

MINA TRENTAI UNU NA LIHESLATURAN GUAHAN
2012 (SECOND) Regular Session

2012 AUG 10 11:38

Bill No. 505-31 (COR)

Introduced by:

DENNIS G. RODRIGUEZ, Jr.

AN ACT TO ESTABLISH THE ADMINISTRATIVE RULES AND REGULATIONS GOVERNING THE GUAM PRESCRIPTION DRUG MONITORING PROGRAM OF THE DEPARTMENT OF PUBLIC HEALTH & SOCIAL SERVICES, UNDER A NEW ARTICLE 18 OF CHAPTER 4, DIVISION 1, TITLE 26, GUAM ADMINISTRATIVE RULES AND REGULATIONS, AND IN CONFORMANCE WITH §67.301(a) OF ARTICLE 3 [REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING OF CONTROLLED SUBSTANCES], CHAPTER 67, TITLE 9, GUAM CODE ANNOTATED.

1 **BE IT ENACTED BY THE PEOPLE OF GUAM:**

2 **Section 1. Legislative Findings and Intent.**

3 *I Liheslaturan Guahan* finds that there is a clear public health and safety
4 need for the implementation of the proposed administrative Rules and Regulations
5 Governing the Guam Drug Monitoring Program of the Department of Public
6 Health & Social Services. Further, that these rules and regulations implement the
7 monitoring of pharmaceutical controlled substances through the establishment of
8 an electronic database and reporting system to prevent the misuse, abuse, and
9 diversion of such drugs without interfering with its legal medical use.

10 *I Liheslaturan Guahan* finds that the proposed administrative rules and
11 regulations as provided and required pursuant to §67.301 of Chapter 67, Title 9,
12 Guam Code Annotated, is appropriate.

Further, *I Liheslaturan Guahan* takes due note that the Department of Public Health & Social Services, in the development of the proposed guidelines addressed

herein, promulgated the proposed rules and regulations pursuant to Article 3 - Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated. The proposed rules and regulations were reviewed by the Office of the Attorney General of Guam prior to submission to the Legislature by *I Maga'låhen Guåhan*, the Governor of Guam.

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

3 **“ARTICLE 18. Guam Prescription Drug Monitoring Program”.**

4 **Section 3. Adoption of Rules.** Notwithstanding any other provision of law,
5 rule, regulation and Executive Order, the Rules and Regulations Governing the
6 Guam Prescription Drug Monitoring Program of the Department of Public Health
7 & Social Services, and attached hereto as Exhibit “A”, are hereby adopted by *I*
8 *Mina'Trenta Na Liheslaturan Guahan*, and shall be codified under Article 18 -
9 Guam Prescription Drug Monitoring Program, of Chapter 4, Division 1, Title 26,
10 Guam Administrative Rules and Regulations.

11 **Section 4. Amendment of Rules.** The Department of Public Health &
12 Social Services *shall*, at a minimum of every five years, and pursuant to Article 3-
13 Rule Making Procedures, of Chapter 9, Title 5, Guam Code Annotated, review and
14 amend, as may be necessary, the administrative rules and regulations adopted
15 pursuant to Section 3 of this Act.

16 **Section 5. Severability.** *If* any provision of this Act or its application to
17 any person or circumstance is found to be invalid or contrary to law, such
18 invalidity shall *not* affect other provisions or applications of this Act which can be
19 given effect without the invalid provisions or application, and to this end the

1 provisions of this Act are severable.

2 **Section 6. Effective Date.** This Act shall become immediately effective
3 upon enactment.

Exhibit “A”

Title 26 Guam Administrative Rules and Regulations

Division 1

Chapter 4

Article 18 - Guam Prescription Drug Monitoring Program

RULES AND REGULATIONS

FOR

GUAM PRESCRIPTION DRUG MONITORING PROGRAM

Department of Public Health and Social Services

Division of Environmental Health

Guam Drug Prescription Monitoring Program

123 Chalan Kareta

Mangilao, Guam 96913-6304

EXEMPTION FROM ECONOMIC IMPACT STATEMENT

The implementation of the following proposed rules and regulations will not have an economic impact to the public of more than Five Hundred Thousand Dollars (\$500,000) annually. As provided in § 9301(i) of Title 5 GCA, Chapter 9, Article 3, an economic impact statement is not required for these proposed rules and regulations.

TABLE OF CONTENTS

1

2

3 § 41801. Purpose 1

4 § 41802. Authority..... 1

5 § 41803. Title 1

6 § 41804. Definitions..... 1

7 § 41805. Guam Prescription Drug Monitoring Program Advisory
8 Committee..... 6

9 § 41806. Reporting Requirements for Dispensers 6

10 § 41807. Electronic Submission Requirement Waiver..... 8

11 § 41808. Access to Prescription Monitoring Information by Patients 9

12 § 41809. Access to Prescription Monitoring Information by Dispensers 10

13 § 41810. Access to Prescription Monitoring Information by Prescribers..... 11

14 § 41811. Access to Prescription Monitoring Information by the Board 13

15 § 41812. Access to Prescription Monitoring Information by local, state, or
16 federal law enforcement or prosecutorial officials 13

17 § 41813. Access to Prescription Monitoring Information by the authorized
18 representatives of the Medicaid and Medically Indigent Program
19 (MIP) within the Department of Public Health and Social
20 Services 14

21 § 41814. Access to Prescription Monitoring Information by the Medical
22 Examiner..... 14

23 § 41815. Access to Prescription Monitoring Information by personnel of
24 any vendor or contractor engaged by the Department 15

25 § 41816. Access to Prescription Monitoring Information by public or
26 private entities for statistical, research, or educational purposes... 15

27 § 41817. Designation of training programs..... 15

1	§ 41818. Confidentiality	16
2	§ 41819. Criminal Penalties	16
3	§ 41820. Administrative Sanctions	16
4	§ 41821. Immunity	17
5	§ 41822. Severability	17
6	§ 41823. Effective Date	17

1 **§ 41801. Purpose.** These rules and regulations implement the monitoring of
2 pharmaceutical controlled substances through the establishment of an electronic
3 database and reporting system to prevent the misuse, abuse, and diversion of such
4 drugs without interfering with its legal medical use.

5
6 **§ 41802. Authority.** These rules and regulations are adopted under the
7 authority of § 67.301(a) of Title 9 Guam Code Annotated, Chapter 67.

8
9 **§ 41803. Title.** These rules and regulations shall be known and cited as the
10 *“Rules and Regulations Governing the Guam Prescription Drug Monitoring*
11 *Program.”*

12
13 **§ 41804. Definitions.** The definitions of terms contained in these rules and
14 regulations are similar to those contained in Title 9 GCA, Chapter 67. If any
15 definitions are amended in the Act, those amendments shall be the definitions of
16 the terms contained in these rules and regulations. The following terms and
17 phrases shall have the following meanings unless the context clearly indicates
18 otherwise:

19
20 (a) *Abuse* means the use of a controlled substance in a manner not intended
21 by the prescriber, which is for a therapeutic or medical use, with the intent to alter
22 one’s mood, emotion, or state of consciousness.

23
24 (b) *Board* means a professional board within the Health Professional
25 Licensing Office of the Department that oversees health professionals who are
26 authorized to dispense controlled substances.

1 (c) *Controlled substance* means a substance listed in Schedules II, III, IV, or
2 V as defined in Title 9 GCA, Chapter 67, Article 2, as may be amended.

3
4 (d) *Controlled Substances Registration* or *CSR* means the Guam Controlled
5 Substances Registration issued by the Department of Public Health and Social
6 Services.

7
8 (e) *Department of Public Health and Social Services (“DPHSS”)* or
9 *Department* means the Director of the Department of Public Health and Social
10 Services of the Government of Guam, or its successor, or any individual or entity
11 of the department he designates.

12
13 (f) *Dispense* or *dispensing* means to deliver a controlled substance to the
14 ultimate user, patient, or research subject by, or pursuant to, the lawful order of a
15 practitioner, including the prescribing, administering, packaging, labeling, or
16 compounding necessary to prepare the substance for that delivery.

17
18 (g) *Dispenser* means any person who dispenses.

19
20 (h) *Diversion* means the transfer of a controlled substance from a lawful to
21 an unlawful channel of distribution or use.

22
23 (i) *Drug Enforcement Administration (“DEA”)* means the Drug
24 Enforcement Administration of the United States Department of Justice, or its
25 successor agency.

1 (j) *Drug* means (i) a substance recognized as a drug in the official United
2 States Pharmacopoeia, National Formulary, or the official Homeopathic
3 Pharmacopoeia of the United States, or a supplement to any of them; (ii) a
4 substance intended for use in the diagnosis, cure, mitigation, treatment, or
5 prevention of disease in individuals or animals; (iii) a substance, other than food,
6 intended to affect the structure or a function of the body of individuals or animals;
7 and (iv) a substance intended for use as a component of an article specified in
8 subsections (i), (ii), and (iii) of this section. The term does not include a device or
9 its components, parts, or accessories.

10
11 (k) *Guam Prescription Drug Monitoring Program (“GPDMP”)* means the
12 program within the Division of Environmental Health of the Department that
13 monitors the dispensing of prescription drugs on Guam.

14
15 (l) *Guam Prescription Drug Monitoring Program Advisory Committee or*
16 *Advisory Committee* means an advisory committee established to assist in the
17 implementation and periodic evaluation of the Guam Prescription Drug Monitoring
18 Program.

19
20 (m) *Guam Uniform Controlled Substances Act* or the *Act* means Title 9
21 Guam Code Annotated, Chapter 67.

22
23 (n) *Medicaid* means the United States health program for individuals and
24 families with low incomes and resources, which is jointly funded by the states and
25 federal government, and is managed by the states.

1 (o) *Medically Indigent Program (“MIP”)* means the Guam healthcare
2 system that provides last resort assistance to persons who do not have health
3 insurance and who are not eligible for other healthcare coverage, such as Medicaid,
4 Medicare, or private health insurance.

5
6 (p) *Misuse* means the use of a controlled substance in an incorrect manner.

7
8 (q) *National Drug Code (“NDC”)* means a unique 10-digit, 3-segment
9 number assigned to each medication listed under Section 510 of the U.S. Federal
10 Food, Drug, and Cosmetic Act, which identifies the labeler or vendor, product, and
11 trade package size.

12
13 (r) *Patient* means a person who receives medical attention, care, or
14 treatment.

15
16 (s) *Person* means an individual, corporation, business trust, estate, trust,
17 partnership, association, joint venture, government or governmental subdivision or
18 agency, or any other legal or commercial entity.

19
20 (t) *Photographic Identification* means a valid and current identification that
21 verifies a person’s identity, such as a Government of Guam identification card, a
22 passport, a Guam driver license, a military identification card, or any other legal
23 photographic identification the Department deems acceptable.

24
25 (u) *Practitioner* means a physician, dentist, veterinarian, scientific
26 investigator, pharmacist, pharmacy, hospital, government operated or government
27 contracted animal shelter, or other person licensed, registered, or otherwise

1 permitted, by Guam, to distribute, dispense, conduct research with respect to,
2 administer, or use in teaching or chemical analysis, a controlled substance in the
3 course of professional practice or research.

4
5 (v) *Prescribe or prescribing* means to give instructions, usually in writing,
6 for the preparation and administering of a drug.

7
8 (w) *Prescriber* means a licensed, registered health care professional with
9 authority to prescribe drugs.

10
11 (x) *Reasonable cause* means information or circumstances which could
12 prompt a reasonable person to believe or suspect that there is or might be abuse or
13 diversion of prescription drugs.

14
15 (y) *Reasonable person* means a person who exercises qualities of attention
16 and judgment that society requires of its members for the protection of their own
17 interest and the interests of others.

18
19 (z) *Registrant* means any person registered pursuant to Title 9 GCA,
20 Chapter 67.

21
22 (aa) *Ultimate User* means an individual who lawfully possesses a
23 controlled substance for the individual's own use or for the use of a member of
24 the individual's household, or for administering to an animal owned by the
25 individual or by a member of the individual's household.

1 **§ 41805. Guam Prescription Drug Monitoring Program Advisory**
2 **Committee.** (a) The Department shall establish an Advisory Committee to consult
3 with and advise the Department on matters related to the establishment,
4 maintenance, and operation of the GPDMP; access to the GPDMP and how it is to
5 be regulated; and security of information contained in the GPDMP database.

6
7 (b) Members of the Advisory Committee shall be determined by the
8 Department.

9
10 **§ 41806. Reporting Requirements for Dispensers.** (a) Each Dispenser
11 shall submit to the Department a report of the dispensing of all locally and
12 federally controlled substances in Schedules II, III, IV, and V of Guam and federal
13 law. The information in the report shall include, at a minimum, the following:

14
15 (1) Prescriber Information:

- 16 (i) Name of prescriber;
17 (ii) Physical and mailing address of prescriber;
18 (iii) Business telephone and fax number of prescriber; and
19 (iv) Professional license, DEA registration number and
20 Controlled Substances Registration (CSR) of prescriber.

21
22 (2) Patient Information:

- 23 (i) Social Security Number of patient;
24 (ii) Name of patient;
25 (iii) Physical and mailing address of patient;
26 (iv) Date of birth of patient;
27 (v) Gender of patient;

1 (vi) Name of person who received the prescription if other than
2 the patient; and

3 (vii) Method of payment for the prescription.
4

5 (3) Prescription Information:

6 (i) Date prescription issued by prescriber;

7 (ii) Date prescription filled;

8 (iii) Prescription number;

9 (iv) Prescription is new or refill;

10 (v) Number refills ordered; and

11 (vi) Quantity dispensed.
12

13 (4) Controlled Substance Information or Drug Information:

14 (i) Prescription Drug dispensed;

15 (ii) National Drug Code (NDC) number for drug dispensed; and

16 (iii) Drug strength and quantity prescribed.
17

18 (5) Dispenser Information:

19 (i) Name of dispenser;

20 (ii) Physical and mailing address of dispenser;

21 (iii) Business telephone and fax number of dispenser; and

22 (iv) Professional license, DEA registration number and

23 Controlled Substances Registration (CSR) of dispenser.
24

25 (b) Each dispenser shall submit the reported information as follows, unless a
26 waiver is granted by the Department:
27

- 1 (1) Electronically;
- 2 (2) In the format required by the Department; and
- 3 (3) In the frequency and schedule determined by the Department.

4
5 **§ 41807. Electronic Submission Requirement Waiver.** (a) The
6 Department may grant a waiver of the electronic submission requirement to a
7 dispenser for good cause. The dispenser requesting the waiver is responsible for
8 establishing the basis for the requested waiver.

9
10 (b) Waivers may be granted for the following circumstances:

11
12 (1) The dispenser demonstrates that for any reason, including because
13 the volume of controlled substances dispensed is low, financial hardship will
14 result from being required to make electronic submissions of prescription
15 monitoring information; or

16 (2) Other good cause.

17
18 (c) Requests for a waiver shall be by application in writing on a form
19 provided by the Department for such a purpose. The dispenser requesting the
20 waiver may provide the Department with any reasonable supplemental materials in
21 support of their request for a waiver, in addition to the written application. The
22 Department may request additional information from the dispenser requesting the
23 waiver as a condition of granting the waiver.

24
25 (d) Requests for a waiver shall be granted or denied by the Department no
26 later than sixty (60) business days from the date of the written application for

1 waiver is submitted to the Department, or the date the last supplemental written
2 materials are received by the Department, whichever is later.

3
4 (e) The decision of the Department to grant or deny a waiver shall constitute
5 final agency action.

6
7 **§ 41808. Access to Prescription Monitoring Information by Patients.** (a)
8 A patient, or a patient's authorized representative, may obtain a report listing all
9 prescription monitoring information that pertains to the patient.

10
11 (b) A patient or a patient's authorized representative seeking access to
12 prescription monitoring information described above shall submit a written request
13 for information in person at the Department, or at any other place specified by the
14 Department. The written request shall be in a format established by the
15 Department and shall contain at least, but not limited to, the following elements:

16
17 (1) The patient's full name and the full name of the patient's
18 authorized representative, if applicable;

19 (2) The patient's date of birth;

20 (3) The patient's physical and mailing address, and the complete
21 physical and mailing address of the patient's authorized representative, if
22 applicable;

23 (4) The patient's telephone number, if any, and the telephone number
24 of the authorized representative, if applicable; and

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

26

1 (c) The patient or the patient's authorized representative shall produce a
2 photographic identification card prior to obtaining access to the information
3 described above. The patient or the patient's authorized representative shall allow
4 photocopying of the identification.

5
6 (d) Prior to obtaining access to the information described above, authorized
7 representatives shall produce either an official attested copy of the judicial order
8 granting them authority to gain access to the health care records of the patient; or
9 in the case of parents of a minor child, a certified copy of the birth certificate of the
10 minor child or other official documents establishing legal guardianship; or in the
11 case of person holding power of attorney, the original document establishing the
12 power of attorney. The patient's authorized representative shall allow
13 photocopying of the documents described above. The Department may verify the
14 patient authorization by any reasonable means prior to providing the information to
15 the authorized representative.

16
17 **§ 41809. Access to Prescription Monitoring Information by Dispensers.**

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

25
26 (b) A dispenser who seeks access to the information described above shall
27 register with the Department in a manner specified, and shall be issued an

1 authorization code. If the authorization code issued by the Department is lost or
2 compromised, the dispenser shall notify the Department by telephone and in
3 writing as soon as reasonably possible. Information regarding more than one
4 patient may be submitted in a single request. Requests shall be in a format
5 established by the Department and shall contain at least, but not limited to, the
6 following elements for each patient:

7

- 8 (1) The name and date of birth of the patient; and
- 9 (2) The time period for which information is being requested.

10

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

15

16 **§ 41810. Access to Prescription Monitoring Information by Prescribers.**

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

24

25 (b) A prescriber, or licensed health care practitioner duly authorized by a
26 prescriber, who seeks access to the information described above shall register with
27 the Department in a manner specified, and shall be issued an authorization code. If

1 the authorization code issued by the Department is lost or compromised, the
2 prescriber shall notify the Department by telephone and in writing as soon as
3 reasonably possible. Information regarding more than one patient may be
4 submitted in a single request. Requests shall be in a format established by the
5 Department and shall contain at least, but not limited to, the following elements for
6 each patient:

7

- 8 (1) The name and date of birth of the patient; and
- 9 (2) The time period for which information is being requested.

10

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

15

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

24

- 25 (1) The patient is a new patient of the prescriber; or
- 26 (2) The patient has not received any prescription for a controlled
27 substance from the prescriber in the preceding twelve (12) months.

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

§ 41811. Access to Prescription Monitoring Information by the Board.

(a) The Board may obtain any prescription monitoring information as required for an investigation, with reasonable cause. 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.

(b) The request from the Board shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The Board shall ensure that the appropriate form provided by the Department is utilized for the request.

§ 41812. Access to Prescription Monitoring Information by local, state,

or federal law enforcement or prosecutorial officials. (a) A local, state, or federal law enforcement or prosecutorial official may obtain any prescription monitoring information as required for an investigation, with reasonable cause. 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.

(b) The request from a local, state, or federal law enforcement or prosecutorial official shall contain identifying information regarding the registrant or patient and the time period for which the information is being requested. The

1 local, state, or federal law enforcement or prosecutorial official shall ensure that
2 the appropriate form provided by the Department is utilized for the request.

3
4 **§ 41813. Access to Prescription Monitoring Information by the**
5 **authorized representatives of the Medicaid and Medically Indigent Program**
6 **(MIP) within the Department of Public Health and Social Services.** (a) An
7 authorized representative of the Medicaid and Medically Indigent Program (MIP)
8 may obtain any prescription monitoring information as required for an
9 investigation, with reasonable cause. The information shall be provided in a
10 format established by the Department, which may include, but is not limited to
11 delivery by electronic means, facsimile transmission, or telephonic communication.

12 (b) The request from the authorized representative of the Medicaid and
13 Medically Indigent Program (MIP) shall contain identifying information regarding
14 the registrant or patient and the time period for which the information is being
15 requested. The authorized representative of the Medicaid and Medically Indigent
16 Program (MIP) shall ensure that the appropriate form provided by the Department
17 is utilized for the request.

18
19 **§ 41814. Access to Prescription Monitoring Information by the Medical**
20 **Examiner .** (a) The Medical Examiner or a designee may obtain any prescription
21 monitoring information as required for an investigation, with reasonable cause.
22 The information shall be provided in a format established by the Department,
23 which may include, but is not limited to delivery by electronic means, facsimile
24 transmission, or telephonic communication.

25
26 (b) The request from the Medical Examiner or a designee shall contain
27 identifying information regarding the registrant or patient and the time period for

1 which the information is being requested. The Medical Examiner or a designee
2 shall ensure that the appropriate form provided by the Department is utilized for
3 the request.

4
5 **§ 41815. Access to Prescription Monitoring Information by personnel of**
6 **any vendor or contractor engaged by the Department.** (a) Personnel of any
7 vendor or contractor engaged by the Department may obtain any prescription
8 monitoring information insofar as the information is necessary for establishing and
9 maintaining the program's electronic system.

10
11 (b) Program vendors or contractors engaged by the Department shall purge
12 all prescription monitoring information more than six (6) years old.

13
14 **§ 41816. Access to Prescription Monitoring Information by public or**
15 **private entities for statistical, research, or educational purposes.** A public or
16 private entity may obtain any prescription monitoring information insofar as the
17 information is necessary for statistical, research, or educational purposes, and
18 insofar as information that can be used to identify a person has been removed. The
19 information shall be provided in a format established by the Department, which
20 may include, but is not limited to delivery by electronic means, facsimile
21 transmission, or telephonic communication.

22
23 **§ 41817. Designation of training programs.** (a) Authorized dispensers
24 shall attend a training course on the transmission, retrieval, and use of prescription
25 monitoring information provided by the Department, which will be developed in
26 consultation with the Advisory Committee, during the implementation phase of the
27 Guam Prescription Drug Monitoring Program.

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(b) Authorized prescribers who will be retrieving prescription monitoring information shall attend the training course indicated in § 41817(a) within these rules and regulations.

§ 41818. Confidentiality. Except as provided in this section, prescription monitoring information submitted to the Department shall be confidential and shall not be subject to public records laws. The Department shall maintain procedures to protect patient privacy, ensure the confidentiality of patient information collected, recorded, transmitted, and maintained, and ensure that information is not disclosed to any person except as provided in §§ 41808 to 41816 within these rules and regulations.

§ 41819. Criminal Penalties. (a) Pursuant to §§ 67.306 and 67.402(a)(3) of the Act, a dispenser who fails to submit the required information to the Department shall be guilty of a felony of the third degree.

(b) Pursuant to §§ 67.306 and 67.403(a)(4) of the Act, a dispenser who furnishes false or fraudulent information to the Department shall be guilty of a felony of the third degree.

§ 41820. Administrative Sanctions. The Department may pursue the suspension or the revocation of the registrant’s CSR in accordance to § 67.304 of the Act for violating the terms of these rules and regulations, and may be subject to disciplinary action by any applicable governing entity.

1 **§ 41821. Immunity.** A dispenser or health care provider shall be immune
2 from civil, criminal, or administrative liability as a result of any action made in
3 good faith pursuant to and in accordance with these rules and regulations, but
4 nothing in this section shall be construed to establish immunity for the failure to
5 follow standards of professional conduct or the failure to exercise due care in the
6 provision of services.

7
8 **§ 41822. Severability.** If any provision of these rules and regulations, its
9 application to any person or circumstance is held invalid, the invalidity does not
10 affect other provisions or applications of these rules and regulations which can be
11 given effect without the invalid provision or application, and to this end, the
12 provisions of these rules and regulations are severable.

13
14 **§ 41823. Effective Date.** These rules and regulations shall be effective
15 immediately upon compliance with Title 5 GCA, Chapter 9, Article 3.

16
17