

SETTLEMENT AGREEMENT

PARTIES

This Agreement is made and entered into this 22nd day of October, 2010, by and between the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania, and the Drug Enforcement Administration ("DEA") (collectively the "United States"); and Temple University Health System ("TUHS") for itself and on behalf of its affiliated hospitals, Jeanes Hospital and Temple University Hospital, Inc., and affiliated hospitals which are now closed, Temple East, Inc., d/b/a/ Northeastern Hospital, and Temple University Children's Medical Center, and their successors and assigns, and each of their respective officers, directors, and employees (collectively the "Hospitals") to settle civil claims asserted by the United States under 21 U.S.C. sections 841, 842 and 843 (collectively, the "Statutes").

RECITALS

1. TUHS is a private, not-for-profit, tax exempt corporation created in 1995 and is the sole member of the Hospitals. Its principal place of business is 2450 West Hunting Park Avenue, Philadelphia, Pennsylvania.
2. Temple University Hospital owns and operates a medical facility with its principal place of business located at 3401 N. Broad Street, Philadelphia, Pennsylvania. Temple University Hospital is licensed to operate pharmacies at 3401 N. Broad Street, Philadelphia, Pennsylvania (DEA registration number BT4870780 with an expiration date of November 30, 2010), as well as at its locations at the Boyer Pavilion (previously the Temple University Children's Medical Center) located at 3509 N. Broad Street, Philadelphia, Pennsylvania (previous DEA registration number BT5794931, registration is now retired), its

medical facility located at 100 E. Lehigh Avenue, Philadelphia, Pennsylvania, known as the Temple University Hospital Episcopal Campus (DEA registration number BT7223631 with an expiration date of November 30, 2012), and at the Northeastern Ambulatory Care Center (previously the Northeastern Hospital with retired DEA registration number AN4254126) located at 2301 East Allegheny Avenue, Philadelphia, Pennsylvania (current DEA registration number FT1483077 with an expiration date of November 30, 2011). Jeanes Hospital is licensed to operate pharmacies at 7600 Central Avenue, Philadelphia, Pennsylvania (DEA registration number BJ4863191 with an expiration date of December 31, 2010).

3. The Hospitals are required to operate their respective facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act (“CSA”), 21 U.S.C. § 801 et seq.

4. The Drug Enforcement Administration (“DEA”) is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating alleged violations of the CSA.

5. The Attorney General, through the United States Attorney for the Eastern District of Pennsylvania, has primary authority to bring civil actions to enforce the CSA in this district. See 21 U.S.C. § 871; see also 28 C.F.R. § 0.55 (c).

6. On or about November 2, 2004, DEA agents arrested Temple University Hospital’s then-Chief Resident of Anesthesiology for selling sixty vials of Ketamine, a schedule III controlled substance to a DEA undercover informant. A subsequent search of the then-Chief Resident’s residence revealed forty-seven (47) vials of Ketamine, eight (8) vials of Fentanyl, eleven (11) vials of Midazolam, and one (1) vial of Morphine.

7. Following this arrest and the suspected drug diversion from Temple University Hospital, DEA investigators, pursuant to 21 U.S.C. § 822(f), conducted an administrative audit and investigation of Temple University Hospital in November 2004 (Audit Period: June 1, 2004 through November 17, 2004). Temple University Hospital cooperated in this administrative audit. This audit and investigation revealed alleged discrepancies, including the following:

- a. Inventory conducted by DEA revealed that Temple University Hospital had no dispensing records for some schedule III-V controlled substances. These controlled drugs could be taken by Temple University Hospital employees without documentation as to who took them and for what the drug was needed.
- b. Forty-three DEA-222 schedule II Order Forms did not include the required notation regarding the number of packages received by Temple University Hospital Pharmacy and the date received.
- c. Temple University Hospital's Pharmacy failed to note the required date of receipt of schedule III-V controlled substance purchase orders and invoices and further failed to verify the amount of incoming controlled substances on the invoice.
- d. The closing inventory of schedule II-V controlled substances was inaccurate.

8. In addition, in January and February of 2007, an anesthesiologist working at Jeanes Hospital bypassed the computerized distribution system and removed thirty-five (35) vials of Fentanyl and five (5) vials of Morphine for his personal use. In March 2007, Jeanes Hospital personnel detected this theft, suspended the physician from the medical staff, and notified both DEA and the Philadelphia Police.

9. After the 2007 discovery of the anesthesiologist's theft from Jeanes Hospital, DEA conducted administrative audits and issued reports for the following TUHS-affiliated medical facilities, each of which cooperated in these administrative audits:

- **Jeanes Hospital, (Audit Period: January 1, 2007 through April 3, 2008);**
- **Temple University Children's Medical Center (now the Boyer Pavilion), (Audit Period: December 14, 2007 through June 4, 2008);**
- **Episcopal Hospital (now the Temple University Hospital – Episcopal Campus), (Audit Period: December 4, 2006 through June 4, 2007); and**
- **Northeastern Hospital (now the Northeastern Ambulatory Care Center), (Audit Period: January 21, 2007 through June 4, 2007).**

These audits revealed additional alleged CSA record-keeping and reporting discrepancies.

10. As a result of the thefts referenced in paragraphs 6 and 8, and the DEA investigations and administrative audits referenced in paragraphs 7 and 9, the United States contends that the Hospitals committed multiple violations of the record-keeping and reporting provisions of the CSA Statutes and related regulations pertaining to the receipt, purchase, handling, dispensing, administration, security, and storage of controlled substances for which a record was required to be created, kept or maintained.

11. At all times relevant to the activity alleged in these Recitals, the CSA (21 U.S.C. § 842(c)(1)), authorized a civil penalty of up to \$10,000 for each violation of the Section.

12. Over time, as a part of planned upgrades in narcotics controls and in response to the thefts and audits, the Hospitals voluntarily initiated and have implemented substantial changes to their Pyxis system and processes, some of which are described in Exhibit A (Hospitals Pyxis Process Summary).

13. For purposes of this Settlement Agreement, the Covered Conduct is (1) the thefts of controlled substances described in paragraphs 6 and 8; and (2) all recordkeeping and other violations of the CSA and related regulations by the individual hospitals, during their respective audit periods as stated in paragraphs 7 and 9, pertaining to the receipt, purchase, handling, dispensing, administration, security and storage of controlled substances, and failure to create and/or maintain adequate records.

14. To avoid the delay, expense, inconvenience and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims that the United States may have under the CSA and related regulations against TUHS and its affiliated hospitals, arising from the Covered Conduct described in paragraph 13. This Agreement is neither an admission of liability by TUHS or the Hospitals, nor is it a concession by the United States that its claims are not well founded. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement the Parties agree as follows:

TERMS OF AND CONDITIONS

15. TUHS, for itself and on behalf of its affiliated Hospitals, will pay to the United States a total of One Hundred Thirty Thousand Dollars (\$130,000.00) (the "Settlement Amount") in the following manner:

a. Form of Payment: The payment will be made by electronic funds transfer pursuant to instructions provided to TUHS's counsel by the U.S. Attorney's Office, 615 Chestnut Street, Suite 1250, Philadelphia, PA 19106.

b. Timing of Payment: TUHS shall make the full payment of \$130,000 within thirty (30) days of the execution of this Agreement.

16. In addition to the monetary payment in ¶ 15, the Hospitals represent that they will continue to employ their best efforts, including but not limited to initiation of such remedial and curative actions as are necessary, so that the types of alleged events that gave rise to this Agreement do not recur in the future. In particular, the Hospitals will continue to follow all measures included in Exhibit A and will implement the Compliance Assessment Plan detailed in Exhibit B, both of which are incorporated into this Agreement. TUHS and/or the Hospitals will jointly hire an independent consultant to implement the Compliance Assessment Plan. The Compliance Assessment Plan takes into account the changes that the Hospitals have implemented, as summarized in Exhibit A. The Hospitals will implement any reasonable remedial measures that the independent consultant recommends to identify and prevent drug diversion. If the Hospitals decline to implement any such recommendations made by the independent consultant, they will submit a report documenting their reasons to DOJ and DEA no later than 30 days after receiving the recommendations. If DOJ/DEA disagree with the Hospitals' position, the parties will engage in 30 days of informal dispute resolution. If the parties cannot resolve their dispute, they may pursue their remedies as set forth in paragraph 22 of this Agreement.

17. In consideration of the undertakings by TUHS and the Hospitals, the United States agrees to settle and relinquish all civil and administrative claims (other than mandatory exclusion) it has or may have under the CSA and all related regulations, against TUHS, the Hospitals, divisions, affiliates, successors or assigns and their respective officers, directors, and employees, arising from the Covered Conduct described in paragraph 13.

18. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and terms as to any entity or person are the following: a) any

potential criminal liability; b) any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service); c) any administrative liability, not arising from the covered conduct described in paragraph 13, including mandatory exclusion from any federal programs; d) any liability to the United States for any conduct other than that covered by the release in paragraph 17; and e) any claims based on such obligations as are created by this Agreement.

19. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the United States' right to enforce the CSA and regulations promulgated thereunder by commencing a civil or administrative action against TUHS or any of its Hospitals, divisions, affiliates, successors or assigns for violations of the CSA unrelated to the Covered Conduct described in paragraph 13 of this Agreement or which occur after the effective date of this Agreement.

20. TUHS agrees that any and all costs it has or will incur in connection with this matter - - including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action - - shall be unallowable costs for government contract accounting and for Medicare, Medicaid, CHAMPUS, and FEHBP reimbursement purposes.

21. This Agreement is not intended by the Parties, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

22. This Agreement shall be governed by the laws of the United States and the Commonwealth of Pennsylvania. Exclusive jurisdiction and venue for any dispute arising under this Agreement shall be the United States District Court for the Eastern District of Pennsylvania.

23. The Parties agree that this Agreement does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact.

24. This Agreement constitutes the entire agreement between the Parties, and cannot be amended, except in writing and signed by all the Parties to this Agreement.

25. TUHS acknowledges that its authorized representatives have read this Agreement and understand that as of its effective date, it will be a matter of public record.

26. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so. The DEA personnel signing this agreement are authorized to bind DEA only with respect to administrative matters arising from the covered conduct; all other matters are under the purview of the United States Attorney's Office.

27. This Agreement shall be effective on the date of signing by all the Parties. It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement.

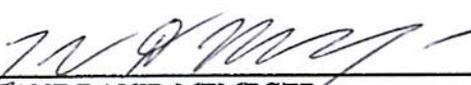
28. TUHS expressly agrees that for purposes of any subsequent proceedings in bankruptcy, the payments made pursuant to this Agreement are penalties and fines pursuant to the Statutes and that such penalties and fines are not compensation for an actual pecuniary loss. TUHS therefore agrees that its liability under this Agreement is non-dischargeable in a bankruptcy pursuant to 11 U.S.C. § 523(a)(7). The parties agree that the United States' claim in any bankruptcy proceeding will be for the full amount of the United States' claim. In the event of any filing for protection under bankruptcy, liquidation, receivership or other insolvency law, TUHS agrees not to contest or oppose any motion filed by the United States seeking relief from the automatic stay imposed by 11 U.S.C. § 362(a), or to seek relief under

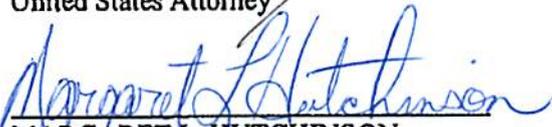
11 U.S.C. § 105 to enjoin or restrain the United States from recovering monies owed arising out of this Agreement or through offset. TUHS recognizes that this express waiver is in consideration for the final settlement of the claims addressed herein. The parties further agree that, in the event of default or bankruptcy, the United States is entitled to declare this Agreement void and to pursue the full amount of its claim.

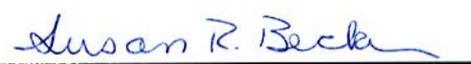
29. TUHS represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever, and that it has had the benefit of an attorney's representation and advice before entering into this agreement.

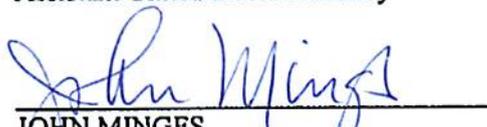
30. This Agreement is binding on each of TUHS's successors, transferees, heirs and assigns.

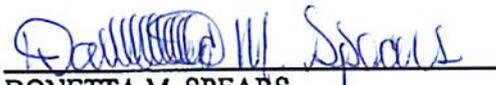
FOR THE UNITED STATES OF AMERICA


ZANE DAVID MEMEGER
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Assistant United States Attorney
Chief, Civil Division

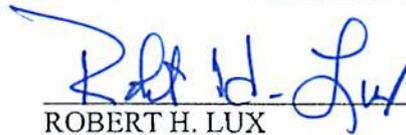

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Division Counsel, Philadelphia

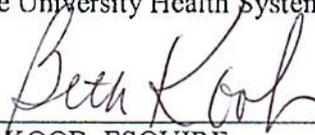

DONETTA M. SPEARS
Drug Enforcement Administration
Diversion Program Manager
Philadelphia Division

Date: 10/22/10

FOR TEMPLE UNIVERSITY HEALTH SYSTEM
For itself and on behalf of its affiliated Hospitals



ROBERT H. LUX
Vice President and Chief Financial Officer
Temple University Health System



BETH KOOB, ESQUIRE
Chief Counsel
Temple University Health System



RONALD H. LEVINE, ESQUIRE
Attorney for Temple University Health System

Date: 10.19.10

Exhibit A

TUHS Pyxis Process Summary

- Every day, every shift, 24/7/365 at each of the 149 Pyxis machines at Temple University Hospital and Jeanes Hospital, a provider must
 - enter a unique PIN and fingerprint for access to narcotics contained in a unit dose or drug drawer,
 - and then must also first perform and enter in the machine a “blind count” of the requested drug.
 - If there is a discrepancy between that count and what should be in that drawer, that event generates a report on the Pyxis machine that is (a) monitored by the nurse manager on the floor each shift, and (b) reviewed by Pharmacy every work day. (c) Moreover, hospital-based executives receive notification of any such discrepancies in reports every work day. (d) Discrepancies are resolved; unresolved discrepancies - however small - are reported to the DEA under TUHS’ zero tolerance policy, consistent with the requirements in 21 C.F.R. 1301.74.
- Every week, two nurses or other licensed providers perform a hard count of all narcotics in every Pyxis machine. The machine has an inventory mode, and reports can be run to verify that the inventory occurred. Any discrepancies must be reconciled by the applicable nursing or anesthesia unit and are monitored by the Pharmacy Administrative Director. If they cannot be resolved, Temple reports them on a DEA 106 form, consistent with the requirements in 21 C.F.R. 1301.74.
- Every month, the hospital pharmacist performs an outlier analysis of all Pyxis users by running a Pandora software Anomalous Usage Report for every Pyxis user. To the extent a particular user of the Pyxis shows usage outside of a standard deviation, a random sample audit of charts for that period is conducted by Nursing or Anesthesia to help to determine if there is a concern raised that must be addressed. Outliers are resolved or reported.
- Every month, a physical hard count of all narcotics in the Pyxis CII safe is conducted by a pharmacist. A record of this inventory is maintained as well. This inventory count is compared to the expected count in the CII safe. Any significant discrepancies that cannot be resolved are reported on a DEA 106 form, consistent with 21 C.F.R. 1301.74.
- The Pyxis CII safe in the pharmacy can only be entered with a pharmacist present; it requires a PIN and a fingerprint for entry; and it too requires a blind count before withdrawal of any drugs. The pharmacist is responsible for those routine CII safe manual counts.

Exhibit B

COMPLIANCE ASSESSMENT PLAN FOR TEMPLE UNIVERSITY HEALTH SYSTEM

Relating To Controlled and Dangerous Substances (CDS)

Phase I: One-time Process Review and Assessment

Facilities to be surveyed:

- Temple University Hospital
- Boyer Pavilion
- Jeanes Hospital
- Northeastern Ambulatory Care Center

- A. **System-wide CDS Review of written Policies and Procedures.**
-review and evaluation of relevant aspects of CDS Policies and Procedures including receipt, storage, inventory, prescribing, preparation, distribution, dispensing, administration, monitoring, record-keeping. Includes comparison to other area teaching hospital CDS Policies and Procedures and American Society of Health Systems Pharmacists (ASHP) Best Practices for CDS.
- B. **System-wide Review of written Policies and Procedures for Pyxis machines and CDS storage.**
-review and evaluation of relevant aspects of Pyxis utilization including access, security, usage and monitoring. Includes comparison to other area teaching hospital Pyxis and/or medication safety cabinet Policies and Procedures and ASHP best practices for CDS.
- C. **System-wide review of all forms and documents relating to CDS inventory control, usage log, wasting and return logs, outlier analysis, discrepancy and resolution documentation, and any other related reports. Includes comparison to other area teaching hospital forms and documents and ASHP best practices relating to CDS.**
- D. **On-site observational assessment focusing on high volume CDS utilization locations (based on a minimum of 40 hours).**
-includes observing the dispensing and inventory process at randomly selected Pyxis locations over two different staffing shifts, comparing actual process practice to written Policies and Procedures of CDS.
- E. **Report preparation**
-Detailed report listing any potential areas of concern with existing operations, identifying any areas for improvement, and assessing benefits and costs of any proposed change. Analysis will be process-based and include suggestions for continuous quality improvement.

Final report documents will be furnished to:

- **Temple University Health System
c/o Beth C. Koob, Esquire**

Chief Counsel for Health Sciences,

**Temple University and Temple University Health System
Corporate Secretary, Temple University Health System
9th Floor, Boyer Pavilion
3509 N. Broad Street
Philadelphia, PA 19140**

- **United States Department of Justice**

**c/o Susan R. Becker
Assistant United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106**

- **Drug Enforcement Agency
Diversion Unit**

**c/o Group Supervisor Regina Spaddy
600 Arch Street, Room 10224
Philadelphia, PA 19106**

The parties anticipate that the independent consultant's process review and assessment, his report, and the resolution of identified areas of concern (if any) will be completed within seven months of the signing of the Settlement Agreement. Phase II of the Compliance Assessment Plan will follow the completion of Phase I.

Date:

COMPLIANCE ASSESSMENT PLAN FOR TEMPLE UNIVERSITY HEALTH SYSTEM

Relating to Controlled and Dangerous Substances (CDS)

Phase II: Three-year Review of TUHS Internal Monitoring

Review of CDS documents submitted by the following facilities:

- **Temple University Hospital**
- **Boyer Pavilion**
- **Jeanes Hospital**
- **Northeastern Ambulatory Care Center**

CDS documents to be submitted will be selected by the independent consultant based on need to properly evaluate systems and processes. Examples of types of documents to be requested and provided include, but are not limited to, the following:

- **Weekly Pyxis inventory documents**
- **Discrepancy and/or resolution documents**
- **Monthly outlier and analysis documents**
- **DEA 106 forms**

The independent consultant will review the TUHS internal monitoring documentation for a period of one-month within the current evaluation period. Documentation related to Pyxis will focus on 20 machines located in CDS high acuity areas including, but not limited to, the following:

- **Operating Room**
- **PACU**
- **Labor and Delivery**
- **C-section**
- **Special Studies**

Additional documentation will be requested and provided from Pyxis machines, or other relevant sources, if problems or discrepancies are found during the review of any of the initial TUHS internal monitoring documents. If in the independent consultant's opinion, onsite observation or a meeting with TUHS personnel will aid him in his review of the TUHS internal monitoring documents, TUHS agrees to provide such access.

TUHS internal monitoring documents will be submitted to the independent consultant according to the following schedule:

- A. Year One – TUHS internal monitoring documents, as requested, will be submitted for review every four months (three times a year)**
- B. Year Two – TUHS internal monitoring documents, as requested, will be submitted for review every six months (two times a year)**
- C. Year Three – TUSH internal monitoring documents, as requested, will be submitted one time, if needed. This determination will be made by the independent consultant, depending if the incident level is within an acceptable range that satisfies regulatory requirements.**

The independent consultant will report in writing upon completion of each review period and will furnish copies to:

- **Temple University Health System
c/o Beth C. Koob, Esq.

Chief Counsel for Health Sciences,**

**Temple University Health System
Corporate Secretary, Temple University Health System
9th Floor, Boyer Pavilion
3509 N. Broad Street
Philadelphia, PA 19140**

- **United States Department of Justice
c/o Susan R. Becker

Assistant United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106**

- **Drug Enforcement Agency
Diversion Unit

c/o Group Supervisor Regina Spaddy
600 Arch Street, Room 10224
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Date: