equitable relief for reporting data to the |
| 8 | PDMP pursuant to Section 103. |
| 9 | (c) Unless the CHCC finds a lack of good faith, a prescriber, |
| 10 | dispenser, pharmacist, or other individual, agency, or entity in |
| 11 | proper possession of PDMP information pursuant to this Act is not |
| 12 | subject to civil liability, administrative action, or other legal or |
| 13 | equitable relief for accessing, using, or disclosing PDMP |
| 14 | information pursuant to Sections 105 and 107. |
| 15 | 110. Unlawful Acts and Penalties. |
| 16 | (a) Administrative Sanctions. |
| 17 | (i) A dispenser who knowingly fails to submit prescription |
| 18 | monitoring information to the Commonwealth Healthcare |
| 19 | Corporation as required by this Act, or who knowingly |
| 20 | submits incorrect prescription information, shall be referred |
| 21 | to the appropriate professional licensing or regulatory board |

| 1 | for administrative sanctions and may be subject to a |
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| 2 | administrative penalty levied by that professional licensing |
| 3 | or regulatory board of no more than \$250.00 per violation |
| 4 | Each such failure to submit prescription monitoring |
| 5 | information shall count as a separate violation. |
| 6 | (ii) A dispenser who knowingly fails to correct or amend |
| 7 | prescription monitoring information submitted to the |
| 8 | Commonwealth Healthcare Corporation after notification by |
| 9 | the Commonwealth Healthcare Corporation shall be referred |
| 10 | to the appropriate professional licensing or regulatory board |
| 11 | for administrative sanctions and may be subject to an |
| 12 | administrative penalty levied by the that professional |
| 13 | licensing or regulatory board of no more than \$250.00 per |
| 14 | violation. Each such failure to correct or amend prescription |
| 15 | monitoring information shall count as a separate violation. |
| 16 | (iii) A prescriber, dispenser, or delegate who knowingly |
| 17 | fails to register with the PDMP as required by this Act shall |
| 18 | be referred to the appropriate professional licensing or |
| 19 | regulatory board for administrative sanctions and may be |
| 20 | subject to an administrative penalty levied by the appropriate |

| 1 | professional licensing or regulatory board of no more than |
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| 2 | \$500.00. |
| 3 | (iv) A prescriber or dispenser who knowingly fails to query |
| 4 | the PDMP as required by this Act shall be referred to the |
| 5 | appropriate licensing or regulatory board for administrative |
| 6 | sanctions and may be subject to an administrative penalty |
| 7 | levied by the appropriate professional licensing or regulatory |
| 8 | board of no more than \$250.00 per violation. Each such |
| 9 | failure to query the PDMP shall count as a separate violation. |
| 0 | (b) Criminal Penalties. |
| 1 | (i) A person, agency, or entity authorized to receive |
| 2 | prescription monitoring information, or audit trail |
| 3 | information pursuant to this Act who knowingly discloses |
| 4 | such information in violation of this Act shall be subject to |
| 5 | punishment by imprisonment for not more than three (3) |
| 6 | years or a fine of not more than \$3,000, or both. |
| 7 | (ii) A person, agency, or entity authorized to receive |
| 8 | prescription monitoring information or audit trail |
| 9 | information pursuant to this Act who knowingly uses such |
| 0 | information in a manner or for a purpose in violation of this |
| 1 | Act shall be subject to punishment by imprisonment for not |

| 1 | more than five (5) years or a fine of not more than \$5,000, |
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| 2 | or both. |
| 3 | (iii) A person, agency, or entity authorized to receive |
| 4 | prescription monitoring information or audit trail |
| 5 | information pursuant to this Act who knowingly requests |
| 6 | such information in violation of this Act shall be subject to |
| 7 | punishment by imprisonment for not more than five (5) years |
| 8 | or a fine of not more than \$5,000, or both. |
| 9 | (iv) A person, agency, or entity not authorized to receive |
| 0 | prescription monitoring information or audit trail |
| 1 | information pursuant to this Act who obtains or attempts to |
| 2 | obtain such information by fraud or deceit from the PDMP |
| 3 | or from a person authorized to receive such information |
| 4 | under this Act shall be subject to punishment by |
| 5 | imprisonment for not more than five (5) years or a fine of |
| 6 | not more than \$10,000, or both. |
| 7 | (v) A person, agency, or entity not authorized to receive |
| 8 | prescription monitoring information or audit trail |
| 9 | information pursuant to this Act knowingly discloses or uses |
| 0 | such information in violation of this Act shall be subject to |

| 1 | punishment by imprisonment for not more than five (5) years |
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| 2 | or a fine of not more than \$10,000, or both. |
| 3 | 111. Rules and Regulations. |
| 4 | The Commonwealth Healthcare Corporation shall promulgate rules and |
| 5 | regulations necessary to implement the provisions of this Act." |
| 6 | Section 3. Severability. If any provision of this Act or the application of |
| 7 | any such provision to any person or circumstance should be held invalid by a court |
| 8 | of competent jurisdiction, the remainder of this Act or the application of its |
| 9 | provisions to persons or circumstances other than those to which it is held invalid |
| 0 | shall not be affected thereby. |
| 1 | Section 4. Savings Clause. This Act and any repealer contained herein |
| 2 | shall not be construed as affecting any existing right acquired under contract or |
| 3 | acquired under statutes repealed or under any rule, regulation or order adopted |
| 4 | under the statutes. Repealers contained in this Act shall not affect any proceeding |
| 5 | instituted under or pursuant to prior law. The enactment of this Act shall not have |
| 6 | the effect of terminating, or in any way modifying, any liability civil or criminal, |
| 7 | which shall already be in existence at the date this Act becomes effective. |
| 8 | Section 5. Effective Date. This Act shall take effect upon its approval by |
| 9 | the Governor or upon its becoming law without such approval |

Prefiled: 5/21/2021 Introduced by: Rep. Christina Marie E. Sablan

Reviewed for Legal Sufficiency by:

House Legal Counsel

Approximate Jangethan Denuta Jangethan