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# SETTLEMENT AGREEMENT

## SECTION ONE

Come now the Knox County Ambulance District (hereinafter the District), and the Missouri Department of Health and Senior Services', Bureau of Narcotics and Dangerous Drugs (hereinafter the Bureau) and enter into this Agreement for the purpose of resolving the question of whether the District's application for a new Missouri Controlled Substances Registration is subject to denial or whether a registration is subject to discipline.

The parties understand that this Agreement is in lieu of a trial-type hearing of the Bureau's charges against the District at the Administrative Hearing Commission where the District would have the right to appear and be represented by legal counsel; the right to have all charges proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending and, subsequently, the right to a disciplinary hearing before the Bureau, at which time evidence in mitigation of discipline may be presented; and the right to a claim for attorney's fees and expenses if the District were a prevailing party. Being aware of these rights, the parties knowingly and voluntarily waive each and every one of these rights and agree to abide by the terms of this document, in lieu of proceedings before the Administrative Hearing Commission.

The District acknowledges that they are aware that they may, at the time this Agreement becomes effective, or within 15 days thereafter, submit this Agreement to the Administrative Hearing Commission for determination that the facts agreed to by the parties constitute grounds for discipline of the District's Missouri Controlled Substance Registration.

The District acknowledges that they has been informed of their right to consult legal counsel in this matter.

## SECTION TWO—STATEMENTS OF FACT

The District and the Bureau stipulate to the following facts:

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 2000 for the purpose of administering, executing and enforcing the provisions of Chapter 195, RSMo, the "Comprehensive Drug Control Act."

2. The District currently has Missouri Controlled Substances Registration number 18267 that authorizes the District to conduct activities with controlled substances. This current registration is set to expire on February 29, 2017, and the District has an application pending for a new registration.

3. The prior District Administrator R.H. was able to engage in activities that were not known to the District Board. There were lapses in oversight by the District and also actions by R.H. that were misleading to the District. Examples are:
   - Controlled substances were purchased in excessive amounts for the personal abuse by R.H. The District was not aware of this at the time.
   - R.H. did not maintain complete receipt and purchase records for the drugs.
   - R.H. did not maintain required drug inventories.
   - R.H. was able to control the District checkbook and funds to pay for the drugs.
   - The District Board and Medical Director had not reviewed the actions, billing invoices, and other documents of R.H. that could have identified the issues.
   - Drug vials and records were found in the home of R.H. that did not enter the District's offices.
   - District employees state that they have not received training and were not aware of certain laws and requirements for the record keeping and security and reporting for controlled substances.

4. The District did not always maintain receipt records for Schedule IV drugs in their possession. The District did not have complete records of all the diazepam purchased.

5. Section 195.050.6, RSMo 2000 states:

> 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.

6. Regulation 19 CSR 30-1.048(1), states:

> (1) Each individual practitioner, institutional practitioner, and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed, or disposed:
>
> (A) The name of the substance;
>
> (B) Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml) vial);
>
> (C) The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;
>
> (D) The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance; and

(E) The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

7. DEA Form 222 Order Forms were not maintained at the registered site as required. Some forms were missing and some forms were found in the residence of an employee.

8. Title 21 CFR 1305.17(a),(c), states:

(a) The purchaser must retain Copy 3 of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

* * *

(c) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under § 1305.12(e)), at the registered location printed on the DEA Form 222.

9. The District has lost and missing DEA Order Forms that have not been reported to the DEA as required by law.

10. Title 21 CFR 1305.16, states:

(a) If a purchaser ascertains that an unfilled DEA Form 222 has been lost, he or she must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the DEA Form 222 first executed. A copy of the statement must be attached to Copies 1 and 2 of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face ''Not accepted'' and return Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement.

(b) Whenever any used or unused DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.

(c) If the theft or loss includes any original DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.

(d) If an entire book of DEA Forms 222 is lost or stolen, and the purchaser is unable to state the serial numbers of the DEA Forms 222 in the book, the purchaser must report, in lieu of the numbers of the forms contained in the book, the date or approximate date of issuance.

(e) If any unused DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

11. The District did not maintain a documented annual inventory of controlled substances as required by law. An inventory was first performed on the day of the inspection.

12. Section 195.050.6, RSMo 2000 states:

> 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.

13. Regulation 19 CSR 30-1.042(2)(A),(3), states:

> (2) Initial Inventory Date.
>
> (A) Every person required to keep records who is registered with the Department of Health after May 1, 1971 and who was not registered previously shall take an inventory of all stocks of controlled substances on hand on the date s/he first engages in the manufacture, distribution or dispensing of controlled substances.
>
> (B) Compliance with federal initial inventory date requirements is deemed satisfactory. Duplicate inventories are not required.
>
> (3) Annual Inventory Date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least once a year. The annual inventory may be taken on any date that is within one year of the previous annual inventory date.

14. The District did not report the loss, theft, and diversion of controlled substances to the bureau as required by law.

15. Regulation 19 CSR 30-1.034(2)(B), states:

> (B) A registrant shall notify the Department of Health and Senior Services of the theft, diversion or significant loss of any controlled substances or regulated chemicals upon discovery.

16. The District allowed an unauthorized employee to execute a DEA Form 222 Order Form. The employee did not have a power of attorney form on file at the time of inspection.

17. Title 21 CFR 1305.05, states:

> (a) A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.

(b) A registrant may revoke any power of attorney at any time by executing a notice of revocation.

18. Section 195.050.3, RSMo 2000, states:

> An official written order for any controlled substance listed in Schedules I and II shall be signed in duplicate by the person giving the order or by his or her duly authorized agent. The original shall be presented to the person who sells or dispenses the controlled substance named therein. In event of the acceptance of such order by the person, each party to the transaction shall preserve his or her copy of such order for a period of two years in such a way asto be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter or chapter 579. It shall be deemed a compliance with this subsection if the parties to the transaction have complied with federal laws, respecting the requirements governing the use of order forms.

19. The District did not maintain controlled substance records on a complete, current, and accurate basis. Receipt records, DEA Forms, and inventory documents were missing so that an audit could not be performed to account for all controlled substances.

20. Section 195.050.6, RSMo 2000 states:

> 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.

21. Regulation 19 CSR 30-1.044(1), states:

> (1) Every registrant required to keep records shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by him/her.

22. The District did not maintain all of its controlled substance records at the registered practice location. Some records were found in the home of an employee.

23. Section 195.050.6, RSMo 2000 states:

> 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.

24. Regulation 19 CSR 30-1.041(2), states:

> (2) Maintenance of Records and Inventories.
> Every inventory and other record required to be kept under 19 CSR 30-1.041–19 CSR 30-1.052, shall be kept by the registrant and be available, for at least two years from the date of the inventory or record, for inspecting and copying by authorized employees of the Department of Health, except that financial and shipping records (such as invoices and packing slips, but not

executed order forms) may be kept at a central location rather than at the registered location if the registrant obtains from the Department of Health approval of his/her central record keeping system and a permit to keep central records.

25. The District did not provide adequate security to detect and prevent the theft and diversion of controlled substances. The following are examples of lapses in standard security practices:

A. The former administrator purchased controlled substances that he administered to himself. The following empty vials were found in the home of the former administrator:

150 Empty vials of Meperidine 100mg
140 Empty vials of Morphine 5mg
19 Empty vials of Hydromorphone 2mg
1 Empty vial of Demerol
9 Empty vials of Diazepam

B. The District Board and Medical Director were not providing sufficient supervision and oversight of the administrator. The use of the check book and expenditures was not being reviewed and verified. Drug purchases were not reviewed and compared to what the District normally used on patients. The former manager purchased over ten times what the District would normally use on patients. The former manager did not have complete records to show how or when these drugs were received. DEA purchasing record forms were missing from the District office. A review by the District Board or Medical Director would have revealed the theft and missing records.

C. The theft and missing records went on for approximately three years without detection.

D. The District lost track of hundreds of vials of drugs and an employee was practicing while abusing and addicted to controlled substances.

E. District staff was not familiar with basic controlled substance laws for record keeping and security. The new administrators had not performed inventory requirements and a DEA Order Form was not executed in a legal manner. The District has not submitted a loss or theft report even 9 months after learning of the theft. Missing DEA forms were not reported to the DEA as required. The District staff said they have not received training in these requirements.

F. The District did not remove or revoke the former administrator's power of attorney privileges to purchase drugs. The former manager could still purchase drugs in the District's name until pointed out by the Bureau.

G. The District continued to allow the former administrator to have access to their controlled substances and recordkeeping until the District received additional information from the Bureau.

26. Title 21 CFR 1301.71(a), states in material part:

> (a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

27. 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.

28. Section 195.040.7(4), RSMo, 2000 states:

> 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:
>
> * * *
>
> (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; or

29. In determining whether to issue a new registration, the Bureau is required to consider Section 195.040.3, (1),(2),(4), & (7), RSMo 2000, states:

> 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:
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> (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.

## SECTION THREE—CONCLUSIONS OF LAW

The District and the Bureau stipulate to the following conclusions of law:

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 2000 for the purpose of administering, executing and enforcing the provisions of Chapter 195, RSMo, the "Comprehensive Drug Control Act of 1989."

2. The District did not always maintain complete and accurate controlled substance records for receipt, inventories, at the correct location, in violation of Section 195.050.6, RSMo 2000 and Regulations 19 CSR 30-1.048(1); 19 CSR 30-1.044(1); 19 CSR 30-1.041(2);19 CSR 30-1.042(2)(A)(3) and Title 21 CFR 1305.17(a),(c).

3. The District did not make required reports to regulatory authorities for lost drugs or DEA Forms in violation of Regulation 19 CSR 30-1.034(2)(B) and Title 21 CFR 1305.16.

4. An employee executed a DEA Order Form without power of attorney in violation Section 195.050.3, RSMo 2000, and Title 21 CFR 1305.05.

5. The District did not provide adequate security and controls to guard against the loss or theft of controlled substances in violation of Regulation 19 CSR 30-1.031(1) and Title 21 CFR 1301.71(a)

6. Cause exists to discipline the District's Missouri Controlled Substances Registration pursuant to Section 195.040.7(4), RSMo 2000.

## SECTION FOUR—TERMS OF PROBATION

In light of the foregoing stipulation of facts and in order to provide adequate security against theft and diversion of controlled substances, the District and the Bureau hereby consent and agree that the Bureau shall grant the District a new Missouri Controlled Substances Registration on probation under the following terms:

1. The conditions of this Agreement shall be in effect for three (3) years from the date of execution of this Agreement. After two (2) years of this Agreement, the District may ask the Bureau to conduct an inspection to determine if the Agreement can be terminated early after the two-year period.

2. The District agrees that if the Bureau issues the District a registration, the Bureau shall not be limited to statutory grounds for revocation as set out in Section 195.040.7, RSMo 2000, but may also use the provisions of Sections 195.040.11 and 195.040.3, RSMo 2000, as part of the basis for a proposed revocation, whenever the Bureau has

reason to believe that the District has violated any federal or state controlled substance laws or regulations.

3. Violation of any term of this Settlement Agreement by the District is sufficient basis for the Bureau to pursue a new and additional disciplinary action against the District's Missouri Controlled Substances Registration, or to deny an application by the District for a new Missouri Controlled Substances Registration, after a new investigation, new conference and due process as provided by law.

4. All state licenses and state and federal drug registrations shall be kept current and not allowed to expire.

5. During the time of this Agreement, at least one representative of the District shall attend the Bureau's class on controlled substance record keeping and security.

6. Copies of this Settlement Agreement shall be forwarded by the Bureau to the Department's Bureau for Emergency Medical Services and to the federal Drug Enforcement Administration in accordance with Section 195.190, RSMo. 2000.

7. The District shall not violate any provision of Chapter 195 of the Revised Statutes of Missouri nor any regulation promulgated thereunder.

8. The District shall keep all inventories, documentation and records for all controlled substances ordered, purchased, received, transferred, administered, dispensed, and wasted or otherwise disposed of, in accordance with state and federal laws.

9. All records for controlled drugs shall be open for inspection by representatives of the Department's Bureau of Emergency Medical Services, the federal Drug Enforcement Administration, and by investigators of the Bureau.

10. Within 30 days of the execution of this agreement, the District shall implement a policy and procedure to verify compliance with controlled substance laws. _____ shall provide the Bureau with a copy of this policy. The policies and procedures shall include, but not be limited to the following:

    A. Who may purchase and order controlled substances and execute DEA forms.
    B. By whom and how controlled substances will be received and secured;
    C. Who will add the received controlled substances to the inventory;
    D. Who will double check the controlled substances added to stock against the records for drugs received;
    E. When the annual inventory is due and how it will be completed;
    F. Who may have access to controlled substances;
    G. Procedures for documentation when controlled substances are removed from a cabinet or storage area;

H. Procedures for the documentation of the administration and wastage of controlled substances;

I. A monthly review and report prepared by the Medical Director to insure compliance.

11. At least once each month, the Medical Director shall personally review the following:

A. All purchases and receipts of controlled substances and record keeping;

B. All transfers of controlled substances and record keeping;

C. Records generated by staff for administering controlled substances;

D. The perpetual inventory;

E. The log of inventories for the safe where controlled substances are stocked; and

F. The logs of the staff counting controlled substances on each ambulance at shift change.

G. The transfers of keys during shift changes.

H. The witnessing and documentation pertaining to wastage of controlled substances.

I. The frequency of breakage or leakage reported by staff.

J. The date of annual inventory.

K. The Medical Director and District shall maintain a monthly report that documents the completion of these reviews so that the monthly reports may be inspected.

12. The District, with any partners, shareholders, officers, directors, heirs, assigns, agents, employees, representatives and attorneys do hereby waive and release, acquit and forever discharge the Department of Health and Senior Services, it respective employees, agents and attorneys, including former employees, agents and attorneys, of, or from any liability, claim, actions, causes of action, fees, costs, expenses and compensation, including, but not limited to, any claim for attorney's fees and expenses, whether or not now known or contemplated, including, but not limited to any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which now or in the future may be based upon, arise out of, or relate to any of the matters raised in this case or its litigation or from the negotiation or execution of this Settlement Agreement. The parties acknowledge this paragraph is severable from the remaining portions of the settlement agreement in that it survives in perpetuity even in the event that any court or administrative tribunal deems this agreement or any portion thereof void or unenforceable.

Richard Hopkins, Dreg.
Representative of the District Board

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

2-/24/2017
Date

2/28/17
Date

Ron Buswell Director
Witness

Christina Duncan
Bureau of Narcotics and Dangerous Drugs
Witness

2/24/2017
Date

2/28/17
Date