

Order Compelling Compliance

CLERK'S OFFICE U.S. DISTRICT COURT
AT ABINGDON, VA
FILED

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
ABINGDON**

JUN 08 2022

JULIA C. DUDLEY, CLERK
BY: *[Signature]*
DEPUTY CLERK

IN RE:

Sovah Health)
)
)
)

Case No.

1:22 mc 9

**AGREED ORDER COMPELLING COMPLIANCE
WITH NON-PROSECUTION AGREEMENT**

Sovah Health (Danville Regional Medical Center LLC d/b/a Sovah Health) has been the subject of an investigation concerning potential violations of federal criminal law concerning controlled substances. The United States and Sovah Health (collectively, "the Parties") have entered into an agreement to resolve this matter by way of a Non-Prosecution Agreement ("NPA") attached as Exhibit 1. The Parties agree the Court has (a) jurisdiction over the subject matter, Parties, and NPA, and (b) authority to enter and enforce this order compelling Sovah Health to comply with the terms of the NPA.

Accordingly, based on the agreement of the Parties and for good cause shown, Sovah Health and any successors in interest are hereby ORDERED to fully comply with the terms of the NPA.


The Court may impose any sanction it deems appropriate for any violation of a term of the NPA and/or this Order. Also, any violation of a term of the NPA and/or this Order by Sovah Health or any successor may be punished as contempt of court, including, but not limited to, criminal contempt, in violation of Title 18, United States Code, Section 401.

Attachment 1 to Non-Prosecution Agreement

Authorized Corporate Officer's Initials *[Signature]*

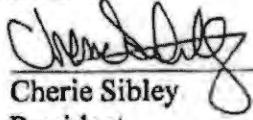
Order Compelling Compliance

Entered this 8th day of June, 2022.


Hon. James P. Jones
Senior United States District Judge

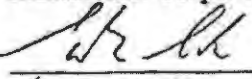
Seen and Agreed to:

Sovah Health

BY: 
Cherie Sibley
President

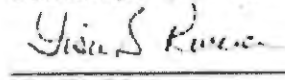
6/7/2022
DATE

Danville Regional Medical Center, LLC (d/b/a Sovah Health)
Authorized Corporate Representative for Sovah Health



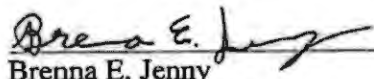
6/7/22
DATE

James M. Cole
SIDLEY AUSTIN LLP
Washington, DC
Counsel for Sovah Health



6/7/22
DATE

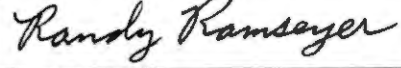
Lisa S. Rivera
BASS, BERRY & SIMS
Nashville, TN
Counsel for Sovah Health



6/7/22
DATE

Brenna E. Jenny
SIDLEY AUSTIN LLP
Washington, DC
Counsel for Sovah Health

Christopher R. Kavanaugh, United States Attorney for the Western District of Virginia:

BY: 
Randy Ramseyer
Abingdon, VA
Assistant United States Attorney

June 8, 2022
DATE

Non-Prosecution Agreement

NON-PROSECUTION AGREEMENT

1. The United States Attorney's Office for the Western District of Virginia ("USAO-WDVA") and Sovah Health (Danville Regional Medical Center LLC d/b/a Sovah Health), pursuant to authority granted by its Board of Directors, enter into this Agreement to resolve a pending investigation of Sovah Health. The subject matter of the investigation is potential violations of controlled substance laws involving the theft and diversion of controlled substances by Sovah Health pharmacy technician Paulette Toller from June 2017 to June 2019 and theft of controlled substances through the adulteration of controlled substances by Sovah Health registered nurse Emilee Poteat from January 2020 to May 2020 (collectively the "Subject Matter").

2. The USAO-WDVA enters into this agreement based on the individual circumstances presented by this case and Sovah Health's acknowledgement of the facts set forth in Addendum A and its commitment to:

- a. Fully comply with all of the obligations set forth in this Agreement;
- b. Agree to the entry of an Order (attached as Attachment 1) requiring Sovah Health to fully comply with the terms of this agreement and be subject to contempt sanctions if it fails to do so; and
- c. Comply fully with the terms of the Civil Settlement Agreement (attached as Attachment 2).

3. Sovah Health agrees it will fulfill all of the obligations set forth in the subparagraphs of Paragraph 2 of this Agreement.

4. The Term of Sovah Health's obligations under this Agreement will be 4 (four) years from the date the Court enters the Agreed Order ("Effective Date"). However, the Term will be extended to include any time during which Sovah Health is not fully complying with all of its commitments, financial and otherwise, set forth in this Agreement.

5. Nothing in this Agreement, the Civil Settlement Agreement, or any related document is an admission by the USAO-WDVA that the amounts paid by Sovah Health are the maximum amounts that could, in the absence of this agreement, be recovered from Sovah Health, nor do these documents constitute an admission by Sovah Health that the amounts paid reflect the financial liability the government could have established at trial. If Sovah Health does not comply with all of its obligations under this Agreement, the USAO-WDVA is not precluded from arguing or presenting

*Exhibit 1 to Consent Order
in re: Sovah Health*

Authorized Corporate Officer's Initials 

Non-Prosecution Agreement

evidence that the total amount to be paid by Sovah Health should be higher, nor is Sovah Health precluded from arguing that the amount should be less or not warranted.

6. Effective beginning not later than the date it signs this agreement, Sovah Health:

- a. Shall abide by all federal, state, and local laws and requirements relating to controlled substances.
- b. Shall allow unlimited access to Sovah Health's controlled substance records, including unannounced inspections by DEA, during hours in which the Sovah Health facility to be inspected is open to the public. Inspections of Sovah Health's controlled substance records which shall be conducted as described in 21 C.F.R. § 1316.08.
- c. Shall permit DEA personnel to enter any Sovah Health facility, during hours in which the facility is open to the public, without an Administrative Inspection Warrant and without prior notification for the purpose of verifying compliance with this Agreement and the Controlled Substances Act (CSA) and its implementing regulations.
- d. Shall maintain all controlled substance records as required by 21 C.F.R. Part 1300 to End. These records must be readily retrievable upon request for inspection by the DEA. Sovah Health is required to maintain these records for two years pursuant to or as required by 21 CFR § 1304.04(a).
- e. Shall install cameras at each Automated Dispensing Machine and appropriately position them to capture the activity of placing/removing controlled substances in/out of the machine. This subparagraph must be complied with by July 1, 2022.
- f. Shall promptly review, by Sovah Health management (Management) (defined to include the Sovah Health Market President, Chief Operating Officer, Chief Nursing Officer, or Pharmacy Director) or a compliance/oversight employee, any discrepancies discovered during an employee's blind count when accessing controlled substances. The software program utilized should monitor which machines and employees have discrepancies, and each discrepancy for those machines and employees shall be reviewed by Management or a compliance/oversight employee. A record of all blind count discrepancies will be maintained, and employees must document what action was taken to resolve discrepancies. A discrepancy report should be generated daily on each business day (Monday through

*Exhibit 1 to Consent Order
In re: Sovah Health*

Authorized Corporate Officer's Initials **CF**

Non-Prosecution Agreement

Friday, excluding holidays) and then reviewed (and reconciled, as needed) by a member of Management or a compliance/oversight employee by the next business day. The review process and any reconciliation steps should also be documented.

- g. Shall maintain reports of disciplinary action taken against employees found to have been responsible for the theft, diversion, or loss of controlled substances. Sovah Health will maintain the reports in an easily accessible manner and produce them to DEA on request.
- h. Shall promptly investigate each potential theft, loss, tampering, or diversion of a controlled substance, and each potential violation of law concerning a controlled substance. Sovah Health will promptly report each potential theft, significant loss, tampering, or diversion of a controlled substance, and each potential violation of law concerning a controlled substance, in writing, to the Virginia State Police and DEA. Such reports will be made not later than one business day from discovery unless it is determined, in the interim, that there was no potential theft, significant loss, tampering, or diversion of a controlled substance, or potential violation of law concerning a controlled substance.
- i. Shall, when it makes a report to an agency that one of its employees has stolen, diverted, or lost a controlled substance or abused or mishandled a controlled substance, promptly send to the Virginia State Police and DEA a copy of the report and the name of the agency to whom such report was made.
- j. Shall promptly notify the Virginia State Police and DEA when Management or the Sovah Health Human Resources Director becomes aware that any Sovah Health employee has been arrested or charged by law enforcement on any charges related to controlled substances. Sovah Health will maintain a policy requiring employees to report such arrests or charges to Management or the Sovah Health Human Resources Director.
- k. Shall conduct a background check of each person who will have access to controlled substances prior to hiring them, and such check will include compliance with the requirements of 21 CFR §§ 1301.90 and 1301.93 and 42 CFR § 424.518. Any information concerning such person relating to criminal convictions, illegal drug use, or adverse licensing issues, shall be shared with the hiring manager and the person's current and each future supervisor.

Non-Prosecution Agreement

- l. Shall not, without obtaining a waiver from the DEA, employ a person who will have access to controlled substances who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause.
- m. Shall maintain a mandatory random drug testing program applicable to any Sovah Health employee with access to controlled substances. Each such employee shall be tested at least once every six months. The dates and the employees chosen for testing shall be determined blindly and randomly. Each test will follow collection steps and procedures to ensure the integrity and security of the collection site, and to ensure that the sample remains unadulterated during and after collection. Any positive test result for a controlled substance, other than a controlled substance taken in accordance with a prescription issued to the employee for a legitimate medical purpose and within the scope of professional practice, shall be reported to human resources, and Sovah Health will make all required reports to licensing agencies (as applicable) and take other employment action as required or reasonably appropriate under applicable law, including any applicable laws and regulations that govern licensed employees.
- n. Shall create and enforce a written policy of progressive discipline as it relates to the violation of Sovah Health's controlled substance policies and procedures, which shall be applicable to all employees with access to controlled substances. Such policy shall be created and in force on or before July 1, 2022.
- o. Shall conduct a full physical inventory annually to represent an actual count of all federally Scheduled II-V controlled substances on hand, consistent with the requirements for a DEA biennial inventory, including what is in the Automated Dispensing Machines and controlled substances vault, witnessed by two individuals. Any discrepancies between the annual count and what should be on hand should be reviewed and reconciled by Management or a compliance/oversight employee. Sovah Health shall provide the results of the inventory to DEA within 24 hours of conducting the inventory. The first such inventory shall be conducted on or before July 1, 2022. An inventory that meets the requirements of this subparagraph, conducted on or after May 15, 2022 and before the date of this agreement, will satisfy the requirement that the first inventory be conducted on or before July 1, 2022.
- p. Shall conduct an accountability audit on a minimum of two Schedule II controlled substance medication formulations per quarter and provide results to DEA within two days of the audit. The beginning inventory number will

Non-Prosecution Agreement

be obtained from the pharmacy's perpetual inventory log and be a date in which a physical count was previously taken in accordance with Virginia Board of Pharmacy regulations (18VAC110-20-240). At the end of the audit period (date chosen by Management but not less than 60 days after the beginning inventory date), another physical count will be conducted. All receipts and dispensations during the two dates will be reviewed in order to ascertain whether all of the audited controlled substances can be accounted for.

- q. Shall conduct, annually, a self-evaluation to review compliance with all requirements of the Controlled Substances Act, the regulations issued under the Act, and this Agreement. At the completion of each evaluation, the Pharmacist in Charge or the DEA-designated person at the registrant will certify that he/she has completed the evaluation and document any corrective action to be taken. Sovah Health will retain the letters of certification, and make them available to the DEA upon request, for two years following the expiration of this agreement. The first such self-evaluation shall be conducted on or before July 1, 2022.

7. Sovah Health must notify the USAO as soon as reasonably practicable, in writing, of any event (including, but not limited to, sale, merger, dissolution, etc.) that would jeopardize its ability to pay any amounts under this Agreement or the Civil Settlement Agreement. If an adverse event (including, but not limited to, sale, merger, dissolution, etc.) would jeopardize Sovah Health's ability to pay any amounts under this Agreement, or if any payment would cause Sovah Health to either (a) violate an existing debt covenant for which the holder(s) will not forbear, forgive or otherwise extend, or (b) incur a negative going concern or viability assessment by its auditors as required by any applicable domestic or foreign corporate governance code, accounting standard or related rule or regulation, Sovah Health shall notify the USAO as soon as reasonably practicable.

8. Sovah Health represents and warrants that it has reviewed its financial situation, it currently is not insolvent as such term is defined in 11 U.S.C. § 101(32), and it reasonably believes it shall remain solvent following payment of the financial obligations set forth in this Agreement. Further, the parties warrant that, in evaluating whether to execute this Agreement, they have (a) intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Sovah Health, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to, and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Sovah Health was or became indebted to on or after the Agreement Date, within the meaning of 11 U.S.C.

Exhibit 1 to Consent Order
In re: Sovah Health

Authorized Corporate Officer's Initials: *EL*

Non-Prosecution Agreement

§548(a)(1). Sovah Health agrees its obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Sovah Health shall not argue or otherwise take the position in any such case, action, or proceeding that (1) Sovah Health's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (2) Sovah Health was insolvent at the time this Agreement was entered into; or (3) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Sovah Health. Sovah Health acknowledges that the agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement. Sovah Health agrees all amounts payable under this agreement are not dischargeable in bankruptcy and shall be considered debt for a fine, penalty, or forfeiture payable to and for the benefit of a governmental unit pursuant to 11 U.S.C. § 523(a)(7).

9. Sovah Health will fully cooperate with all investigations and prosecutions, if any, by the Department of Justice related, in any way, to controlled substances.

10. Sovah Health will execute and transmit all documents needed to effectuate the terms of this Agreement.

11. Sovah Health will not, through its present or future directors, officers, employees, or agents; (1) make any public statement or (2) make any statement or take any position in litigation in which any United States department or agency is a party, contradicting any statement or provision set forth in the Agreement or its attachments. For the purposes of this paragraph, the term "public statement" means any statement made or authorized by Sovah Health's directors, officers, employees, or attorneys and includes, but is not limited to, a statement in (1) a press release, (2) public relations material, or (3) Sovah Health's websites. Sovah Health shall be granted a period of 24 hours from the time of being notified of a breach of this provision, to cure or repudiate any public statement that may violate this provision. Notwithstanding the above, Sovah Health may avail itself of any legal or factual arguments available in defending litigation brought by a party other than the United States. This paragraph does not apply to any statement made by any individual in the course of any actual or contemplated criminal, regulatory, administrative, or civil case initiated by any governmental or private party against such individual. This paragraph also does not prevent Sovah Health Danville from taking the position that it did not violate the Agreement and presenting relevant evidence in any proceeding with the United States.

12. Sovah Health agrees if, during the Term, it undertakes any material change in corporate form, including if it sells, merges, or transfers any portion of its business operations material to Sovah Health's consolidated operations as they existed as of January 1, 2021, whether such change is structured as a sale, asset sale, merger, transfer, or other material change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the

Exhibit 1 to Consent Order
In re: Sovah Health

Authorized Corporate Officer's Initials: *CA*

Non-Prosecution Agreement

purchaser, or any successor in interest thereto, to the obligations described in this Agreement unless the USAO-WDVA otherwise agrees in writing. Sovah Health shall provide notice to the USAO-WDVA at least 30 (thirty) days prior to undertaking any such sale, merger, transfer, or other change in corporate form. Nothing herein shall restrict Sovah Health from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the USAO-WDVA.

13. If, throughout the Term, Sovah Health fully complies with this Agreement, the USAO-WDVA agrees it will not bring criminal charges (except as to potential criminal tax violations, as to which the Government makes no agreement) based on the Subject Matter.

14. Notwithstanding any other provision of this Agreement, if the USAO-WDVA, in its sole discretion, determines Sovah Health (a) provided deliberately false, incomplete, or misleading information at any time in connection with this Agreement; (b) committed a felony during the Term; or (c) knowingly and intentionally violated any provision of this Agreement, (1) the USAO-WDVA will not be bound by its agreement not to prosecute Sovah Health for matters relating to the Subject Matter, (2) Sovah Health will not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other rule or law, that any statements or testimony made by or on behalf of Sovah Health prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed or are otherwise inadmissible, and (3) the USAO-WDVA may file any charges which could have been filed against Sovah Health relating to the Subject Matter. Sovah Health, aware of its rights concerning statutes of limitation, agrees any prosecution not time-barred by the applicable statute of limitations on the Effective Date of this Agreement may be commenced against Sovah Health in the event of its violation of a provision of this Agreement (this statute of limitations tolling provision only applies to a prosecution brought by the USAO-WDVA within one year and one month of the USAO-WDVA providing written notice of a violation as set forth in the following sentence.) Should the USAO-WDVA determine that Sovah Health has violated any provision of this Agreement, the USAO-WDVA shall provide prompt written notice to Sovah Health and provide Sovah Health with a 30 (thirty) day period from the date of receipt of notice in which to make a presentation to the USAO-WDVA to demonstrate that no violation occurred, that any violation was unintentional or inadvertent, or, to the extent applicable, that the violation should not result in adverse action, including because the violation has been cured by Sovah Health.

Non-Prosecution Agreement

15. Sovah Health agrees to the entry of an order of the Court (attached as Attachment 1) in which Sovah Health is ordered to comply with the terms of this Agreement and be subject to, in addition to the other remedies available in this Agreement, the jurisdiction of the Court whether for a proceeding that could result in contempt or any other remedy the Court deems appropriate should it fail to comply with any term of the Agreement. For the purposes of a dispute over an alleged violation of the Agreement, a determination by the USAO-WDVA that Sovah Health failed to comply with a term of the agreement shall not be binding on the Court. Sovah Health agrees nothing will divest the Court of jurisdiction, including, but not limited to, any proceeding relating to bankruptcy, insolvency, reorganization, or relief of debtors.

16. Sovah Health shall comply with (a) the FDCA, as amended, and implementing regulations governing the manufacture, marketing, sale, promotion, and distribution of drugs in the United States, (b) the Controlled Substances Act, as amended, and implementing regulations, and (c) Title 18, United States Code, Section 1365.

17. This Agreement binds the United States Attorney's Office for the Western District of Virginia. Notwithstanding the foregoing, it does not bind the Tax Division of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities.

18. Sovah Health waives all rights, whether asserted directly or by a representative, to request or receive from the United States Department of Justice, United States Food and Drug Administration – Office of Criminal Investigations, United States Drug Enforcement Administration, and Virginia State Police any records pertaining to the investigation or prosecution of this case, including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, the Privacy Act of 1974, 5 U.S.C. § 552a, or the Virginia Freedom of Information Act, Va. Code § 2.2-3700- 3714.

19. Under no circumstances will any money paid pursuant to this agreement or the related civil settlement be returned to Sovah Health. However, if Sovah Health violates this agreement and is convicted of a crime based on the Subject Matter, the United States will recommend that the court consider the payments made pursuant to the civil settlement agreement in fashioning an appropriate monetary penalty.

20. Nothing in this Agreement resolves, in any way, any liability of any individual.

21. This Agreement, its Addendum A, and Attachments 1 and 2 set forth all the terms of the agreement between Sovah Health and the USAO-WDVA. No

*Exhibit 1 to Consent Order
In re: Sovah Health*

Authorized Corporate Officer's Initials *CS*

Non-Prosecution Agreement

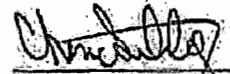
amendments, modifications, or additions to this Agreement will be valid unless they are in writing signed by the USAO-WDVA and an attorney for Sovah Health.

22. Sovah Health acknowledges its acceptance of this Agreement by the signature of its counsel and Officer(s). A copy of a resolution authorizing the Officer(s) to execute this Agreement and all other documents to resolve this matter on behalf of Sovah Health is attached as Addendum B.

Agreed to:

Sovah Health

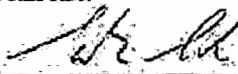
BY:


Cherie Sibley
President


6/7/2022
DATE

Danville Regional Medical Center, LLC (d/b/a Sovah Health)
Authorized Corporate Representative for Sovah Health


Counsel has fully explained to the Board of Directors of Sovah Health the facts and circumstances of the prosecution and the consequences of entering into this Agreement. Counsel has reviewed this entire Agreement and documents referenced herein with the client, through its Officer. Sovah Health understands the terms and conditions of this Agreement, and Sovah Health's decision to enter into this Agreement is knowing and voluntary. Sovah Health's execution of and entry into this Agreement is done with Counsel's consent.


James M. Cole
SIDLEY AUSTIN LLP
Washington, DC
Counsel for Sovah Health

6/6/22
DATE


Lisa S. Rivera
BASS, BERRY & SIMS
Nashville, TN
Counsel for Sovah Health

6/6/22
DATE


Brenna E. Jenny
SIDLEY AUSTIN LLP
Washington, DC

6/7/22
DATE

Authorized Corporate Officer's Initials: 

Non-Prosecution Agreement

Counsel for Sovah Health

*Exhibit F in Consent Order
In re: Sovah Health*

Authorized Corporate Officer's Initials:

Handwritten initials, possibly "CJ", in black ink.

Non-Prosecution Agreement

Christopher R. Kavanaugh, United States Attorney for the Western District of Virginia:

BY: *Randy Ramseyer*
Randy Ramseyer
Abingdon, VA
Assistant United States Attorney

June 8, 2022

DATE

*Addendum A to Non-Prosecution Agreement
Sovah Health*

Agreed Facts

ADDENDUM A

AGREED FACTS

1. Sovah Health is a regional health care delivery system comprised of a hospital with two campuses - Danville and Martinsville. In 2017, Danville (formerly Danville Regional Medical Center) and Martinsville (formerly Memorial Hospital of Martinsville & Henry County) united to form Sovah Health.
2. Paulette Toller was a pharmacy technician at Sovah Health's Danville hospital (Sovah Health - Danville). From June 2017 to June 2019, Toller diverted and stole more than 11,000 Schedule II controlled substances and more than 1,900 Schedule III and IV controlled substances from Sovah Health - Danville, exploiting a flaw in Sovah Health's computer system used to track controlled substances. Each time Toller diverted and stole controlled substances, she would enter the necessary information in Sovah Health - Danville's computer system and indicate certain controlled substances were to be moved from the central controlled substance storage location to a location that was in the system but that no longer was used by Sovah Health - Danville. As with all transfers of controlled substances, a form was generated and printed with a sequential serial number. Such forms were required to be signed by two witnesses and returned and saved by Sovah Health - Danville. In the instances when Toller diverted medications, she destroyed the forms and did not place the forms in the location where such forms were to be saved. During the time period of Toller's diversion at Sovah Health - Danville:
 - a. No full physical inventory was conducted of Sovah Health - Danville's controlled substances which would have identified Toller's theft and diversion of controlled substances which she accomplished by exploiting the fact that a non-utilized location remained in the computer system.
 - b. Access to the pharmacy was controlled with a key card. In addition, because of the heightened risk of diversion of controlled substances, a key card was required to enter the controlled substances room within the pharmacy. However, a number of employees stated that the controlled substances room door was often propped open, defeating the requirement that a key card be used to access the room.
 - c. Every time controlled substances were dispensed, a form was created with a sequential serial number. Each form was stored in one of two binders - one for Schedule II controlled substances and one for all other controlled substances. No procedure was in place to ensure that forms were not

*Exhibit 1 (Addendum A) to Consent Order
In re: Sovah Health*

Authorized Corporate Officer's Initials



*Addendum A to Non-Prosecution Agreement
Sovah Health*

Agreed Facts

missing, such as checking the sequential serial numbers on the forms in the two binders to see if a number was missing.

- d. To prevent diversion, each transfer is required to be witnessed by someone other than the person who was making the transfer. The witness is required to sign the transfer form. However, no one reviewed the transfer forms to determine if the transfers had, in fact, been witnessed. Several forms indicate transfers were not witnessed as they bear no signature of a witness.
3. Emilee Poteat was a registered nurse who worked at Sovah Health – Danville. From January 2020 through May 2020, Poteat, on a daily basis (according to her), at Sovah Health – Danville, tampered with Schedule II controlled substances -- fentanyl vials and hydromorphone injectables and stole the active ingredients. Poteat used a syringe to remove the controlled substances from their containers and, again using a syringe, replaced the controlled substances with saline. The tampered vials and injectables were then available to be administered by Sovah Health – Danville personnel to patients. Although no patient harm was reported, during the time period in which Poteat was tampering with drugs, Sovah Health employees administered medications to patients, even after seeing signs on some of the containers of possible tampering.

*Exhibit 1 (Addendum A) to Consent Order
In re: Sovah Health*

Authorized Corporate Officer's Initials



Civil Settlement Agreement

SETTLEMENT AGREEMENT

This Settlement Agreement (the "Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the United States Drug Enforcement Administration ("DEA") (collectively the "United States"), and Danville Regional Medical Center, LLC, d/b/a SOVAH Health Danville ("SOVAH Danville"), (hereinafter collectively referred to as "the Parties"), through their authorized representatives.

Recitals

A. SOVAH Danville is a hospital system and a Virginia company with its principal place of business in Danville, Virginia. SOVAH Danville conducts business in Danville, Virginia, by dispensing prescription drugs, including controlled substances, patients in both an inpatient and outpatient setting. SOVAH Danville, at all times relevant to the Covered Conduct discussed herein, was registered with the DEA and is assigned a unique DEA registration number that authorized the pharmacy to dispense controlled substances pursuant to the provisions of the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.* ("the CSA"), and its implementing regulations.

B. The DEA is the component agency of the United States Department of Justice primarily responsible for administering the CSA and is responsible for investigating violations of the Act. The CSA regulates persons and companies that manufacture, distribute and dispense controlled substances in order to prevent diversion, and the CSA aims to protect the public's health and safety from dangers posed by highly addictive or dangerous controlled substances that are diverted into the illicit market, while also ensuring that patients have access to pharmaceutical controlled substances for legitimate medical purposes. Entities that dispense controlled

Civil Settlement Agreement

substances are required to have a valid DEA registration number and are referred to as "registrants." Among other preventive measures, DEA registrants must comply with various recordkeeping requirements. Remedies resulting from violations of the CSA or its regulations (21 C.F.R. § 1300.01 *et seq.*) include civil penalties.

C. SOVAH Danville acknowledges that, at all times relevant to the Covered Conduct discussed herein, it was required to comply with the CSA and the regulations promulgated thereunder.

D. The United States contends that it has certain civil and/or administrative claims under the CSA and its implementing regulations against SOVAH Danville. Specifically, the United States contends that, between 2017 and 2020, SOVAH Danville violated the CSA and its implementing regulations, including without limitation by:

- Unlawfully dispensing a controlled substance in violation of 21 U.S.C. § 842(a)(2), as well as 21 C.F.R. § 1305.15, on at least 502 occasions.
- SOVAH Danville failed to provide effective controls and procedures to guard against diversion of controlled substances in violation of 21 U.S.C. § 823, as well as 21 C.F.R. § 1301.71(a);
- SOVAH Danville filed orders for controlled substances without designing and operating a system to disclose suspicious orders of controlled substances in violation of 21 U.S.C. § 832(a)(1), as well as 21 C.F.R. § 1301.74(a)-(b); and
- SOVAH Danville failed to maintain readily retrievable records of controlled substances in violation of 21 U.S.C. § 827(b), as well as 21 C.F.R. § 1304.4(h).

The United States' claims and allegations against SOVAH Danville under the CSA and its implementing regulations also incorporate by reference the Agreed Facts attached as Addendum

A. All of the information as set forth above in this Paragraph D as well as in Addendum A shall

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hereinafter be referred to as the "Covered Conduct."

E. This Agreement is neither an admission of liability by SOVAH Danville, nor a concession by the United States that its claims are not well founded. Nothing in this Agreement is an admission by the United States that the amounts paid by SOVAH Danville are the maximum amounts that could, in the absence of this Agreement, be recovered from SOVAH Danville, nor does this Agreement constitute an admission by SOVAH Danville that the amounts paid reflect the financial liability the government could have established at trial.

F. To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant to the Terms of Agreement below.

Terms of Agreement

1. SOVAH Danville shall pay the United States Four Million Three Hundred Sixty-Six Thousand Dollars (\$4,366,000.00) (the "Settlement Amount"), which shall be paid no later than fourteen (14) business days after the Effective Date of this Agreement. Payment of the Settlement Amount shall be by electronic funds transfer in accordance with written instructions from the Office of the United States Attorney.

2. Subject to the exceptions in Paragraph 5 (concerning excluded claims) herein, and conditioned upon SOVAH Danville's full payment of the Settlement Amount under this agreement, the United States releases SOVAH Danville from any civil or administrative claim the United States has for the Covered Conduct.

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3. This Agreement in no way alters or restricts the United States' right to enforce the CSA and regulations promulgated thereunder by commencing an administrative or civil action against SOVAH Danville for any conduct that does not arise from the Covered Conduct or that occurs after the Effective Date of this Agreement. Nothing in this Agreement, however, waives or limits SOVAH Danville's right or ability to raise any defenses to such an action.

4. The obligations imposed upon SOVAH Danville pursuant to this Agreement are in addition to, and not in derogation of, obligations imposed upon SOVAH Danville pursuant to any federal, state or local law, including without limitation the CSA and the regulations promulgated thereunder.

5. Notwithstanding the releases given in Paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released by this Agreement:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals.

6. SOVAH Danville fully and finally releases the United States, its agencies,

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employees, servants, and agents from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) which SOVAH Danville could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct, or arising from the United States' investigation and resolution of claims based upon the Covered Conduct.

7. SOVAH Danville waives and shall not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

8. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity.

10. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

11. Each party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

12. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District

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Court for the Western District of Virginia. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

13. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

14. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

15. This Agreement shall become final and binding only upon signing by all parties hereto.

16. This Agreement may be executed in one or more counterparts, each of which shall constitute an original and all of which shall together constitute one and the same agreement, and for purposes of this agreement, facsimile signatures shall be treated as equivalent to originals.

17. This Agreement is binding on SOVAH Danville's successors, transferees, heirs, and assigns.

18. The Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

19. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date" of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

Civil Settlement Agreement

Dated: _____

CHRISTOPHER R. KAVANAUGH
United States Attorney



Digitally signed by
JUSTIN LUGAR
Date: 2022.06.08
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Justin M. Lugar
Assistant United States Attorney
310 1st Street SW, Room 906
Roanoke, VA 24011
Counsel for the United States

Dated: _____

JAROD FORGET

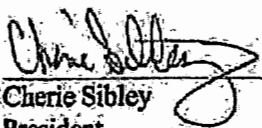
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JAROD FORGET
Date: 2022.06.08
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Jarod A. Forget
Special Agent in Charge
Washington, DC Division
Drug Enforcement Administration
800 K Street, N.W.
Suite 500
Washington, DC 20001


Civil Settlement Agreement

Dated: 6/7/22

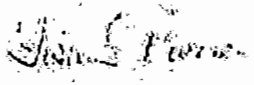
SOVAH Danville
142 South Main Street
Danville, VA 24541


Cherie Sibley
President
Danville Regional Medical Center, LLC
(d/b/a Sovah Health)
Authorized Corporate Representative for
SOVAH Danville

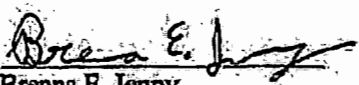
Dated: 6/16/22


James M. Cole
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Dated: 6/16/22


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Dated: 6/17/22


Brenna E. Jenny
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Counsel for SOVAH Danville

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ADDENDUM A

AGREED FACTS

1. Sovah Health is a regional health care delivery system comprised of a hospital with two campuses - Danville and Martinsville. In 2017, Danville (formerly Danville Regional Medical Center) and Martinsville (formerly Memorial Hospital of Martinsville & Henry County) united to form Sovah Health.
2. Paulette Toller was a pharmacy technician at Sovah Health's Danville hospital (Sovah Health – Danville). From June 2017 to June 2019, Toller diverted and stole more than 11,000 Schedule II controlled substances and more than 1,900 Schedule III and IV controlled substances from Sovah Health – Danville, exploiting a flaw in Sovah Health's computer system used to track controlled substances. Each time Toller diverted and stole controlled substances, she would enter the necessary information in Sovah Health – Danville's computer system and indicate certain controlled substances were to be moved from the central controlled substance storage location to a location that was in the system but that no longer was used by Sovah Health – Danville. As with all transfers of controlled substances, a form was generated and printed with a sequential serial number. Such forms were required to be signed by two witnesses and returned and saved by Sovah Health – Danville. In the instances when Toller diverted medications, she destroyed the forms and did not place the forms in the location where such forms were to be saved. During the time period of Toller's diversion at Sovah Health – Danville:
 - a. No full physical inventory was conducted of Sovah Health – Danville's controlled substances which would have identified Toller's theft and diversion of controlled substances which she accomplished by exploiting the fact that a non-utilized location remained in the computer system.
 - b. Access to the pharmacy was controlled with a key card. In addition, because of the heightened risk of diversion of controlled substances, a key card was required to enter the controlled substances room within the pharmacy. However, a number of employees stated that the controlled substances room door was often propped open, defeating the requirement that a key card be used to access the room.
 - c. Every time controlled substances were dispensed, a form was created with a sequential serial number. Each form was stored in one of two binders – one for Schedule II controlled substances and one for all other controlled substances. No procedure was in place to ensure that forms were not missing, such as checking the sequential serial numbers on the forms in the two binders to see if a number was missing.
 - d. To prevent diversion, each transfer is required to be witnessed by someone other

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than the person who was making the transfer. The witness is required to sign the transfer form. However, no one reviewed the transfer forms to determine if the transfers had, in fact, been witnessed. Several forms indicate transfers were not witnessed as they bear no signature of a witness.

3. Emilee Poteat was a registered nurse who worked at Sovah Health – Danville. From January 2020 through May 2020, Poteat, on a daily basis (according to her), at Sovah Health – Danville, tampered with Schedule II controlled substances -- fentanyl vials and hydromorphone injectables and stole the active ingredients. Poteat used a syringe to remove the controlled substances from their containers and, again using a syringe, replaced the controlled substances with saline. The tampered vials and injectables were then available to be administered by Sovah Health – Danville personnel to patients. Although no patient harm was reported, during the time period in which Poteat was tampering with drugs, Sovah Health employees administered medications to patients, even after seeing signs on some of the containers of possible tampering.