

I Mina'trentai Sais Na Liheslaturan Guåhan
BILL STATUS

BILL NO.	SPONSOR	TITLE	DATE INTRODUCED	DATE REFERRED	CMTE REFERRED	PUBLIC HEARING DATE	DATE COMMITTEE REPORT FILED	FISCAL NOTES	NOTES
6-36 (COR)	Telena Cruz Nelson	AN ACT TO ADD §§ 41806.1, §§ 41817.1, §§ 41823, AND §§ 41823.1, AMEND §§ 41806(b)(3), §§ 41809(a), §§ 41810(a)(d), OF ARTICLE 18, CHAPTER 4, DIVISION, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATION, AMEND §§ 67.101, §§ 67.304(a)(5)(6)(7)(8), ADD §§ 67.308.1(j)(k) AND §§ 67.308.3 OF CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED, RELATIVE TO THE REQUIRED REGISTRATION OF PRESCRIBERS TO THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM (PDMP), THE IMPLEMENTATION OF PRACTITIONER PRESCRIPTION REPORT CARDS, MANDATORY USE OF PDMP DATABASE FOR PRESCRIBERS AND DISPENSERS PRIOR TO PRESCRIBING INITIAL PRESCRIPTIONS, LIMIT ON PRESCRIBING OPIOID CONTROLLED SUBSTANCE TO SEVEN DAYS FOR NON CHRONIC PAIN, ENFORCEMENT OF THE PATIENT UTILIZATION REPORT, THE REQUIRED DISCUSSION OF POTENTIAL RISKS TO PROVIDE AN OPTION TO FILL FOR AN ALTERNATIVE NON-OPIOID OPTION OR A LOWER QUANTITY PRESCRIPTION, AND THE ESTABLISHMENT OF A PRESCRIBER PATIENT AGREEMENT.	1/4/21 11:39 a.m.						

I MINA'TRENTAI SAIS NA LIHESLATURAN GUÅHAN
2021 (FIRST) Regular Session

Bill No. 6 -36 (COR)

Introduced by:

Telena Cruz Nelson



AN ACT TO *ADD* §§ 41806.1, §§ 41817.1, §§ 41823, AND §§ 41823.1, *AMEND* §§ 41806(b)(3), §§ 41809(a), §§ 41810(a)(d), OF ARTICLE 18, CHAPTER 4, DIVISION, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATION, *AMEND* §§ 67.101, §§ 67.304(a)(5)(6)(7)(8), *ADD* §§ 67.308.1(j)(k) AND §§ 67.308.3 OF CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED, RELATIVE TO THE REQUIRED REGISTRATION OF PRESCRIBERS TO THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM (PDMP), THE IMPLEMENTATION OF PRACTITIONER PRESCRIPTION REPORT CARDS, MANDATORY USE OF PDMP DATABASE FOR PRESCRIBERS AND DISPENSERS PRIOR TO PRESCRIBING INITIAL PRESCRIPTIONS, LIMIT ON PRESCRIBING OPIOID CONTROLLED SUBSTANCE TO SEVEN DAYS FOR NON CHRONIC PAIN, ENFORCEMENT OF THE PATIENT UTILIZATION REPORT, THE REQUIRED DISCUSSION OF POTENTIAL RISKS TO PROVIDE AN OPTION TO FILL FOR AN ALTERNATIVE NON-OPIOID OPTION OR A LOWER QUANTITY PRESCRIPTION, AND THE ESTABLISHMENT OF A PRESCRIBER PATIENT AGREEMENT.

BE IT ENACTED BY THE PEOPLE OF GUAM:

Section 1. Legislative Findings and Intent.

I Liheslaturan Guåhan finds that Schedule II, Schedule III, or Schedule IV substances and other controlled substances are widely prescribed in the medical field, but these medications may also be misused, abused, or diverted for nonmedical purposes. The Guam Prescription Drug Monitoring Program (PDMP) was established to ensure the integrity in the health care community by providing prescribers and pharmacies information of their patients to assure legitimate use of controlled substances. The Department of Public Health and Social Services (DPHSS) has the authority to adopt rules relating to the control of the manufacture, distribution, prescribing, and dispensing of controlled substances in Guam, and such rules implement the monitoring of pharmaceutical controlled substances. Prescribers in 42 states are currently required to check their respective state PDMP prior to prescribing controlled substances. As of December 2020, Guam currently has a total of 364 unique physicians with a controlled substance registration, however only 37 are registered to the PDMP database. Only 22 percent of all prescriptions on Guam have reports generated from the PDMP database by a pharmacist or physician. The mandated use and review of the database within the PDMP is intended to help reduce misuse, abuse, and diversion of controlled substances.

Several states have implemented various systems that can be integrated within the PDMP database to reduce the incidence of opioid use disorder, which include updating the reporting requirements for dispensers and the utilization of a prescriber report card. Currently the reporting requirements for dispensers to report prescription activity to the PDMP in Guam is for every 15th and last day of each month, which causes delayed access to data information. Starting on January 1, 2021 in California, the dispensing of a controlled substance must be reported within one working day after the medication is released to the patient. The

previous deadline to report was seven days after dispensing. Enabling such legislation will provide access to live data which will enable better utilization of the PDMP system, alongside the use of a practitioner report card. Many states including the District of Columbia use their state PDMP's to send doctors individualized report cards that show how their prescribing of opioid controlled substances compared with their peers. A practitioner report card is intended to provide an opportunity for the practitioner to examine their prescribing behaviors in the context of improving the quality of their patient's care. The state of Tennessee for example, analyzes the top prescribers of controlled substances and releases to prescribers a report card identifying those individuals prescribing controlled substances at a high rate. In Minnesota, practitioner report cards show that the number of annual opioid prescriptions for patients dropped by at least 30%, according to new data from the Minnesota Department of Human Health Services. Some physicians have found that informing doctors about their prescribing levels was an important step in reducing the number of opioid prescriptions.

Prescription opioids are powerful pain-reducing medications that have both benefits as well as potential serious risks. Nearly 2 million Americans ages 12 and older have a substance abuse disorder involving prescription opioids. The medications can also provide as a gateway to other drugs such as heroin, according to the National Institute of Drug Abuse, which reported that nearly half of young heroin users have stated the misuse of prescription opioids first. The Center for Disease Control and Prevention (CDC) finds that the likelihood of long-term opioid use increases based on the length of initial prescriptions, increasing sharply after taking the third and fifth days of a prescription. The CDC's "Guidelines for Prescribing Opioids for Chronic Pain" suggest that before starting and periodically

during opioid therapy, practitioners shall discuss with patients the risks or benefits of opioid therapy and the responsibilities of both parties for managing therapy. It is also recommended that prior to prescribing to a patient, the practitioner shall assess pain to consider if non-opioid therapies are appropriate, talk to patients about a treatment plan (considering such forms as a Practitioner Patient agreement), and evaluate the risk of harm or misuse (through the review of the patient's utilization report in the PDMP).

In efforts of curbing the nation's opioid crisis, many states promote laws which aim to restrict the duration or total dosage, as a way to prevent overly generous prescribing that might lead to an opioid addiction. As recommended in the CDC's Guideline for Prescribing Opioids for Chronic Pain, a practitioner or delegate who is authorized to prescribe an opioid drug shall not issue a prescription for more than a seven-day supply. Several states have developed limitations to a seven-day supply following the guidelines including Connecticut, Delaware, Massachusetts, New Hampshire, New York, Pennsylvania, Utah, and District of Columbia. New Jersey has placed further restriction on prescriptions to no more than a five-day supply, while Florida limits to a three-day supply. Other states like Maine, Rhode Island, and Vermont place restrictions based on the total MME (morphine milligram equivalent) dosage per day. CDC recommends that the lowest effective dose of opioid should be prescribed when opioids are used for acute pain, in no greater quantity than needed for the expected duration of pain. The study found that the greater amount of early exposure to opioids significantly increases risk of physical dependence without adding benefits. Clinicians should also carefully reassess evidence of individual benefits and risks of continued therapy with patients. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize therapies and work with patients to taper opioid to lower

doses or to taper and discontinue opioids. Clinicians should review the patient's history of controlled substance prescriptions using the PDMP at least every 3 months to determine whether the patient is receiving unnecessary opioid dosages or dangerous combinations that may put the patient at high risk for overdose.

In 2012 the US Food and Drug Administration (FDA), through the Safe Use Initiative Opioid Patient-Prescriber Agreement Working Group, convened to develop a model Opioid Patient-Prescriber Agreement (PPA) and test is for acceptability as an educational and shared decision-making tool in therapy. The purpose of a PPA is to be used as a decision-making tool before an opioid is prescribed and to inform patients about their responsibilities and expected behaviors regarding drugs with high risk to potential dependence. Additionally, the PPA shall provide an opportunity for the practitioner to discuss with the patient the risks of addiction, the amount to be prescribed, an option to fill in a lesser amount, or non-opioid treatment options available, if applicable. The PPA is perceived by both patients and prescribers as helpful in deciding a course of treatment and unbiased in terms of presentation of the risks and benefits of opioid therapy. Since the inception of these guidelines, various states have adopted the enforcement of opioid agreement laws, including in New Hampshire, Massachusetts, Pennsylvania, Ohio, Oklahoma, and New Jersey. Similarly, Guam shall allow the DPHSS the authority to adopt rules and regulations based on recommendations of local medical boards and federal guidelines.

It is therefore the intent of *I Liheslaturan Guåhan* to require any practitioner on Guam who engages in the practice of dispensing, prescribing, or administering of a controlled substance to be registered in the Guam PDMP. Dispensers and prescribers shall be required to utilize the PDMP and obtain any prescription information insofar as the information relates to the patient under the purview of

the dispenser or prescriber. A practitioner shall review a patient's utilization report at least every three (3) months to determine if the opioid treatment is necessary and review other substances being prescribed to the patient. In order to utilize the PDMP more effectively, the reporting requirements for dispensers shall be updated to require the report within one (1) working day after the medication is released to the patient. DPHSS shall integrate the PDMP database to produce Practitioner Prescription Report Cards that provide comparative data and notifications based on data which would be useful to practitioners. DPHSS may contract with another government agency or with a private vendor to ensure the proper implementation and utilization of the report cards. A patient's initial opioid prescription must not exceed a seven (7)-day supply for acute and postoperative pain patients, with exceptions as listed in § 67.308.1(k)(1)(a)(b)(c). If further treatment is required, the practitioner shall review the patient utilization report initially and at least once every three (3) months to establish if the drug is necessary for any further treatments. A written consent from the patient will be required after initial discussions conducted with the physician and will be stored in the patient's medical record along with the PPA. The Practitioner Patient Agreement shall be utilized as a tool for patients undergoing long-term pain treatment, to discuss and exchange information prior to providing consent to be prescribed an opioid controlled substance. DPHSS shall carry the authority to adopt rules and regulations relative to the PPA based on collaborative recommendations from local medical boards and federal guidelines. Failure to obtain and review the patient's utilization report, to discuss risks associated to the controlled substance, review and sign a Practitioner Patient Agreement (PPA), and the unauthorized use of confidential information may be grounds for potential suspension or revocation of a controlled substance registration.

Section 2. § 41806.1 of Article 18, Division 1, Chapter 4, Title 26, Guam Administrative Rules and Regulations, is hereby *added* to read:

“§ 41806.1. Registration Requirement.

Any person or practitioner on Guam who intends to engage in the practice of dispensing, prescribing, or administering of a controlled substance within Guam shall be registered in the Guam Prescription Drug Monitoring Program.

Section 3. § 41806 of Article 18, Division 1, Chapter 4, Title 26, Guam Administrative Rules and Regulations, is hereby *amended* to read:

“§ 41806. Reporting Requirements for Dispensers.

(b) Each dispenser shall submit the reported information as follows, unless a waiver is granted by the Department:

- (1) Electronically;
- (2) In the format required by the Department; and
- ~~(3) In the frequency and schedule determined by the Department~~
- (3) Within one (1) working day after the medication is released to the patient.

Section 4. § 41809 (a) of Article 18, Division 1, Chapter 4, Title 26, Guam Administrative Rules and Regulations, is hereby *amended* to read:

“§ 41809. Access to Prescription Monitoring Information by Dispensers.

(a) A dispenser, or a licensed pharmacy technician authorized by a supervising pharmacist, ~~may~~ shall obtain any prescription monitoring information insofar as the information relates to a customer of the dispenser seeking to have a prescription filled. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the prescriber’s request.

Section 5. § 41810 (a)(d) of Article 18, Division 1, Chapter 4, Title 26, Guam Administrative Rules and Regulations, is hereby *amended* to read:

“§ 41810. Access to Prescription Monitoring Information by Prescribers.

(a) A prescriber, or licensed health care practitioner duly authorized by a prescriber, ~~may~~ shall obtain any prescription monitoring information insofar as the information relates to a patient under the prescriber’s care. The information shall be provided in a format established by the Department, which may include, but is not limited to delivery by electronic means, facsimile transmission, or telephonic communication. The information shall be provided within twenty-four (24) business hours of the prescriber’s request.

(b) A prescriber, or licensed health care practitioner duly authorized by a prescriber, who seeks access to the information described above shall register with the Department in a manner specified, and shall be issued an authorization code. If the authorization code issued by the Department is lost or compromised, the prescriber shall notify the Department by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request. Requests shall be in a format established by the Department and shall contain at least, but not limited to, the following elements for each patient:

(1) The name and date of birth of the patient; and

(2) The time period for which information is being requested.

(c) The Department shall take reasonable steps to verify each registration, such as, but not limited to, making a telephone call to the prescriber or to an agent of the prescriber at a telephone number known to belong to the prescriber’s place of business.

(d) A prescriber, or licensed health care practitioner duly authorized by a prescriber, shall, before writing a prescription for a controlled substance listed in Schedule II, III, IV, or V for a patient, obtain a patient utilization report regarding the patient for the preceding twelve (12) months from the computerized program established by the Department pursuant to § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67; ~~if the prescriber has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and-~~

(1) The patient is a new patient of the prescriber, or

(2) The patient has not received any prescription for a controlled substance from the prescriber in the preceding twelve (12) months.

The prescriber shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.

Section 6. § 41823 of Article 18, Division 1, Chapter 4, Title 26, Guam Administrative Rules and Regulations, is hereby *added* to read:

“§ 41823 Practitioner Prescription Report Cards.

(a) The Department shall develop and maintain as part of the Guam Prescription Monitoring Program a system to provide prescription report cards to practitioners to inform the practitioners about certain prescribing trends. The report card must provide, at a minimum:

(1) A comparison of the practitioner’s number of prescriptions issued per month by class code or by specific substances to peer averages by specialty;

(2) A comparison of the practitioner’s number of milligrams prescribed per month by class code or by specific substances to peer averages by specialty;

(3) The total number of patients receiving ninety morphine milligram equivalents (MME's) or more a day;

(4) The total number of patients receiving opioid medications for thirty days or more;

(5) The total number of patients receiving opioids and benzodiazepines medications at the same time;

(6) The total number of patients issued prescriptions from three or more practitioners;

(7) The total number of patients filling prescriptions at three or more pharmacies;

(8) The total number of patients with controlled substance prescriptions whose dispensing dates overlap;

(9) The total number of patients obtaining refills on their prescriptions more than one week early; and

(10) The total number of prescription drug monitoring program queries made by the practitioner and a ratio of the queries to the number of patients or prescriptions issued.

The report card shall also provide data on the number of practitioners registered against which the comparisons of section (a) and (b) are being made and any other demographic data relating to the pool of practitioners and may include regional or nationwide prescribing comparison data that would be useful to the practitioner. Prescription report cards, data, documents, records, and any other information accessed or compiled in preparing prescription report cards, are confidential and not subject to discovery, subpoena, or introduction into evidence in any civil action, unless confidentiality is waived by the practitioner.

(b) The Department shall coordinate with the Guam Board of Medical Examiners and other professional boards as part of the development and

implementation of a prescription report card program. The department may contract with another agency or with a private vendor, as necessary, to ensure effective operation of the report card program, as provided in §§ 41823.1, and may apply for public or private grants or other funding to develop, implement, and maintain the program.

Section 7. § 41823.1 of Article 18, Division 1, Chapter 4, Title 26, Guam Administrative Rules and Regulations, is hereby *added* to read:

“§ 41823.1 Contract for Administration by Other Agency or Private Vendor.

DPHSS may contract with another agency or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. A contractor shall comply with the provisions regarding confidentiality of prescription information in §§ 41818.

Section 8. § 67.101 of Chapter 67, of Title 9, Guam Code Annotated is hereby *amended* to read:

(a) Acute Pain means a type of pain, whether resulting from disease, accidental, or intentional trauma, or other cause, that the practitioner reasonably expects to last only a short period of time.

(b) Chronic Pain means a type of pain being treated as a part of cancer care, hospice or other end-of-life care, or as part of palliative care practices, or pain that lasts beyond the time of normal tissue healing.

(c) Postoperative Pain means acute pain experienced immediately after surgical procedure.

(d) Patient Prescriber Agreement means a written contract or agreement that is executed between a practitioner and a patient, prior to the commencement of treatment for chronic pain using a controlled substance containing opioids, as a means to:

- (1) Deter the patient from the possible development of physical or physiological dependence from the controlled substance;
- (2) Document the understanding of both practitioner and the patient regarding the patient's pain management plan;
- (3) Specify the measures the practitioner may employ to monitor the patient's compliance; and
- (4) Describe the potential of terminating the agreement, including the consequences if the practitioner has reason to believe that the patient is not complying with the terms of the agreement.

Section 9. § 67.304 (a)(5)(6)(7)(8) of Chapter 67, of Title 9, Guam Code Annotated is hereby *amended* to read:

“(a) DPHSS may suspend or revoke a registration under § 67.303 to manufacture, distribute, ~~or~~ dispense, or prescribe a controlled substance upon finding that the registrant has:

- (1) furnished false or fraudulent material information in an application filed under this Act;
- (2) been convicted of a felony under state or Federal law relating to a controlled substance;
- (3) had the registrant's Federal registration suspended or revoked and is no longer authorized by Federal law to manufacture, distribute or dispense controlled substances; ~~or~~
- (4) committed an act that would render registration under § 67.303 inconsistent with the public interest as determined under that Section;
- (5) failed to obtain and review a patient's utilization report prior to prescribing a controlled substance listed in Schedule II, III, IV, or V as required under GARR § 41810 (d);

(6) failed to advise and discuss with the patient of the risks associated with Schedule II and Schedule III controlled substances as required under 9 GCA § 67.308(k)(2);

(7) failed to review and sign a Practitioner Patient Agreement form as required under 9 GCA § 67.308(k)(3); or

(8) engaged in the unauthorized use or disclosure of the Practitioner Patient Agreement or other confidential prescription monitoring information.”

Section 10. § 67.308.1(j)(k) of Chapter 67, of the Title 9, Guam Code Annotated is hereby *added* to read:

“(j) Initial opioid prescriptions for acute pain management or postoperative pain management must not exceed a seven-day supply, except when clinically indicated for cancer pain, hospice care, palliative care, or a major surgery. Upon any subsequent consultation for the same pain, the practitioner may issue, in accordance with existing rules and regulations, any appropriate renewal, refill, or new prescription for an opioid.

(k) Before the prescriber issues to an individual the initial prescription order for a Schedule II through IV opiate controlled substance to the patient:

(1) The practitioner, or the practitioner’s authorized delegate, shall review the patient utilization report at least once every three (3) months thereafter for patients receiving an opiate for treatment of chronic pain. If an authorized delegate reviews a patient’s utilization report, the practitioner must consult with the authorized delegate regarding the prescription history before issuing a prescription for a Schedule II through IV controlled substance. The consultation must be documented in the patient’s medical record.

Exceptions to § 67.308.1(k)(1) shall apply if:

(a) The patient is receiving palliative care, or hospice or other end-of-life care;

(b) The patient is being treated for pain due to cancer or the treatment of cancer;

(c) The prescription order is for a number of doses that is intended to last the patient seven days or less and is not subject to a refill.

(2) Discuss with the individual:

(a) The risks of addiction and overdose associated with the controlled substance

(b) The amount to be prescribed and the option to fill the prescription in a lesser amount, if applicable.

(c) The increased risk of addiction to a controlled substance if the individual suffers from a mental disorder or substance use disorder.

(d) The nonopioid treatment options available, if applicable.

(3) Review and sign a Patient Prescriber Agreement (PPA) Form

(4) Obtain written consent for the prescription from the individual. The prescriber may utilize electronic methods to obtain the written consent of the individual.

(5) Consent obtained from the patient, as specified under § 67.301 (k)(4) must be recorded in the Patient Prescriber Agreement Form.

Section 11. § 67.308.3 of Chapter 67, of Title 9, Guam Code Annotated is hereby *added* to read:

“§ 67.308.3 Practitioner Patient Agreement.

(a) In the event that a practitioner recommends that an opioid be utilized during the course of long-term pain management, the practitioner registered under § 67.302 shall enter into a written Practitioner Patient Agreement (PPA) with the

patient. The prescribing practitioner shall review and sign the PPA form, which includes:

(1) The goals of the treatment

(2) The prescription drug prescribing policies of the prescriber, which include:

(a) A requirement that the individual take the medication as prescribed;

(b) A prohibition on sharing the prescribed medication with other individuals;

(c) A requirement that the individual inform the prescriber about any other controlled substances prescribed or taken by the individual;

(d) Any reason the opioid therapy may be changed or discontinued by the prescriber; and

(e) Appropriate disposal methods for opioids that are no longer being used by the individual.

(3) Conditions under which the Practitioner Patient Agreement may be terminated:

(a) Falsifying medical information/history;

(b) Failing to adhere to treatment plans; or

(c) Patient demand treatments/prescriptions that the physician is unwilling to provide

(b) The Practitioner Patient Agreement form under § 67.308.3(a) shall be maintained by the prescriber in the medical record of the individual and include:

(1) The brand name or generic name, quantity, and initial dose of the controlled substance containing an opioid being prescribed;

(2) A statement indicating that a controlled substance is a drug or other substance that the United States Drug Enforcement Administration has identified as having a potential for abuse;

(3) A statement certifying that the prescriber engaged in discussions with the patient as required under § 67.308.1(k)(2)(3)(4); and

(4) The signature of the individual and the date of signing. The prescriber may utilize electronic methods to obtain the signature of the individual and the date of signing.

(c) DPHSS shall adopt rules and regulations relative to the PPA based on recommendations from the Guam Board of Medical Examiners, Guam Board of Examiner for Pharmacy, and as recommended by federal guidelines set forth by the US Food and Drug Administration (FDA).

Section 12. Severability. If any provision of this Act or its application to any person or circumstance is found to be invalid or contrary to law, such invalidity *shall not* affect other provisions or applications of this Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.