

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is made and entered into by and between the United States of America, acting through the United States Department of Justice (“DOJ”) and its Drug Enforcement Administration (“DEA”) (collectively, the “United States”), and the University of Michigan, d/b/a the University of Michigan Health System (“UMHS”). The United States and UMHS are each referred to as a “Party” and are collectively referred to as the “Parties.”

RECITALS

The University of Michigan Health System

1. UMHS is the wholly-owned academic medical center of the University of Michigan. It is one of the largest public, not-for-profit, tax-exempt health systems in Michigan and is one of two major teaching hospitals in Michigan.
2. At all times relevant to this Agreement, UMHS included the following 22 locations, among others: (1) University of Michigan Medical Center, DEA registration [REDACTED], located at 1500 East Medical Center Drive, Ann Arbor, Michigan; (2) University of Michigan - East Ann Arbor Medical Center, East Pharmacy, DEA registration [REDACTED], located at 4260 Plymouth Road, Ann Arbor, Michigan; (3) Kellogg Eye Center Pharmacy, DEA registration [REDACTED], located at 1000 Wall Street, Ann Arbor, Michigan; (4) Briarwood Hearing Rehabilitation/Center for Reproductive Medicine, DEA registration [REDACTED], located at 475 Market Place, Ann Arbor, Michigan; (5) Burlington Building, DEA registration [REDACTED], located at 325 East Eisenhower Parkway, Ann Arbor, Michigan; (6) Canton Health Center, DEA registration [REDACTED], located at 1051 Canton Center Road, Canton, Michigan; (7) Domino’s Farms, DEA registration [REDACTED], located at 24 Frank Lloyd Wright Drive, Ann Arbor, Michigan; (8) Livingston County Airport, DEA registration [REDACTED], located at

1911 Tooley Road, Howell, Michigan; (9) Livonia Center for Specialty Care, DEA registration [REDACTED], located at 19900 Haggerty Road, Livonia, Michigan; (10) University of Michigan Medical Center Survival Flight, Ann Arbor Airport Base, DEA registration [REDACTED], located at 747 Airport Drive, Ann Arbor, Michigan; (11) University of Michigan Northville Health Center/Infusion Pharmacy, DEA registration [REDACTED], located at 39901 Traditions Drive, Northville, Michigan; and (12) University of Michigan HomeMed, DEA registration [REDACTED], located at 2850 South Industrial Highway, Suite #50, Ann Arbor, Michigan; (13) Clark Road Rheumatology, DEA registration [REDACTED], located at 3145 Clark Road, Ypsilanti, Michigan; and (14) UMHS Brighton Center for Specialty Care Pharmacy, DEA registration [REDACTED], located at 7500 Challis Road, Brighton, Michigan. The following locations have retired DEA registrations: (15) Briarwood Center for Women, Children & Young Adults, located at 400 East Eisenhower Parkway, Ann Arbor, Michigan; (16) Brighton Health Center, located at 8001 Challis Road, Brighton, Michigan; (17) Chelsea Health Center, located at 14700 East Old US 12, Chelsea, Michigan; (18) Howell Pediatrics and Teen Center, located at 711 Byron, Howell, Michigan; (19) Livonia Health Center, located at 20321 Farmington Road, Livonia, Michigan; (20) Saline Health Center, located at 700 Woodland Drive East, Saline, Michigan; (21) West Ann Arbor Health Center, located at 4900A Jackson Road, Ann Arbor, Michigan; and (22) Ypsilanti Health Center, located at 200 Arnet Street, Ypsilanti, Michigan.

3. As of the Effective Date of this Agreement, UMHS holds an active DEA Certificate of Registration at fourteen UMHS locations. The list of all these locations is appended hereto as Attachment 1.

The Statutory Scheme and Role of DEA and DOJ

4. At all times relevant to this Agreement, UMHS was required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801-904 (the "CSA" or the "Act"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300, *et seq.*

5. Under the CSA, any entity that proposes to manufacture, distribute, or dispense any controlled substance must first register with the DEA. 21 U.S.C. § 822; 21 C.F.R. § 1301.11.

6. A separate registration is required for each principal place of business and/or professional practice where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person. 21 U.S.C. § 822(e); 21 C.F.R. § 1301.12.

7. Once registered, registrants are authorized to possess, manufacture, distribute or dispense only to the extent authorized by their registration and in conformity with the other provisions of the CSA. 21 U.S.C. § 822(b).

8. The act of "dispensing" a controlled substance and "distributing" a controlled substance are different acts under the CSA and require different registrations. 21 U.S.C. §§ 822(a)(1), (2); 823(b), (e), (f).

9. It is unlawful for a registrant to distribute or dispense to another registrant or authorized person a controlled substance not authorized by its registration. 21 U.S.C. § 842(a)(2).

10. For the time period relevant to this matter, a registrant who violated the CSA by distributing or dispensing a controlled substance not authorized by its registration is subject to a civil monetary penalty of up to \$25,000 per violation. 21 U.S.C. § 842(c)(1)(A).

11. Under the CSA, registrants are also subject to a variety of recordkeeping, reporting, and security requirements relating to controlled substances.

12. It is unlawful for a registrant “to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information” required under the CSA. 21 U.S.C. § 842(a)(5).

13. For the time period relevant to this matter, a registrant who refused or negligently failed to make, keep, or furnish any requisite record, report, notification, declaration, order or order form, statement, invoice, or information is subject to a civil monetary penalty of up to \$10,000 per violation. 21 U.S.C. § 842(c)(1)(B).

14. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder and is vested with the responsibility of investigating CSA violations.

15. The United States Attorney General, through the United States Attorney’s Office, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

The Covered Conduct

16. The United States contends that it has civil claims against UMHS based on the alleged conduct set forth in Attachment 2, the United States’ Statement of Covered Conduct (“Covered Conduct”), from May 2012 to the effective date of this Agreement (“Covered Time Period”).

17. This Agreement is not an admission of liability for civil penalties for the Covered Conduct under the CSA. However, UMHS admits during the Covered Time Period:

- a. While it maintained the proper state licenses, UMHS (i) did not register with the DEA 15 UMHS ambulatory care locations through which UMHS dispensed controlled substances; and (ii) distributed controlled substances to those 15 unregistered UMHS ambulatory care locations from a registered

UMHS location (whose DEA registration authorized it to dispense, but not to distribute, controlled substances).

- b. UMHS did not maintain complete and accurate records of certain controlled substances that it received, sold, delivered, or otherwise disposed of, from approximately May 2012 through November 2015.
- c. Some of UMHS's recordkeeping practices routinely were not consistent with DEA regulations during certain times.
- d. Some of UMHS's controls and procedures to guard against theft and diversion of controlled substances were not consistent with DEA regulations and UMHS's policies.
- e. Theft and diversion of controlled substances occurred at UMHS.

18. In response to the DEA's diversion investigation, UMHS has invested significant resources toward and made substantial improvements to its oversight and processes regarding its handling of controlled substances. These improvements are discussed in paragraphs 7 and 8 of the MOA.

TERMS AND CONDITIONS

In consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

19. UMHS shall pay to the United States Four Million, Three Hundred Thousand Dollars (\$4,300,000.00) (the "Settlement Amount"). The Settlement Amount shall be paid in three installments, in the following amounts: (1) \$1,433,334.00; (2) \$1,433,333.00; and (3) \$1,433,333.00. The first installment shall be paid no later than 30 days after the Effective Date of this Agreement. The second installment shall be paid on or before the one-year anniversary of the first installment payment date, and the third installment shall be paid on or before the two-

year anniversary of the first installment payment date. Each installment shall be paid by electronic funds transfer pursuant to written instructions from the United States.

20. So long as UMHS is in compliance with the terms of this Agreement, the United States agrees to refrain from filing against UMHS any action for civil penalty claims under the CSA that is based on the Covered Conduct. In consideration of UMHS's fulfillment of its obligations under this Agreement, expressly conditioned upon UMHS's timely paying the Settlement Amount pursuant to Paragraph 19, and subject to the exceptions in Paragraph 23 below concerning excluded claims, the United States fully and finally releases UMHS and the Board of Regents of the University of Michigan (the "Board") and their assigns, successors, principals, management, officers, directors, agents, and employees from any civil or administrative claims the United States has, could have, or may assert in the future under the CSA concerning the Covered Conduct.

21. Contemporaneously with the execution of this Agreement, UMHS and DEA will enter into a three-year Memorandum of Agreement ("MOA"), which will resolve administrative claims that DEA has or may have against UMHS related to the Covered Conduct. See MOA appended hereto as Attachment 3.

22. UMHS fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including, without limitation, attorney's fees, costs, and expenses of every kind and however denominated) that UMHS has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, or servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

23. Notwithstanding the release given in paragraph 20 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code;
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement or in the MOA appended as Attachment 3, any administrative liability, including the suspension and debarment rights of any federal agency;
- 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, except as expressly stated in Paragraph 20.

24. Nothing in this Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against UMHS for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct or which occur after the Effective Date of this Agreement. However, nothing in this Agreement waives or limits UMHS's right or ability to raise any defenses to such an action.

25. The obligations imposed upon UMHS pursuant to this Agreement and the MOA are in addition to, and not in derogation of, all requirements imposed upon UMHS pursuant to all applicable federal, state and local laws and regulations, including but not limited to the requirements set forth in Title 21 of the United States Code and the regulations promulgated thereunder.

26. Nothing in 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.

27. UMHS agrees that any and all costs it has, will or may incur in connection with this matter – including payment of the Settlement Amount under this Agreement, attorney’s fees, costs of investigation, negotiation, past and future compliance efforts, and remedial action – shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

28. This Agreement is intended to be for the benefit of the Parties only. It does not provide any rights or benefits to third parties. The Parties do not release any claims against any other person or entity.

29. The Parties acknowledge their promises in this Agreement are provided in exchange for valuable consideration provided by and through this Agreement.

30. All Parties consent to the United States’ disclosure of this Agreement, and information about this Agreement, to the public.

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

32. Each Party and signatory to this Agreement represents that it/he/she freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

33. 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 Court for the Eastern District of Michigan.

34. 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.

35. This Agreement, including Attachments, constitutes the complete agreement between the Parties with respect to the settlement of the United States' civil and administrative CSA claims against UMHS based on the Covered Conduct. This Agreement may not be amended except by written consent of the Parties.

36. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

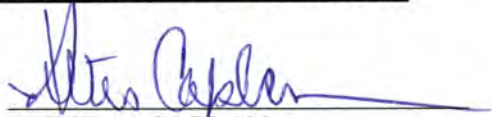
37. This Agreement is binding on UMHS's successors, transferees, heirs, and assigns.

38. 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.

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

THE UNITED STATES OF AMERICA

DATED: 8/29/18

BY: 
PETER A. CAPLAN
CAROLINE BURGUNDER
Assistant U.S. Attorneys
United States Attorney's Office
Eastern District of Michigan

DATED: _____

BY: _____
TIMOTHY J. PLANCON
U.S. Drug Enforcement Administration
Special Agent in Charge
Detroit Field Division

UNIVERSITY OF MICHIGAN

DATED: _____

BY: _____
MARSCHALL S. RUNGE
Executive Vice President for Medical Affairs
University of Michigan

DATED: _____

BY: _____
TIMOTHY G. LYNCH
Vice President and General Counsel
University of Michigan

DATED: _____

BY: _____
THOMAS J. PERRELLI
Jenner & Block LLP
Counsel for University of Michigan

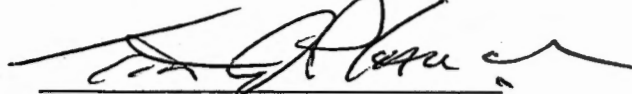
THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

PETER A. CAPLAN
CAROLINE BURGUNDER
Assistant U.S. Attorneys
United States Attorney's Office
Eastern District of Michigan

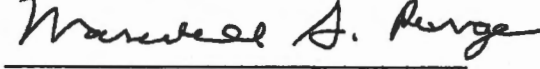
DATED: 8/29/2018

BY: 

TIMOTHY J. PLANCON
U.S. Drug Enforcement Administration
Special Agent in Charge
Detroit Field Division

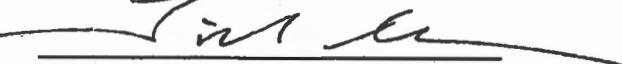
UNIVERSITY OF MICHIGAN

DATED: 07/26/18

BY: 

MARSCHALL S. RUNGE
Executive Vice President for Medical Affairs
University of Michigan

DATED: 30 Jul 2018

BY: 

TIMOTHY G. LYNCH
Vice President and General Counsel
University of Michigan

DATED: _____

BY: _____

THOMAS J. PERRELLI
Jenner & Block LLP
Counsel for University of Michigan

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

PETER A. CAPLAN
CAROLINE BURGUNDER
Assistant U.S. Attorneys
United States Attorney's Office
Eastern District of Michigan

DATED: _____

BY: _____

TIMOTHY J. PLANCON
U.S. Drug Enforcement Administration
Special Agent in Charge
Detroit Field Division

UNIVERSITY OF MICHIGAN

DATED: _____

BY: _____

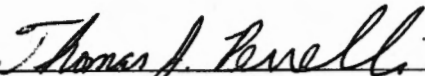
MARSCHALL S. RUNGE
Executive Vice President for Medical Affairs
University of Michigan

DATED: _____

BY: _____

TIMOTHY G. LYNCH
Vice President and General Counsel
University of Michigan

DATED: 8/28/18

BY: 

THOMAS J. PERRELLI
Jenner & Block LLP
Counsel for University of Michigan

ATTACHMENT #1

1. [REDACTED] – HOSPITAL/CLINIC

UNIVERSITY OF MICHIGAN MEDICAL CENTER
UH-B2D301
1500 EAST MEDICAL CENTER DRIVE
ANN ARBOR, MI 48109-5008

2. [REDACTED] – HOSPITAL/CLINIC

THE UNIVERSITY OF MICHIGAN
EAST ANN ARBOR MEDICAL CENTER, EAST PHARMACY
4260 PLYMOUTH ROAD
ANN ARBOR, MI 48109-2700

3. [REDACTED] – HOSPITAL/CLINIC

KEC PHARMACY
UNIVERSITY OF MICHIGAN HEALTH SYSTEM
1000 WALL STREET
ROOM 4114
ANN ARBOR, MI 48105-1912

4. [REDACTED] – HOSPITAL/CLINIC

UNIVERSITY OF MICHIGAN
BRIARWOOD HEARING REHABILITATION/
CENTER FOR REPRODUCTIVE MEDICINE
475 MARKET PLACE
ANN ARBOR, MI 48108

5. [REDACTED] – HOSPITAL/CLINIC
UNIVERSITY OF MICHIGAN BURLINGTON BUILDING
325 E. EISENHOWER PARKWAY
ANN ARBOR, MI 48108

6. [REDACTED] – HOSPITAL/CLINIC
U OF M HEALTH SYSTEM
CANTON HEALTH CENTER INFUSION PHARMACY
1051 N. CANTON CENTER ROAD
CANTON, MI 48187

7. [REDACTED] – HOSPITAL/CLINIC
UNIVERSITY OF MICHIGAN DOMINO'S FARMS
24 FRANK LLOYD WRIGHT DRIVE
ANN ARBOR, MI 48105

8. [REDACTED] – HOSPITAL/CLINIC
UNIVERSITY OF MICHIGAN MEDICAL CENTER
1911 TOOLEY ROAD
HOWELL, MI 48855

9. [REDACTED] – HOSPITAL/CLINIC
UNIVERSITY OF MICHIGAN LIVONIA
CENTER FOR SPECIALTY CARE
19900 HAGGERTY ROAD
LIVONIA, MI 48152

10. [REDACTED] – HOSPITAL/CLINIC

UNIVERSITY OF MICHIGAN MEDICAL CENTER
SURVIVAL FLIGHT ANN ARBOR AIRPORT BASE
747 AIRPORT DR.
ANN ARBOR, MI 48108

11. [REDACTED] – HOSPITAL/CLINIC

UNIVERSITY OF MICHIGAN HEALTH SYSTEM
NORTHVILLE HEALTH CENTER/INFUSION PHARMACY
39901 TRADITIONS DRIVE
NORTHVILLE, MI 48168

12. [REDACTED] – RETAIL PHARMACY

UNIVERSITY OF MICHIGAN HOMEMED
2850 SOUTH INDUSTRIAL HIGHWAY
SUITE #50
ANN ARBOR, MI 48104-9821

13. [REDACTED] – HOSPITAL/CLINIC

UNIVERSITY OF MICHIGAN HEALTH SYSTEM
CLARK PROFESSIONAL PLAZA II
3145 CLARK ROAD
YPSILANTI, MI 48197

14. [REDACTED] – HOSPITAL/CLINIC

UMHS BRIGHTON CENTER FOR SPECIALTY CARE PHARMACY
7500 CHALLIS ROAD
BRIGHTON, MI 48116

ATTACHMENT #2

United States' Statement of Covered Conduct

Based on the following alleged conduct, the United States contends that it has grounds to pursue civil monetary penalty claims against UMHS.

Unauthorized Distribution and Failure to Register

1. During the time period of May 2012 through June 2014, UMHS dispensed and distributed controlled substances in violation of 21 U.S.C. § 822 and 21 C.F.R. § 1301.12, by:
 - a. failing to register with the DEA 15 UMHS ambulatory care locations through which UMHS dispensed controlled substances, even though UMHS knew it was required to register these facilities with the DEA; and
 - b. distributing controlled substances to 15 unregistered UMHS ambulatory care locations from a registered UMHS location (whose DEA registration authorized it to dispense, but not to distribute, controlled substances).
2. Each distribution to the 15 unregistered locations, and each subsequent dispensing of controlled substances by these unregistered locations, to end users or otherwise, was a violation of the CSA.

Recordkeeping Violations

3. In violation of 21 U.S.C. §§ 827(a)(3), 828(a), 842(a)(5) and 21 C.F.R. §§ 1304.21, 1304.22(b), 1304.22(c) and 1305.03, UMHS failed to maintain complete and accurate records of certain Schedule II and III controlled substances that it received, sold, delivered, or otherwise disposed of, from approximately May 2012 through November 2015.
4. UMHS's recordkeeping violations took various forms, some of which included the following examples:
 - a. failing to properly document controlled substance dispensing;
 - b. failing to properly document the "wasting" of controlled substances;

- c. failing to maintain invoices, physicians' orders for controlled substances, or prescriptions with required information, such as the patient's address;
 - d. failing to properly keep records of which prescriptions were unfilled and which were filled;
 - e. failing to maintain adequate records documenting the transfer of controlled substances from one registered UMHS facility to another;
 - f. failing to use the requisite DEA Form-222, and failing to use invoices containing all requisite information, when distributing controlled substances to ambulatory care sites; and
 - g. failing to notify the DEA in a timely manner regarding some instances of thefts or significant losses of controlled substances.
- 5. Each failure to maintain complete and accurate records was a violation of the CSA.
 - 6. UMHS's deficient recordkeeping contributed to its failure to consistently detect, monitor and report to the DEA suspected diversion, as required by 21 C.F.R. § 1301.76(b).
 - 7. UMHS's deficient recordkeeping facilitated its ultimate failure to guard against the theft and diversion of controlled substances, as required by 21 C.F.R. § 1301.71.

Theft and Diversion

- 8. Theft and diversion occurred at UMHS, as a result of UMHS's failure to maintain effective controls and procedures to guard against the theft and diversion of controlled substances. For example:
 - a. In December 2013, two tragic incidents occurred involving two UMHS employees. One involved the death of a nurse, and the other involved the cardiac arrest of an anesthesiology resident. Both overdosed on controlled substances at a UMHS facility.
 - b. Between May 2011 and January 2012, 16,000 hydrocodone pills were stolen from UMHS by one or more UMHS employees.
 - c. From April 2012 through April 2014, controlled substances were at times diverted from Omnicells – medication inventory management and dispensing systems – located throughout UMHS facilities.

- d. Other thefts involved registered nurses who diverted controlled substances from UMHS for months, and in some instances, years. Some of these nurses diverted vials of fentanyl, then refilled the vials with saline before returning them to the Omnicell for administration to patients for whom fentanyl had been prescribed. Some cases of diversion went on for a significant period of time.

Additional Considerations

9. The United States alleges that, at a minimum, UMHS committed thousands of violations of the CSA, many of which occurred on dates uncertain and may have continued through the effective date of the settlement agreement entered into by the United States and UMHS.
10. In response to the DEA's diversion investigation, UMHS has invested significant resources toward and made significant and substantial improvements to its oversight and processes regarding its handling of controlled substances.

ATTACHMENT #3

UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF:

The University of Michigan, d/b/a The University of Michigan Health System (UMHS) and its registered locations as described in Attachment 1.

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement ("Agreement") is made and entered into by the Drug Enforcement Administration ("DEA") and the University of Michigan d/b/a/ the University of Michigan Health System ("UMHS") with its 14 registered locations (see Attachment 1), collectively referred to as UMHS. The Parties enter into this Agreement in an effort to work together to ensure high quality and safe patient care and to safeguard UMHS staff and the community.

I. DEA FINDINGS OF FACT

1. As of December 2013, UMHS had approximately 15 off-site facilities that were individually licensed by the State of Michigan but not individually registered with DEA and were receiving, storing, dispensing and/or administering controlled substances obtained from the main hospital to treat patients.
2. DEA began its investigation after learning that two UMHS employees had overdosed on controlled substances at University of Michigan Medical Center, located at 1500 East Medical Center Drive, Ann Arbor, Michigan (the "Hospital") in December 2013. A nurse was found deceased in the hospital from an overdose of fentanyl and midazolam that the nurse had withdrawn for a patient. An anesthesia resident was found in cardiac arrest in the hospital from an overdose of fentanyl and morphine taken from the resident's narcotic "kit" issued to provide anesthesia care to patients.
3. DEA arranged for a meeting with UMHS key personnel to gather more information and conduct a closing inventory of specific controlled substances for use in a potential audit. During the course of the meeting and closing inventory, DEA concluded that UMHS key personnel were not sufficiently knowledgeable regarding some aspects of their own ambulatory controlled substance-related operations, policies, and procedures, nor could they identify all locations where controlled substances were stored.
4. On July 8, 2014, UMHS key personnel met with Diversion Investigators from DEA and discussed what DEA concluded were deficiencies in UMHS's system of inventory control for specific controlled substances and Omnicell systems. UMHS indicated that it

was aware of the deficiencies and had implemented new safeguards, policies, and procedures in order to comply with DEA recommendations and rules.

5. DEA investigators conducted a review of UMHS Security reports and Omnicell reports related to controlled substance discrepancies for the time period January 2012 through April 2014. DEA concluded that certain reportable thefts or significant losses of controlled substances were not consistently reported to the DEA as required by law. DEA conducted an inspection of UMHS's East Ann Arbor facility and found additional recordkeeping-related issues.
6. DEA made the following specific factual findings:
 - a) Regarding UNIVERSITY OF MICHIGAN MEDICAL CENTER, [REDACTED] 1500 East Medical Center Drive, Ann Arbor, MI 48109, DEA Registration [REDACTED] (the "B2 Vault"): The B2 Vault distributed in excess of 30,000 units of controlled substances in Schedules II through V to at least 15 of its off-site locations that were licensed to use controlled substances by the state but did not hold individual DEA Registrations. These transfers did not include the required DEA Form-222, and the invoices did not contain all required elements. Some transfers to UMHS researchers also lacked appropriate documentation.
 - b) Regarding UNIVERSITY OF MICHIGAN (East Ann Arbor Medical Center), East Pharmacy, 4260 Plymouth Road, Ann Arbor, Michigan, DEA Registration [REDACTED] ("East Ann Arbor"): This is a "satellite" facility of the main University of Michigan hospital facility that conducts ambulatory surgery, medical procedures, primary care, and geriatric treatments. It also has a retail pharmacy operation. Investigators reviewed a random sampling of prescriptions and labeling and found that some were missing required information (*e.g.*, DEA number, practitioner suffix). DEA investigators made the following additional findings:
 - i) SURGERY CENTER/PACU
 - a. Some staff members did not consistently properly document controlled substance-related activities (*e.g.*, usage, wasting, witness name, patient name) on their "kit sheet."
 - b. Some staff members did not consistently follow controlled substance-related processes and procedures (*e.g.*, wasting with a witness, kit sheet receipt/reconciliation).
 - c. Controlled substance discrepancies were not consistently supported by documentation to demonstrate they were appropriately identified, investigated, or resolved.

ii) MPU

- a. Some staff members administered controlled substances without appropriate ordering documentation (i.e., doctor's order) or inconsistent with ordering documentation (e.g., administered an amount greater than ordered).
- b. Some staff members did not consistently perform an appropriate reconciliation of controlled substances.

iii) CLINIC

- a. Staff did not consistently maintain accurate and/or complete records (e.g., missing invoices).
- b. Some staff did not consistently provide effective controls to guard against theft and diversion.

iv) RETAIL PHARMACY

- a. Some prescriptions filled in the retail pharmacy were missing required elements (e.g., patient's address).
- b. In filling some prescriptions, some staff reduced the amount of controlled substances and changed the frequency of prescriptions without following proper procedure.
- c. Some records were inappropriately maintained (e.g., unfilled prescriptions stored with filled prescriptions without annotating on their face that they were unfilled).

II. UMHS's REMEDIATION

7. UMHS has taken substantial steps to address deficiencies with its handling of controlled substances, including the following:
- a) UMHS has implemented an enhanced system of monitoring the distribution of controlled substances within all components of UMHS, including its pharmacies, hospitals, research centers, outpatient centers, outpatient surgical centers, mental health facilities, and any other component of UMHS that may manufacture, distribute, or dispense controlled substances.
 - b) UMHS has invested significant time, technology, and financial resources to comply with the rules and regulations of the CSA and the rules promulgated under that authority.

8. UMHS has taken steps to improve its controls and enhance its efforts at handling controlled substances including the following:
- a) Hired leaders who have revamped UMHS's compliance efforts and replaced individuals who had been in charge of these efforts;
 - b) As part of planned upgrades, and in response to DEA's review, UMHS made and continues to make significant and substantial improvements and expenditures to its oversight of the ordering, receiving, storage, security, dispensing, prescribing, administering, monitoring, wasting, disposal, and destruction of controlled substances with the goal of preventing diversion and improving accountability and ensuring security.
 - c) UMHS Pharmacy, Nursing, Anesthesiology, Ambulatory Care, Office of Patient Relations and Clinical Risk, Office of Clinical Affairs, Human Resources, Division of Public Safety and Security, Office of the Vice President and General Counsel, and Compliance have worked together collaboratively to assess how best to improve accountability and ensure security, and in implementing and maintaining the improvements referenced above.
 - d) UMHS has created an executive-level Controlled Substance Safety and Compliance Oversight Committee to ensure institutional oversight, direction, and support of UMHS's controlled substance initiatives.
 - e) UMHS has created the Diversion Prevention Program, which is tasked with preventing, detecting, and responding to diversion. Within the program, the Diversion Prevention Team provides education and support to front-line staff, monitors and analyzes data, and works to help UMHS progress in controlled substance efforts. Also within the program, the multidisciplinary Diversion Prevention Review Team reviews diversion-related incidents.
 - f) UMHS has established policies and procedures governing monitoring responsibilities designed to detect and prevent the diversion of controlled substances.
 - g) UMHS has designed and implemented a controlled substance database that synthesizes multiple data streams into a single source and performs advanced transactional analysis, and has also implemented and improved upon commercially available diversion detection programs. UMHS's system allows the Diversion Prevention Team to conduct complex regression analyses to identify and investigate outliers that may otherwise be difficult to spot.
 - h) UMHS designed and implemented a software application referred to as the Controlled Substance Tool (CST) to electronically track and reconcile anesthesia drug "kit" preparation, storage, distribution, chain of custody, administration, and breakdown. The CST ensures that providers adhere to appropriate workflows by tracking the

chain of custody of controlled substances and sending alerts and reminders, as well as daily reports to leadership identifying any discrepancies or other issues that may require follow up.

- i) UMHS has made major capital investments to physically secure controlled substances and provide the staffing and resources necessary to further implement and maintain controlled substance-related improvements.
- j) UMHS has, as part of its public health mission, worked to bring awareness to substance use disorders and the prevalence of diversion through research projects, public speaking and educational initiatives, collaboration with local law enforcement, and other means.
- k) UMHS is a co-founder and leader of the Michigan Opioid Prescribing Engagement Network (“Michigan OPEN”), an initiative focused on a preventative approach to the opioid epidemic in the state of Michigan. Among other things, Michigan-OPEN is focused on reducing postoperative opioid prescribing and patient consumption to reduce the number of opioids sent into the community, and working with law enforcement to recover opioids that have already been prescribed.
- l) UMHS is also engaged in a new Precision Health initiative that seeks to study the University of Michigan’s existing databases to drive discovery, treatment, and implementation across healthcare. The program’s initial project will be to identify risk factors that may increase the likelihood of someone becoming a chronic opioid user, which can then be used to create guidelines to tailor pain management plans and reduce opioid prescriptions.

III. STIPULATION AND AGREEMENT

- 9. The period of this Agreement shall be three (3) years. This Agreement shall become effective when all parties have signed and dated.
- 10. This MOA integrates the current Memorandum of Agreement (dated July 14, 2014) in place at University of Michigan Health System - Northville Health Center/Infusion Pharmacy, 39902 Traditions Drive, Northville, MI 48168, DEA Registration [REDACTED] (Northville Memorandum of Agreement) (Attachment 4) and the Memorandum of Agreement (dated June 6, 2017) which approved eight pending DEA registration applications of UMHS facilities (Attachment 5).
- 11. UMHS agrees to abide by the conditions set forth below:
 - a) In addition to following all applicable laws and codes, UMHS shall register with DEA all locations that handle controlled substances that are required to be registered under the Controlled Substances Act.

- b) UMHS shall maintain complete and accurate records for all distributions and dispensing activity.
 - c) UMHS shall maintain effective controls against diversion at all locations consistent with the Controlled Substances Act.
12. Following execution of this Agreement, each location with a DEA Registration (e.g., those locations identified in Attachment 1) will complete an initial physical inventory pursuant to 21 C.F.R. § 1304.11(b). Further, UMHS will provide the DEA with a copy of a physical count for all controlled substances at all UMHS institutional DEA registered locations, no later than 30 days following the signing of this Agreement. UMHS shall also provide DEA a copy of a physical count for all controlled substances at all UMHS institutional DEA registered locations, six months after the signing of this MOA, and annually thereafter for the duration of this MOA.
13. Following execution of this Agreement, UMHS shall complete an evaluation of University of Michigan Medical Center, [REDACTED], DEA registration [REDACTED], to determine if distributions of controlled substances exceed 5% of the total number of dosage units of all controlled substances distributed or dispensed for the 2017 calendar year to assess compliance with 21 C.F.R. § 1307.11(a) (iv). The audit of the 2017 calendar year shall include all distributions to DEA registrants and any/all other distributions to physical locations where there was no approved DEA registration. UMHS will complete an evaluation of University of Michigan Medical Center, [REDACTED], [REDACTED], DEA registration [REDACTED], for each year covered by the MOA to determine if distributions of controlled substances exceed 5% of the total number of dosage units of all controlled substances distributed or dispensed for the calendar year. UMHS will provide the DEA with a copy of the 5% compliance audit and findings within 30 days of completion. UMHS will provide the DEA with a copy of any controlled substance inventory audits completed by UMHS Compliance. The audit findings will be submitted to the DEA within 30 days of completion. The audits shall specify the type and form of drugs audited and whether the audit was based on a physical count or computerized records. The findings will also document any record-keeping deficiencies identified and corrected during the audit.
14. UMHS will hire an external auditor to conduct unannounced audits of five (5) schedule II-V controlled substances randomly chosen by the auditor. The audits will be conducted quarterly following the Effective Date of this Agreement and will review compliance with applicable requirements of the CSA and this Agreement. The pharmacist-in-charge will review and sign the audits. Any discrepancies or deficiencies found by the audits will be resolved within thirty (30) days and documented on the audit report. UMHS will retain the audit and corrective action and make them available to the DEA upon request.
15. UMHS will utilize the Controlled Substance Tool (CST) to track the dispensing, usage, administration, and wasting of controlled substances at all sites that Anesthesia provides services and the Anesthesia Information System is used for documentation. At sites where the Anesthesia Information System is not used, UMHS will follow its policy on

removal of controlled substances from Omnicell. UMHS will implement a written policy/procedure that describes UMHS's response when there is a failure to comply with the following requirements:

- a) Per policy, an anesthesia provider will only remove one patient-specific controlled substance drug kit from the Pharmacy or Omnicell for a scheduled procedure, excluding the exception under which multiple kits may be removed to accommodate emergency situations (*e.g.* OB and Code Blue kits).
- b) During a procedure, if an anesthesia provider requires additional controlled substances from the pharmacy and/or Omnicell, it must be removed for a specific patient. The anesthesia provider must ensure the additional controlled substances are added to the CST. A compliance system will be in place to ensure any additional controlled substances removed by an anesthesia provider are properly entered into the CST.
- c) The anesthesia provider will link the drug kit to the patient case in the Anesthesia Information System within the time frame outlined in Anesthesia policy/procedure after the "anesthesia start" time. Failure to link the kit within the specific time period will generate an alert by the CST and be recorded in the CST.
- d) During each procedure, the CST will extract data on controlled substance administration to the patient from the Anesthesia Information System. At the conclusion of the case, the anesthesia provider linked to the drug kit will document the return of the kit in the CST.
- e) The anesthesia provider will submit all unused controlled substances in their drug kit back to Pharmacy, either in person or via a safe/dropbox. If returning in person, the date, time, and person receiving the drug kit in Pharmacy shall be recorded. If returning to a safe/dropbox, the anesthesia provider and a second licensed professional will record the date, time, and second licensed professional's name. Within the next scheduled business day, a reconciliation of the returned controlled substances will be initiated including a review of the administration recorded in the CST.
- f) The CST will generate an alert if a kit is not returned within the time frame outlined in Anesthesia policy/procedure after "anesthesia end" time. A daily report of this kit alert will be sent to Anesthesia Leadership and DPT for review.
- g) The CST will generate an alert if a discrepancy is found during drug kit reconciliation. A daily report of this kit alert will be sent to Anesthesia Leadership and DPT for review.
- h) Security controls and procedures must be in place to prevent controlled substance waste from being diverted. Destruction and witnessing of controlled substances will

occur per UMHS policy. To detect potential controlled substance diversion, a multidisciplinary committee (Controlled Substances Surveillance Committee) will review anesthesia providers' controlled substance data. The review may include errors recorded by the CST, sick calls of a short duration prior to scheduled work, excessive documentation errors, and/or excessive controlled substance administration.

- i) The DPT will investigate and document when employees are involved in any theft of controlled substances or significant loss, when there is a concern for diversion, or upon case referral from the Controlled Substances Surveillance Committee. If a theft of controlled substances or significant loss occurs, UMHS will report the significant loss or theft in compliance with 21 U.S.C. § 823 and 21 C.F.R. § 1301.76(b).
 - j) Review of any Anesthesia controlled substance compliance issues will be documented by Anesthesia. Cases of concern will be referred by Anesthesia to the Diversion Prevention Team (DPT), which will investigate and escalate concerns to the Diversion Prevention Review Team (DPRT) as needed. The DPT will provide a quarterly report of investigations to the DEA.
16. UMHS will implement a policy to comply with the requirement that a DEA Registrant may only distribute controlled substances to another DEA Registrant as set forth in 21 C.F.R. § 1301.74 (a).
17. UMHS shall institute a broad-based educational program that focuses on prevention of drug diversion in the workplace. The program shall identify signs and symptoms of addiction and diversion, threats to patient care, threats to life, impact on personal careers, and effect on public trust. UMHS shall, at minimum, create and/or implement the following:
- i) Employee orientation materials designed to educate employees on the potential of drug diversion in the workplace.
 - ii) Annual mandatory online employee training module designed to prevent drug diversion and create awareness of the necessity for the safe handling of controlled substances. The training module shall also include information on the proper ways to respond to diversion and responsibilities to report diversion if it is suspected. At the conclusion of each calendar year, a report will be submitted to the DEA providing a brief description of the training and the number of employees who received the training.
 - iii) An "Employee Compliance Hotline" that will encourage and permit the anonymous reporting of any suspected illegal controlled substance handling, use, diversion, and/or drug impairment.
 - a. On a quarterly basis, UMHS will provide a report to the DEA containing the following information related to Employee Compliance Hotline calls, which reference controlled substance compliance issues as noted above:

- Date of Call;
- Description of content of the Hotline call;
- Description of any investigation and/or action taken as a result of the Hotline call.

18. UMHS will utilize its internally created software analytics systems and commercially available systems to identify employees potentially engaged in the diversion of controlled substances. The DPT will maintain a record of each event that requires evaluation of the employee for anomalous use or possible diversion. The DPT will maintain a database either documenting the reconciliation of the event or the referral to the DPRT for further review. The DPRT will document the referral and review, and will provide a quarterly report to the DEA.

19. UMHS agrees to take the following actions:

- a) Within 90 days after execution of this Agreement, implement the requirement that a comprehensive background check be performed for any employee hired after the Effective Date of this Agreement that will be engaged in the direct handling of controlled substances to identify any history of drug diversion. The comprehensive background check will include a criminal background check, search by vendors of national criminal databases and search of the State of Michigan Licensing and Regulatory Affairs website to verify any complaints or administrative action against a licensee.
- b) Take steps to ensure each employee is aware of UMHS's workplace diversion program.
- c) Establish a written progressive discipline policy as it relates to violation of UMHS controlled substance policies and procedures.
- d) Within 90 days after execution of this Agreement, establish a database of employees who are discharged and/or resign from employment due to the diversion of controlled substances and disclose that information to another health facility who conducts any pre-employment inquiry.
- e) Notify the State of Michigan Licensing and Regulatory Affairs and DEA of any licensed employee who has been discharged and/or resigned from employment due to diversion of controlled substances.
- f) Conduct pre-employment drug screen testing of any employees hired after execution of this Agreement who will be handling controlled substances.
- g) Initiate attempts to negotiate a policy of random drug testing of all employees who handle or have access to controlled substances.

- h) Notify the DEA of any employee who resigns his/her position due to diversion of controlled substances and/or any other mishandling of controlled substances.
- 20. UMHS will continue to report any theft of controlled substances or significant loss to the University of Michigan Police Department (UMPD) and to the DEA.
- 21. UMHS shall provide a designated "Point of Contact" for each registered location listed in the Agreement and provide the DEA with the full name, title, telephone number, and email address for each individual.
- 22. UMHS shall allow DEA representatives to perform inspections with 24 hours' notice of any DEA registered UMHS facility that handles, or is suspected of handling, controlled substances at any time during the period of the Agreement without an Administrative Inspection Warrant.
- 23. UMHS shall not, after the date of execution of this Agreement, hire as an employee who has access to controlled substances, any person 1) who UMHS knows to have been convicted of a felony offense relating to controlled substances if, after individualized review of the facts and circumstances of the conviction, UMHS determines that person is unfit for the position or 2) who UMHS knows to have had an application for registration with the DEA denied, revoked or has surrendered a DEA Registration for cause. In the event that UMHS desires to employ an individual otherwise prohibited by this provision, UMHS must request, pursuant to 21 C.F.R. § 1307.03, a waiver from DEA.
- 24. Any deviations of these requirements must be documented and provided to the DEA within 30 days of the deviation.
- 25. For any part of this MOA that requires reporting to DEA, UMHS shall submit documents in either physical form mailed to DEA Detroit Field Division, Attention: UMHS COMPLIANCE 431 Howard Street Detroit, MI 48226 or in electronic format to UMHSCOMPLIANCE@usdoj.gov.

FOR THE UNIVERSITY OF MICHIGAN HEALTH SYSTEM

Marschall S. Runge, Executive Vice President for Medical Affairs, acknowledges and states that he has read the foregoing and agrees with the terms and conditions of the Memorandum of Agreement, has the authority and responsibility to act on this matter on behalf of UMHS and that he has signed the Memorandum of Agreement pursuant to said authority.

Marschall S. Runge Date: 07/26/18

Marschall S. Runge
Executive Vice President for Medical Affairs
University of Michigan

FOR THE DRUG ENFORCEMENT ADMINISTRATION:

Timothy J. Plancon, Special Agent in Charge, DEA Detroit Field Division, acknowledges and states he has read the foregoing and agrees with the contents thereof; that he has authority to act on behalf of said Administration in this matter; and that he has signed this Memorandum of Agreement pursuant to said authority.

Timothy J. Plancon Date: 8/29/2018

Timothy J. Plancon
Special Agent in Charge
Detroit Field Division

Cathy A. Gallagher, Diversion Program Manager, DEA Detroit Field Division, acknowledges and states she has read the foregoing and agrees with the contents thereof; that she has authority to act on behalf of said Administration in this matter; and that she has signed this Memorandum of Agreement pursuant to said authority.

Cathy A. Gallagher Date: 8/29/2018

Cathy A. Gallagher
Diversion Program Manager
Detroit Field Division

Attachment #4

UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF

UNIVERSITY OF MICHIGAN HEALTH SYSTEM - NORTHVILLE HEALTH
CENTER/INFUSION PHARMACY
39901 Traditions Drive
Northville, Michigan 48168

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement (MOA) is entered into between the Drug Enforcement Administration (DEA) and University of Michigan Health System - Northville Health Center/Infusion Pharmacy.

On July 3, 2014, the DEA received a copy of DEA Form 224, Application for Registration, from the University of Michigan Health System - Northville Health Center/Infusion Pharmacy requesting a controlled substance registration as a hospital/clinic with authority to handle schedule II through schedule V controlled substances. The University of Michigan Health System - Northville Health Center/Infusion Pharmacy has requested a registered location at 39901 Traditions Drive, Northville, Michigan 48168.

On July 8, 2014, the University of Michigan Health System - Northville Health Center/Infusion Pharmacy was issued a State of Michigan Pharmacy license with permanent ID# [REDACTED] and a State of Michigan Controlled Substance Facility license with permanent ID# [REDACTED], both with an expiration date of June 30, 2015.

In March of 2014, the Detroit office of the DEA initiated an investigation against the University of Michigan Health System and found numerous regulatory violations pertaining to the handling of controlled substances. On July 8, 2014, a meeting was held between representatives of the University of Michigan Health System and the government. From this meeting, the University of Michigan Health System indicated its desire to seek a resolution to this matter. As part of this resolution, the University of Michigan Health System has agreed to enter into a preliminary MOA that will extend to all DEA registered locations of the University's Health System, to include Northville Health Center/Infusion Pharmacy. The University of

Michigan Health System - Northville Health Center/Infusion Pharmacy agrees to abide by the terms of this preliminary MOA.

The conditions of this preliminary MOA are as follows:

- 1. The DEA agrees to approve the application for registration submitted by the University of Michigan Health System - Northville Health Center/Infusion Pharmacy as a Hospital/Clinic authorized to handle controlled substances in schedules II through V.**
- 2. The University of Michigan Health System - Northville Health Center/Infusion Pharmacy is responsible for the safe distribution, handling and disposal of all controlled substances and agrees to abide by all Federal, state and local statutes and regulations relating to controlled substances.**
- 3. The parties agree this preliminary MOA shall remain in effect from the date this Agreement is fully executed up until it is supplanted by a second MOA that includes a three year oversight term and encompasses all University of Michigan Health System DEA registrations.**
- 4. Any material breach of this Agreement by the University of Michigan Health System - Northville Health Center/Infusion Pharmacy after the effective date of this Agreement may be the basis upon which DEA can issue an Order to Show Cause seeking the revocation of its DEA registration.**
- 5. The University of Michigan Health System - Northville Health Center/Infusion Pharmacy agrees to notify DEA of the initiation of any action by any state entity to restrict, deny, rescind, suspend, revoke, or otherwise limit their authority to handle controlled substances.**

The University of Michigan Health System - Northville Health Center/Infusion Pharmacy acknowledges and states they have read the foregoing conditions and understands and agrees with the contents thereof; that they have the authority and responsibility to act on this matter; and have signed this preliminary Memorandum of Agreement pursuant to said authority.

The University of Michigan Health System - Northville Health Center/Infusion Pharmacy

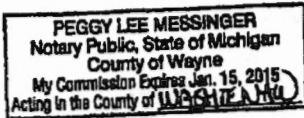
Timothy G. Lynch

Timothy G. Lynch

Vice President and General Counsel

(Representative)

Sworn to before me this 11th day of July, 2014



Attest: Peggy Lee Messinger

James V. Geldhof, Diversion Program Manager, DEA Detroit Field Division, acknowledges and states that he has read the foregoing and knows and agrees with the contents thereof; that he has authority to act on behalf of said Administration in this matter; and he has signed this preliminary Memorandum of Agreement pursuant to said authority.

James V. Geldhof

James V. Geldhof
Diversion Program Manager
DEA Detroit Divisional Office

7/11/14

Date

Attachment #5

**UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION**

IN THE MATTER OF

UNIVERSITY OF MICHIGAN HEALTH SYSTEM

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement (MOA) is entered into between the Drug Enforcement Administration (DEA) and University of Michigan Health System.

On July 2, 2014, the DEA received copies of DEA Form 224s, Application for Registration, from the following University of Michigan Health System facilities:

1. University of Michigan Domino's Farms requested a controlled substance registration as a hospital/clinic with authority to handle Schedules II through V controlled substances. The University of Michigan Domino Farm's was issued a state of Michigan CS-Facility license with permanent ID# [REDACTED].
2. University of Michigan Livonia Center for Specialty Care requested a controlled substance registration as a hospital/clinic with authority to handle Schedules II through V controlled substances. The University of Michigan Livonia Center for Specialty Care was issued a state of Michigan CS-Facility license with permanent ID# [REDACTED].
3. University of Michigan Burlington Building requested a controlled substance registration as a hospital/clinic with authority to handle Schedules II through V controlled substances. The University of Michigan Burlington Building was issued a state of Michigan CS-Facility license with permanent ID# [REDACTED].

4. University of Michigan Briarwood Hearing Rehabilitation Center / Center for Reproductive Medicine requested a controlled substance registration as a hospital/clinic with authority to handle Schedules II through V controlled substances. The University of Michigan Briarwood Hearing Rehabilitation Center / Center for Reproductive Medicine was issued a state of Michigan CS-Facility license with permanent ID# [REDACTED].
5. University of Michigan Canton Health Center Infusion Pharmacy requested a controlled substance registration as a hospital/clinic with authority to handle Schedules II through V controlled substances. The University of Michigan Canton Health Center Infusion Pharmacy was issued a state of Michigan CS-Facility license with permanent ID# [REDACTED].

On October 14, 2014, the DEA received a DEA Form 224a, Renewal for Registration from University of Michigan East Ann Arbor Health and Geriatrics Center (East Ann Arbor Pharmacy), DEA number [REDACTED]. The University of Michigan East Ann Arbor Health and Geriatrics Center (East Ann Arbor Pharmacy) was issued a state of Michigan CS Facility license and Pharmacy license both assigned permanent ID# [REDACTED].

On December 24, 2014, the DEA received a DEA Form 224, Application for Registration, from University of Michigan Survival Flight Livingston County Base (LCB) requesting a controlled substance registration as a hospital/clinic with authority to handle Schedules II through V controlled substances. The University of Michigan Survival Flight Livingston County Base (LCB) was issued a state of Michigan CS-Facility license with permanent ID# [REDACTED].

On September 21, 2015, the DEA received a copy of DEA Form 224, Application for Registration, from University of Michigan Survival Flight Ann Arbor Airport Base requesting a

controlled substance registration as a hospital/clinic with authority to handle Schedules II through V controlled substances. The University of Michigan Survival Flight Ann Arbor Airport Base was issued a state of Michigan CS-Facility license with permanent ID# [REDACTED].

The Detroit Division office of the DEA and University of Michigan Health System will enter into this MOA and agree to abide by the terms of the MOA.

The conditions of this MOA are as follows:

1. The DEA agrees to approve the DEA Applications and issue Certificates of Registration for the University of Michigan Health System applicants listed in the MOA, with authority to handle controlled substances in Schedules II through V. Certificates of Registration will be issued to match the name and address on each site's state controlled substance license, as set forth in Exhibit A.
2. Upon execution of the MOA, each location covered by the MOA must complete an initial physical inventory as required by 21 C.F.R. § 1304.11(b). The University of Michigan Health System will provide the DEA with a copy of each initial physical count no later than 30 days following the signing of the MOA.
3. The University of Michigan Health System shall allow DEA representatives to perform unannounced inspections of any DEA registered or unregistered UMHS facility that handles, or is suspected of handling, controlled substances, in accordance with DEA's statutory and regulatory authority to conduct said inspections, at any time during the period of the MOA without an Administrative Inspection Warrant.
4. The University of Michigan Health System facilities listed in this MOA agrees to abide by all federal, state and local statutes and regulations relating to controlled substances.
5. The parties agree this MOA shall remain in effect from the date the agreement is fully executed and until it is supplanted by a second MOA encompassing all University of Michigan Health System DEA registrations.
6. The University of Michigan Health System agrees to notify DEA of the initiation of any action by any state entity to restrict, deny, rescind, suspend, revoke, or otherwise limit their authority to handle controlled substances for any University of Michigan Health System facilities listed in this MOA.

The University of Michigan Health System acknowledges and states they have read the foregoing and knows and agrees with the contents thereof; that they have the authority and responsibility to act on this matter; and have signed this Memorandum of Agreement pursuant to said authority.

Stanley Kent

5/25/17

Stanley Kent
Chief Pharmacy Officer
University of Michigan Health System

Date

Cathy A. Gallagher, Diversion Program Manager, DEA Detroit Field Division, acknowledges and states that she has read the foregoing and knows and agrees with the contents thereof; that she has authority to act on behalf of said Administration in this matter; and she has signed this Memorandum of Agreement pursuant to said authority.

Cathy A. Gallagher

6/6/17

Cathy A. Gallagher
Diversion Program Manager
DEA Detroit

Date

Exhibit A
Name and address conventions

	Common Name	State License Name	State License Address	State CS License Number
1	Briarwood Hearing Rehabilitation Center / Center for Reproductive Medicine	UNIVERSITY OF MICHIGAN MEDICAL CENTER	Center for Reproductive Medicine 475 Market Place Ste B, Ann Arbor, MI 48108	██████████
2	Burlington Building	UNIVERSITY OF MICHIGAN MEDICAL CENTER	325 E Eisenhower Pkwy Ste 100, Ann Arbor, MI 48108	██████████
3	Canton Health Center Infusion Pharmacy	U OF M HLTH SYS CANTON HLTH CTR INFUSION PHARMACY	1051 N Canton Center Road, Canton, MI 48187	██████████
4	Domino's Farms	UNIVERSITY OF MICHIGAN MEDICAL CENTER	Family Medicine @ Domino's Farms 24 Frank Lloyd Wright Drive - Lobby H P O Box 431, Ann Arbor, MI 48106	██████████
5	East Ann Arbor Health and Geriatrics Center (East Ann Arbor Pharmacy)	UNIVERSITY OF MICHIGAN EAST PHARMACY:THE	4260 Plymouth Road, Ann Arbor, MI 481092700	██████████
6	Livonia Center for Specialty Care	UNIVERSITY OF MICHIGAN MEDICAL CENTER	Surgery Center 19900 Haggerty Road Ste 100, Livonia, MI 48152	██████████
7	Survival Flight Ann Arbor Airport Base	UNIVERSITY OF MICHIGAN MEDICAL CENTER	Survival Flight Ann Arbor Airport Base 747 Airport Dr, Ann Arbor, MI 48108	██████████
8	Survival Flight Livingston County Base (LCB)	UNIVERSITY OF MICHIGAN MEDICAL CENTER	University of Michigan Health System Survival Flight Livingston County Base 1911 Tooley Rd, Howell, MI 48855	██████████