SETTLEMENT AGREEMENT

The parties, the Missouri Department of Health and Senior Services' Bureau of Narcotics and Dangerous Drugs (hereinafter "Department" or "Bureau"), through counsel, and Patricia Derges, A.P., (hereinafter "Dr. Derges"), announce they are entering into the following Settlement Agreement for the purpose of disciplining Dr. Derges' Missouri Controlled Substances Registration. Dr. Derges and the Department jointly stipulate and agree that a final disposition of this matter, as detailed below is authorized under section 621.045, RSMo. The parties understand that this Settlement Agreement is in lieu of Dr. Derges' right to a hearing before the Administrative Hearing Commission.

1. Dr. Derges acknowledges that she understands the various rights and privileges afforded by law, the right to a hearing of the allegations against her, the right to appear and be represented by legal counsel, the right to have all charges against her proven upon the record by competent and substantial evidence, the right to cross-examine any witnesses appearing at the hearing against her, the right to present evidence on her own behalf, and the right to a decision based upon the record by a fair and impartial administrative hearing commissioner concerning the allegations pending against her. Dr. Derges acknowledges that she understands her rights under the law and that she knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to her.

2. Dr. Derges acknowledges that pursuant to section 621.045.4(3), RSMo, she may submit a copy of this Settlement Agreement signed by all of the parties within fifteen days after signature to the Administrative Hearing Commission for determination that the facts

agreed to by the parties to the settlement constitute grounds for disciplining Dr. Derges' Missouri Controlled Substances Registration.

3. Dr. Derges acknowledges that pursuant to section 621.045.4(4), RSMo, she has been informed of her right to consult legal counsel in this matter.

4. The parties acknowledge that this Settlement Agreement has been freely entered into, voluntarily, with full knowledge, and without duress, and that in executing this Settlement Agreement, the parties are not relying on representations or statements, either written or oral, express or implied made to them by one another or by any other person, and that the consideration received by them has been actual and adequate.

5. Dr. Derges also acknowledges that pursuant to section 621.045.5, RSMo, that any Settlement Agreement submitted to the Administrative Hearing Commission shall not be effective and final unless and until findings of fact and conclusions of law are entered by the Administrative Hearing Commission that the facts agreed to by the parties to the settlement constitute grounds for denying or disciplining the license of the licensee.

6. The parties stipulate and agree that the order regarding the discipline of Dr. Derges' Missouri Controlled Substances Registration is based only on the facts and law set out in Part I.

7. Dr. Derges understands and agrees that the Department will maintain this Settlement Agreement as an open record of the Department.

Part I: JOINT FINDINGS OF FACT AND CONCLUSIONS OF LAW

Based on the foregoing, the Department and Dr. Derges jointly stipulate to the following:

JOINT FINDINGS OF FACT

1. The Bureau of Narcotics and Dangerous Drugs is a bureau within the Missouri Department of Health and Senior Services created and established pursuant to section 192.005, RSMo, for the purpose of administering, executing and enforcing the provisions of Chapter 195, RSMo, the "Comprehensive Drug Control Act."

2. Dr. Derges is licensed in Missouri as an Assistant Physician (AP) which is a mid-level practitioner. Dr. Derges is registered by the Bureau to conduct activities with controlled substances and that current registration expires on January 31, 2022. Dr. Derges has an application pending for a new Missouri Controlled Substances Registration.

3. The Bureau conducted an investigation regarding controlled substance activities by Dr. Derges. Dr. Derges and her legal counsel were provided with copies of the investigation and all attachments and met with representatives of the Bureau in a conference.

4. The investigation revealed violations of state and federal controlled substance laws. Dr. Derges stated that controlled substance laws were not taught in her medical school and she has not participated in a residency. She received her license as an Assistant Physician and obtained her state and federal drug registrations. She began practicing with controlled substances and has been learning as she goes. The violations revealed were not intentional and were because she did not know. Once she learned of the violations, she took prompt corrective measures.

5. Dr. Derges prescribed controlled substances in the absence of a current and active controlled substances registration. A mid-level practitioner must have a collaborating physician with an active state drug registration. Dr. Derges had a collaborating agreement with Dr. Trask, who did not have a state controlled substance registration. This terminated Dr. Derges' controlled substance authority until she provided the Bureau

with a new collaborating physician. All of the controlled substance prescriptions issued while Dr. Trask was the collaborating physician were without a current registration.

Section 195.030.3, RSMo states:

> 3. Persons registered by the department of health and senior services pursuant to this chapter to manufacture, distribute, or dispense or conduct research with controlled substances are authorized to possess, manufacture, distribute or dispense such substances, including any such activity in the conduct of research, to the extent authorized by their registration and in conformity with other provisions of this chapter and chapter 579.

State Regulation 19 CSR 30-1.023(2)(B), states:

> (B) A mid-level practitioner's registration shall be contingent upon the physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, having a current and valid registration. When such physician's registration expires, closes, or is no longer valid, any mid-level practitioner(s) with whom he or she has entered into an agreement shall no longer have controlled substance authority. The mid-level practitioner(s) shall cease controlled drug activities until the physician has obtained a new registration or the mid-level practitioner(s) obtain(s) another agreement with another physician pursuant to Chapter 334, RSMo. Mid-level practitioners and any physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, shall notify the Department of Health and Senior Services of the termination of any such agreement.

Federal DEA Regulation 21 CFR 1306.03(a),(1), states:

> (a) A prescription for a controlled substance may be issued only by an individual practitioner who is:
>
> > (1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession.

6. Dr. Derges is only authorized to prescribe Schedule II controlled substances that contain hydrocodone. No other Schedule II controlled substances may be prescribed. Dr. Derges prescribed other Schedule II controlled substances such as oxycodone and amphetamines outside of what is authorized.

Section 195.030.3, RSMo states:

> 3. Persons registered by the department of health and senior services pursuant to this chapter to manufacture, distribute, or dispense or conduct research with controlled substances are authorized to possess, manufacture, distribute or dispense such substances, including any such activity in the conduct of research, to the extent authorized by their registration and in conformity with other provisions of this chapter and chapter 579.
>
> *(The definition of "dispense" in Section 195.010, RSMo includes the act of prescribing.)*

Section 195.070.1, RSMo states in material part:

> 1. A physician, podiatrist, dentist, a registered optometrist certified to administer pharmaceutical agents as provided in section 336.220, or an assistant physician in accordance with section 334.037 or a physician assistant in accordance with section 334.747 in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances or he or she may cause the same to be administered or dispensed by an individual as authorized by statute.

Section 334.037.12(1), RSMo states:

> An assistant physician with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in Schedule III, IV, or V of section 195.017, and may have restricted authority in Schedule II, when delegated the authority to prescribe controlled substances in a collaborative practice arrangement. Prescriptions for Schedule II medications prescribed by an assistant physician who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone. Such authority shall be filed with the state board of registration for the healing arts. The collaborating physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the assistant physician is permitted to prescribe. Any limitations shall be listed in the collaborative practice arrangement. Assistant physicians shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances and Schedule II - hydrocodone prescriptions shall be limited to a five-day supply without refill, except that buprenorphine may be prescribed for up to a thirty-day supply without refill for patients receiving medication-assisted treatment for substance use disorders under the direction of the collaborating physician. Assistant physicians who are authorized to prescribe controlled substances under

this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include the Drug Enforcement Administration registration number on prescriptions for controlled substances.

Federal DEA Regulation 21 CFR 1306.03(a)(1), states:

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession.

7. Dr. Derges possessed tramadol, a controlled substance, in a manner not authorized by law. Dr. Derges purchased and stocked tramadol at a Branson, Missouri location and later at an Ozark, Missouri location when there were not separate controlled substance registrations for those locations. The Branson location did not have a state or federal registration number. The Ozark location did not have a Missouri state number. Mid-level practitioners are given prescriptive authority only and are not authorized to stock and dispense their own controlled substances.

Section 334.037.12(1), RSMo states:

An assistant physician with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in Schedule III, IV, or V of section 195.017, and may have restricted authority in Schedule II, when delegated the authority to prescribe controlled substances in a collaborative practice arrangement. Prescriptions for Schedule II medications prescribed by an assistant physician who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone. Such authority shall be filed with the state board of registration for the healing arts. The collaborating physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the assistant physician is permitted to prescribe. Any limitations shall be listed in the collaborative practice arrangement. Assistant physicians shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances and Schedule II - hydrocodone prescriptions shall be limited to a five-day supply without refill, except that buprenorphine may be prescribed for up to a thirty-day

supply without refill for patients receiving medication-assisted treatment for substance use disorders under the direction of the collaborating physician. Assistant physicians who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include the Drug Enforcement Administration registration number on prescriptions for controlled substances.

Section 195.030.6, RSMo states:

> 6. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

Section 195.070.1, RSMo states:

> 1. A physician, podiatrist, dentist, a registered optometrist certified to administer pharmaceutical agents as provided in section 336.220, or an assistant physician in accordance with section 334.037 or a physician assistant in accordance with section 334.747 in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances or he or she may cause the same to be administered or dispensed by an individual as authorized by statute.

State Regulation 19 CSR 30-1.026(3), states:

> (3) Separate Locations. A separate registration is required for each principal place of business or professional practice at one (1) general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

Federal DEA Regulation 21 CFR 1301.12(a), states:

> (a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

8. Dr. Derges dispensed controlled substances in a manner not authorized by law. Mid-level practitioners are granted prescriptive authority only and not authority to dispense from their own stock of drugs. Mid-level practitioners may only dispense from the stock of their

collaborating physician or a hospital. Dr. Derges also authorized unlicensed employees to dispense controlled drugs and also in the absence of authority from a physician.

Section 334.037.12(1), RSMo states:

> An assistant physician with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in Schedule III, IV, or V of section 195.017, and may have restricted authority in Schedule II, when delegated the authority to prescribe controlled substances in a collaborative practice arrangement. Prescriptions for Schedule II medications prescribed by an assistant physician who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone. Such authority shall be filed with the state board of registration for the healing arts. The collaborating physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the assistant physician is permitted to prescribe. Any limitations shall be listed in the collaborative practice arrangement. Assistant physicians shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances and Schedule II - hydrocodone prescriptions shall be limited to a five-day supply without refill, except that buprenorphine may be prescribed for up to a thirty-day supply without refill for patients receiving medication-assisted treatment for substance use disorders under the direction of the collaborating physician. Assistant physicians who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include the Drug Enforcement Administration registration number on prescriptions for controlled substances.

Section 195.070.1, RSMo states in material part:

> 1. A physician assistant in accordance with section 334.747 in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances or he or she may cause the same to be administered or dispensed by an individual as authorized by statute.

State Regulation 19 CSR 30-1.066(1)(A) and (2), state:

> (1) An individual practitioner who dispenses controlled substances shall—

(A) Provide direct supervision to employees or agents who assist in the administering or dispensing of controlled substances. Controlled substances shall not be dispensed from an individual practitioner's inventory unless a practitioner is physically in the registered location except pursuant to the provisions of section (2) of this rule;

(2) Mid-level practitioners shall not independently purchase, stock, administer, and dispense controlled substances. Controlled substances may be administered or dispensed from an individual practitioner's inventory by a mid-level practitioner with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, when the practitioner is not present at the registered location.

9. Dr. Derges did not properly document and maintain a controlled substance dispensing log as required by law. The dispensing log provided to the state mixed the dispensings of controlled substances along with non-controlled drugs. The controlled drug dispensings were not logged separately away from other records. The dispensing log provided did not document the patients' addresses.

Section 195.050.6, RSMo states:

6. Every person registered to manufacture, distribute or dispense controlled substances under this chapter shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the department of health and senior services.

State Regulation 19 CSR 30-1.041(3)(B), states:

(B) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in a form that the information required is readily retrievable from the ordinary business records of the registrant.

State Regulation 19 CSR 30-1.048(2) and (3) state:

(2) Each individual practitioner shall maintain a record of the date, full name and address of the patient, the drug name, strength, dosage form, and quantity for all controlled substances prescribed or administered. This record may be maintained in the patient's medical record. When the controlled substance record is maintained in the patient's medical record and the practitioner is not the custodian

of the medical record, the practitioner shall make the controlled substance record available as required in 19 CSR 30-1.041 and 19 CSR 30-1.044.

(3) Individual practitioners shall maintain the records listed in subsections (1)(A)–(E) of this rule separately from patient medical records.

10. Dr. Derges did not maintain complete and accurate receipt or transfer records for controlled substances entering and leaving her practice locations. All receipt and transfer records require practitioners to document their federal DEA number on the record for that location. Not having federal DEA registrations in Branson or Ozark, Missouri would make it impossible to document the receipt and transfer records completely and accurately.

Section 195.050.6, RSMo states:

> 6. Every person registered to manufacture, distribute or dispense controlled substances under this chapter shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the department of health and senior services.

State Regulation 19 CSR 30-1.048(4) states:

> (4) A registrant who transfers a controlled substance to or receives a controlled substance from another registrant shall maintain a written record of the transfer which contains the following information: the date of transfer, drug name, strength, dosage form, quantity, name, address and registration number of the transferring registrant, and the name, address and registration number of the receiving registrant.

11. Dr. Derges did not always provide adequate security to guard against the diversion of controlled substances into unauthorized channels. In this case there was no known theft, but drugs were diverted outside their normal and legal channels causing lapses in security. Examples of lapses are:

- Controlled substances were prescribed in a manner not authorized by law, causing pharmacies to dispense based upon unlawful prescriptions;
- Drugs were possessed in a manner not authorized by law;

- Drugs were dispensed by employees in a manner not authorized by law. The drugs were not owned by a physician. There was no authorization from a physician to dispense.
- The staff dispensing controlled drugs were not licensed to practice in Missouri.

State Regulation 19 CSR 30-1.031(1), states in material part:

> (1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032–19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion.

DEA Federal Regulation 21 CFR 1301.71(a) states:

> (a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.
>
> (b) Substantial compliance with the standards set forth in §§1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

Section 195.040.3(1),(2),(4),& (7), RSMo, states in material parts:

> 3. The department of health and senior services shall register an applicant to manufacture, distribute or dispense controlled substances unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:
>
> (1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable state and local law;

* * *

(4) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;

* * *

(7) Any other factors relevant to and consistent with the public health and safety.

JOINT CONCLUSIONS OF LAW

1. For all relevant times herein, to present, 192.006, RSMo, stated, in pertinent part, as follows:

> The department of health and senior services may adopt, appeal and amend rules necessary to carry out the duties assigned to it.

2. For all relevant times herein, to present, 195.040, RSMo, stated, in pertinent part, as follows:

> 7. A registration to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the department of health and senior services upon a finding that the registrant:
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> (1) Has furnished false or fraudulent material information in any application filed under this chapter;
>
> ...
>
> (4) Has violated any federal controlled substances statute or regulation, or any provision of this chapter or chapter 579 or regulation promulgated under this chapter;
>
> ...
>
> 8. The department of health and senior services may ... restrict or limit a registration under such terms and conditions as the department of health and senior services considers appropriate ... Any registration placed under a limitation or restriction by the department of health and senior services shall be termed "under probation".

3. Dr. Derges prescribed controlled substances in a manner not authorized by law by not having a registered collaborating physician, and prescribing unauthorized drugs in

Schedule II, in violation of Sections 195.030.3, and 195.070.1, and 334.037.12(1), RSMo and State Regulation 19 CSR 30-1.023(2)(B), and Federal DEA Regulation 21 CFR 1306.03(a)(1).

4. Dr. Derges possessed and dispensed controlled substances in a manner not authorized by law by not having required registrations, not having orders from a physician, and allowing unlicensed employees to dispense, in violation of Sections 334.037.12(1); 195.030.6; 195.070.1; State Regulation 19 CSR 30-1.026(3) and Federal DEA Regulation 21 CFR 1301.12(a).

5. Dr. Derges did not maintain all controlled substance records as required by not separating controlled drug records from non-controlled drug records; not having patient addresses on dispensing logs; and not having DEA numbers on required drug transfer records, in violation of Section 195.050.6, RSMo, and State Regulations 19 CSR 30-1.041(3)(B) and 19 CSR 30-1.048(2),(3), and (4).

6. Dr. Derges did not always provide adequate controls, policies and security to prevent the diversion of controlled drugs into unauthorized channels in violation of State Regulation 19 CSR 30-1.031(1) and Federal DEA Regulation 21 CFR 1301.71(a).

7. Cause exists to discipline Dr. Derges's Missouri Controlled Substances Registration pursuant to Section 195.040.3, RSMo.

Part II: TERMS AND CONDITIONS

Based on the above, the parties agree and stipulate that the Department shall grant Dr. Derges a Missouri Controlled Substance Registration on a probationary status, under the following terms and conditions:

1. The conditions of this Settlement Agreement shall be in effect for three (3) years from the date of execution of this Settlement Agreement. After two (2) years have passed, Dr. Derges may approach the Bureau for an inspection and show compliance and ask to have this Agreement terminated after the second year.

2. Dr. Derges shall apply for Missouri Controlled Substance Registrations and professional licenses in a timely fashion and shall be current in her registrations at all times, including the reporting of any change in her practice address.

3. Dr. Derges understands that should she relocate her primary registered professional practice address, the controlled substance registration for this current practice address will terminate immediately, and she may not conduct activities with controlled substances until she has been issued a new certificate of registration for the new practice location.

4. Dr. Derges understands that she only has the independent authority to prescribe controlled substances. She shall not take possession of any controlled substances. Dr. Derges is authorized to dispense from the stock of a hospital or her collaborating physician.

5. During the first year of this agreement, Dr. Derges shall download the Bureau's Controlled Substance Guidelines for Missouri Practitioners that is available on the Bureau's website. Dr. Derges shall review this document and train her staff so that they are aware of state and federal controlled substance laws pertaining to registrations,

prescribing, record keeping, and other security requirements. Dr. Derges shall notify the Bureau in writing once this training has been completed.

6. Dr. Derges shall not violate any provision of Chapter 195 of the Revised Statutes of Missouri nor any regulation promulgated thereunder or the federal Controlled Substances Act 21 U.S.C. 801—966 and its federal regulations 21 CFR 1300—1399.

7. Violation of any term of this Settlement Agreement by Dr. Derges is sufficient basis for the Bureau to pursue a new and additional action against her controlled substances registration or deny a pending application for a controlled substances registration, after Dr. Derges has been afforded due process and a conference with the Bureau.

8. Copies of this Settlement Agreement shall be forwarded by the Bureau to the Missouri State Board of Registration for the Healing Arts and to the Federal Drug Enforcement Administration (DEA) in accordance with Section 195.190, RSMo.

9. All costs and expenses incurred by Dr. Derges in complying with this Settlement Agreement shall be the sole responsibility of Dr. Derges, and shall in no way be the obligation of the Missouri Department of Health and Senior Services. Dr. Derges hereby waives and releases the Department, and any of its employees, agents, or attorneys, including any former Department employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees costs and expenses, and compensation, including, but not limited to any claims for attorney's fees and expenses, including any

claims pursuant to Section 536.087, RSMo, or any claim arising under 42 USC 1983, which may be based upon, arise out of, or relate to any of the matters raised in this agreement, or from the negotiation or execution of this agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this agreement in that it survives in perpetuity even in the event that any court of law deems this agreement or any portion thereof void or unenforceable.

Patricia Derges, A.P.

Michael R. Boeger, Administrator
on behalf of the Missouri Department of Health and Senior Services, Bureau of Narcotics and Dangerous Drugs.

1-27-22
Date

1/28/22
Date