

## SETTLEMENT AGREEMENT

This Settlement Agreement (the “Agreement”) is made and entered into by and between the United States of America, acting through the United States Attorney’s Office for the Western District of Michigan, on behalf of the Drug Enforcement Administration (“DEA”) (collectively, the “United States”), and Sixth Street Drugs, Inc. (“Sixth Street Drugs”), through their authorized representatives. The United States and Sixth Street Drugs are each referred to as a “Party” and are collectively referred to as the “Parties.”

### RECITALS

A. Sixth Street Drugs is a Michigan corporation. It is headquartered at 1105 Sixth Street, Traverse City, Michigan, and provides retail pharmacy services and dispenses controlled substances at its location at 1020 Sixth Street, Traverse City, Michigan. Sixth Street Drugs is a subsidiary of Munson Services, Inc., which is a subsidiary of Munson Healthcare. Sixth Street Drugs is registered with the DEA as a retail pharmacy, DEA registration number [REDACTED]

#### B. Statutory and Regulatory Background

1. At all times relevant to this Agreement, Sixth Street Drugs 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 “Controlled Substances Act,” or the “CSA”), and regulations promulgated thereunder, 21 C.F.R. Part 1300, *et seq.* (the “CSA Regulations”).

2. Under the CSA, 21 U.S.C. § 842(a)(1), it is unlawful for a DEA registrant to dispense a controlled substance in the absence of a valid prescription, in violation of 21 U.S.C. § 829.

3. The CSA provides, in relevant part, that “no controlled substance in [S]chedule II . . . may be dispensed without the written prescription of a practitioner . . . .” 21 U.S.C. § 829(a).

4. Prescriptions for controlled substances may only be issued “for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04. Pharmacists and DEA-registered pharmacies have an equal and corresponding responsibility for the proper prescribing and dispensing of controlled substances. *Id.*

5. DEA registrants are subject to a civil monetary penalty of up to \$72,683.00 for each dispensing violation, if the violation occurred after November 2, 2015, and if the penalty was imposed after December 13, 2021. 21 U.S.C. § 842(c)(1)(A); 28 C.F.R. § 85.5.

6. DEA is a Department of Justice component agency. DEA is primarily responsible for administering the CSA and is vested with the responsibility for investigating violations of the CSA. The United States Attorney General, through the United States Attorneys’ Offices, has primary authority to bring civil actions to enforce the CSA and the CSA Regulations. 21 U.S.C. § 871; 28 C.F.R. § 0.55(c).

C. The United States contends that it has civil claims arising from Sixth Street Drugs’ dispensing of controlled substances in violation of the CSA during the period from January 1, 2016, through November 1, 2020, by filling controlled substances prescriptions that lacked a legitimate medical purpose and were outside the usual course of professional practice and by ignoring “red flag” warning signs regarding prescriptions that it filled during that time. That conduct is referred to below as the “Covered Conduct.”

D. This Settlement Agreement is neither an admission of liability by Sixth Street Drugs nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

### **TERMS AND CONDITIONS**

1. Sixth Street Drugs shall pay to the United States ONE MILLION, FIVE HUNDRED THOUSAND DOLLARS (\$1,500,000.00) (the “Settlement Amount”) by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney’s Office for the Western District of Michigan. No later than 30 days after the Effective Date of this Agreement, Sixth Street Drugs will make a payment to the United States of seven hundred and fifty thousand dollars (\$750,000). Sixth Street drugs will pay the remaining seven hundred and fifty thousand dollars (\$750,000), within one year of the Effective Date of this Agreement.

2. Subject to the exceptions in Paragraph 4 (concerning reserved claims) below, and paragraph 11 (concerning bankruptcy) below, and upon the United States’ receipt of the Settlement Amount, the United States releases Sixth Street Drugs from any civil monetary penalty claim under the CSA that is based on the Covered Conduct.

3. Contemporaneously with the execution of this Agreement, Sixth Street Drugs and DEA will enter into a three-year Memorandum of Agreement (“MOA”), which will resolve administrative claims that DEA has or may have against Sixth Street Drugs related to the Covered Conduct. *See* MOA, appended hereto as **Attachment 1**.

4. Notwithstanding the release given in Paragraphs 2 and 3 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 of the United States Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement or in the MOA appended as **Attachment 1**, 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.

5. Sixth Street Drugs waives and shall not assert any defenses Sixth Street Drugs 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.

6. Sixth Street Drugs fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Sixth Street Drugs has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

7. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Sixth Street Drugs agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

8. Sixth Street Drugs agrees to the following:

a. Unallowable Costs Defined: All 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. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Sixth Street Drugs, its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Sixth Street Drugs' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payments Sixth Street Drugs makes to the United States pursuant to this Agreement; and
- (6) the negotiation of, and obligations undertaken pursuant to the MOA,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in paragraph 8.a.(6) that may apply to the obligations undertaken pursuant to the MOA affects the status of costs that are not allowable based on any other authority applicable to Sixth Street Drugs.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Sixth Street Drugs, and Sixth Street Drugs shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Sixth Street Drugs or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Sixth Street Drugs further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Sixth Street Drugs or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Sixth Street

Drugs agrees that the United States, at a minimum, shall be entitled to recoup from Sixth Street Drugs any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Sixth Street Drugs or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Sixth Street Drugs or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Sixth Street Drugs' books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

9. Sixth Street Drugs agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Sixth Street Drugs shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Sixth Street Drugs further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning

any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

10. The Settlement Amount represents the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct.

a. In the event that Sixth Street Drugs fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above, Sixth Street Drugs shall be in Default of its payment obligations (“Default”). The United States will provide a written Notice of Default, and Sixth Street Drugs shall have an opportunity to cure such Default within seven (7) calendar days from the date of receipt of the Notice of Default by making the payment due under the payment schedule and paying any additional interest accruing under the Settlement Agreement up to the date of payment. Notice of Default will be delivered to Sixth Street Drugs, or to such other representative as it shall designate in advance in writing. If Sixth Street Drugs fails to cure the Default within seven (7) calendar days of receiving the Notice of Default and in the absence of an agreement with the United States to a modified payment schedule (“Uncured Default”), the remaining unpaid balance of the Settlement Amount shall become immediately due and payable, and interest on the remaining unpaid balance shall thereafter accrue at the rate of 12% per annum, compounded daily from the date of Default, on the remaining unpaid total (principal and interest balance).

b. In the event of Uncured Default, Sixth Street Drugs agrees that the United States, at its sole discretion, may (i) retain any payments previously made, rescind this Agreement and pursue the Civil Action or bring any civil and/or administrative claim, action, or proceeding against Sixth Street Drugs for the claims that would otherwise be covered by the releases provided in Paragraphs 2 and 3 above, with any recovery reduced by the amount of any payments previously



made by Sixth Street Drugs to the United States under this Agreement; (ii) take any action to enforce this Agreement in a new action or by reinstating the Civil Action; (iii) offset the remaining unpaid balance from any amounts due and owing to Sixth Street Drugs and/or affiliated companies by any department, agency, or agent of the United States at the time of Default or subsequently; and/or (iv) exercise any other right granted by law, or under the terms of this Agreement, or recognizable at common law or in equity. The United States shall be entitled to any other rights granted by law or in equity by reason of Default, including referral of this matter for private collection. In the event the United States pursues a collection action, Sixth Street Drugs agrees immediately to pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected, as allowed by 28 U.S.C. § 3011(a), or (ii) the United States' reasonable attorneys' fees and expenses incurred in such an action. In the event that the United States opts to rescind this Agreement pursuant to this paragraph, Sixth Street Drugs waives and agrees not to plead, argue, or otherwise raise any defenses of statute of limitations, laches, estoppel or similar theories, to any civil or administrative claims that are (i) filed by the United States against Sixth Street Drugs within 120 days of written notification that this Agreement has been rescinded, and (ii) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement. Sixth Street Drugs agrees not to contest any offset, recoupment, and /or collection action undertaken by the United States pursuant to this paragraph, either administratively or in any state or federal court, except on the grounds of actual payment to the United States.

11. In exchange for valuable consideration provided in this Agreement, Sixth Street Drugs acknowledges the following:

a. Sixth Street Drugs has reviewed its financial situation and warrants that it is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I) and shall remain solvent following payment to the United States of the Settlement Amount.

b. In evaluating whether to execute this Agreement, the Parties intend that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to Sixth Street Drugs, within the meaning of 11 U.S.C. § 547(c)(1), and the Parties conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange.

c. The mutual promises, covenants, and obligations set forth herein are intended by the Parties to, and do in fact, constitute a reasonably equivalent exchange of value.

d. The Parties do not intend to hinder, delay, or defraud any entity to which Sixth Street Drugs was or became indebted to on or after the date of any transfer contemplated in this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

e. If Sixth Street Drugs' obligations under this Agreement are avoided for any reason (including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code) or if, before the Settlement Amount is paid in full, Sixth Street Drugs or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of Sixth Street Drugs' debts, or to adjudicate Sixth Street Drugs as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for Sixth Street Drugs or for all or any substantial part of Sixth Street Drugs' assets:

i. the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against Sixth Street Drugs for the claims that would otherwise be covered by the releases provided in Paragraphs 2 and 3 above;

ii. the United States has an undisputed, noncontingent, and liquidated allowed claim against Sixth Street Drugs in the amount of \$3 million less any payments received pursuant to Paragraph 1 of this Agreement, provided, however, that such payments are not otherwise avoided and recovered from the United States by a receiver, trustee, creditor, custodian, or similar official.

f. Sixth Street Drugs agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 11.e is not subject to an “automatic stay” pursuant to 11 U.S.C. § 362(a) because it would be an exercise of the United States’ police and regulatory power. Sixth Street Drugs shall not argue or otherwise contend that the United States’ claim, action, or proceeding is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1). Sixth Street Drugs waives and shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claim, action, or proceeding brought by the United States within 120 days of written notification to Sixth Street Drugs that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the Effective Date of this Agreement.

12. 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.

13. 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.

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

15. 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 Western District of Michigan. 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.

16. This Agreement and the Attachment constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

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

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

19. This Agreement is binding on Sixth Street Drugs' successors, transferees, heirs, and assigns.

20. All Parties consent to the United States' disclosure of this Agreement (including all attachments) and information about this Agreement, to the public, except that DEA Registration Numbers shall be redacted and not disclosed to the public.

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

THE UNITED STATES OF AMERICA

DATED: 5-26-2022

BY:

MARK A. TOTTEN  
United States Attorney



RYAN D. COBB  
Assistant U.S. Attorney  
U.S. Attorney's Office  
Western District of Michigan

DATED: \_\_\_\_\_

BY:

KENT  
KLEINSCHMIDT

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KLEINSCHMIDT  
Date: 2022.05.26 12:22:27 -04'00'

KENT R. KLEINSCHMIDT  
Acting Special Agent in Charge  
Detroit Field Division  
U.S. Drug Enforcement Administration

DATED: \_\_\_\_\_

BY:

KATHY  
FEDERICO


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FEDERICO  
Date: 2022.05.26 12:33:15  
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KATHY L. FEDERICO  
Diversion Program Manager  
Detroit Filed Division  
U.S. Drug Enforcement Administration

SIXTH STREET DRUGS


DATED: 5/25/22

BY:

  
CHRIS PODGES  
President,  
Sixth Street Drugs, Inc.


DATED: 5/26/22

BY:

  
RACHEL BROCHERT ROE  
Chief Legal Officer,  
Munson Healthcare

DATED: 5/26/22

BY:

  
ALAN T. ROGALSKI  
MADELAINE C. LANE  
Warner Norcross & Judd LLP  
Counsel for Sixth Street Drugs

# Attachment 1

Memorandum of Agreement

UNITED STATES DEPARTMENT OF  
JUSTICE DRUG ENFORCEMENT  
ADMINISTRATION

IN THE MATTER OF:

Munson Healthcare on behalf of Sixth Street Drugs, Inc., (Sixth Street Drugs). This MOA applies only to Sixth Street Drugs and no other Munson Healthcare subsidiaries or registered locations.

MEMORANDUM OF AGREEMENT

This Memorandum of Agreement (MOA) is made and entered into by the Drug Enforcement Administration (DEA) and Sixth Street Drugs. This MOA applies only to Sixth Street Drugs and none of Munson Healthcare subsidiaries or other DEA registrants under the Munson Healthcare umbrella. The Parties enter into this MOA in an effort to work together to ensure high quality and safe patient care and to safeguard Sixth Street Drugs staff and the community.

I. DEA FINDINGS OF FACT

The DEA investigated Sixth Street Drugs, in which numerous violations were identified arising from the pharmacy's dispensing of controlled substances in violation of the Controlled Substances Act (CSA) from January 1, 2016, through November 1, 2020. The investigation revealed that the pharmacy filled controlled substance prescriptions that lacked a legitimate medical purpose and were outside the usual course of professional practice and by ignoring "red flag" warning signs regarding controlled substance prescriptions that it filled during that time.

- A. The DEA made the following specific factual findings, which may not include all violations:
1. DEA identified Sixth Street Drugs as a problematic pharmacy based, in part, on its dispensing data, and began an investigation in conjunction with the United States Attorney's Office (USAO) for potential violations of the Controlled Substances Act (CSA).
  2. An analysis of Sixth Street Drugs' controlled substances purchasing data revealed the pharmacy had been both a nationwide and statewide outlier with regards to its procuring of scheduled II controlled substances.
  3. On August 28, 2019, the DEA executed an Administrative Inspection Warrant at Sixth Street Drugs to review the records that are required to be kept under the Controlled Substances Act.



4. The DEA provided a sampling of Sixth Street Drugs' dispensing data to a consulting pharmacy expert for review. The review was conducted to determine the pharmacy's compliance with Title 21, Code of Federal Regulations, Section 1306.04(a).
5. The expert review revealed that numerous red flags existed, including:
  - a) High percentage of prescriptions filled that were controlled substances (27-29%) (National average is around 10-15%)
  - b) Many patients traveling from long distances (e.g. Muskegon patients traveling 5-hour round trips; patients from out of state)
  - c) High number of drug cocktails (i.e., opioids with benzodiazepines, stimulants, and muscle relaxants)
  - d) Early refills
  - e) High Morphine Milligram Equivalents (MME) – Sixth Street Drugs filled prescriptions from physicians where the physician wrote two prescriptions for the same controlled substance: One that would be covered by insurance and one the patient would pay cash. The two prescriptions exceeded the MME for the controlled substance.
  - f) High methadone doses – Sixth Street Drugs routinely filled prescriptions for 450 tablets of methadone every month.
6. During the time period of the Settlement, Sixth Street Drugs dispensed controlled substances including, opioids and benzodiazepine combinations:
  - a) 479 patients were dispensed combinations on the same day at least once. One patient received the combination 39 times.
  - b) 661 patients were dispensed combinations in the same month. 74 patients got this combination over 20 times. One patient for 37 consecutive months.
7. During the time period of the Settlement, Sixth Street Drugs dispensed controlled substances including, opioids, benzodiazepines, and muscle relaxants combinations:
  - a) 8 patients received this combination on same day. One patient received this combination 12 times on the same day.
  - b) 15 patients received this combination in the same month.

8. During the time period of the Settlement, Sixth Street Drugs dispensed controlled substances to patients traveling long distances:
  - a) 389 patients from Michigan whose address was over 50 miles from the pharmacy.
9. During the time period of the Settlement, Sixth Street Drugs dispensed controlled substances that were issued by prescribers whose offices were over 50 miles from the pharmacy.
  - a) 257 prescribers whose address was over 50 miles from the pharmacy.
  - b) 47 out-of-state prescribers
10. During the time period of the Settlement, Sixth Street Drugs filled controlled substance prescription refills early. For the purposes of this MOA, an early refill is defined as refilling a prescription more than 3 days prior to the expected refill date.
  - a) Sixth Street Drugs refilled controlled substance prescriptions for 207 patients. One patient received early refills 74 different times, of which 53 were for oxycodone.
11. During the time period of the Settlement, Sixth Street Drugs filled prescriptions large quantities of controlled substances:
  - a) The pharmacy filled controlled substance prescriptions for 111 patients for more than 300 tablets at one time, including, but not limited to, methadone, morphine, oxycodone, hydromorphone, tramadol, and clonazepam.
  - b) The pharmacy filled controlled substance prescriptions for 43 patients for three or more for opioids on same day.
12. Sixth Street Drugs Employee Responsibilities:
  - a) Lack of appropriate policies and procedures related to the dispensing of controlled substances.
  - b) The presence of red flags of diversion was evident to the pharmacy and it's staff but they continued to fill the prescriptions.
13. Supplier Review Information:
  - a) In March 2019, Sixth Street Drugs' primary controlled substance supplier identified controlled substance prescriptions from one practitioner that exceeded multiple peer group parameters, including trinity cocktail combinations, opioid/ benzo combinations, and opioid/carisoprodol combinations.

- b) The controlled substance supplier review revealed Sixth Street Drugs lacked written policies and procedures it had previously informed the controlled substance supplier that it had.
- c) The controlled substance supplier review noted the following concerns:
  - i) Trinity combinations
  - ii) Opioid and carisoprodol combinations
  - iii) Opioid and benzodiazepine combinations
  - iv) Large % of single ingredient buprenorphine products by individual practitioner
  - v) Large % (tablet count) of opioid prescriptions, including methadone, often with other opioids
  - vi) Mid-level and general practitioners prescribing predominantly for chronic pain

## II. REQUIREMENTS OF THE MOA

The period of this MOA shall be three (3) years. This MOA shall become effective when all parties have signed and dated.

### A. Sixth Street Drugs agrees to abide by the conditions set forth below:

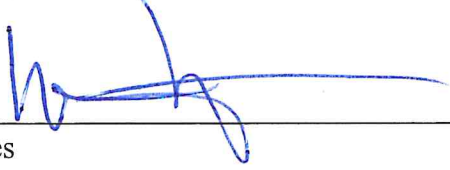
1. In addition to following all applicable laws and codes, Sixth Street Drugs shall register with DEA all locations that handle controlled substances that are required to be registered under the CSA.
2. Sixth Street Drugs shall maintain complete and accurate records for all distributions and dispensing activity.
3. Sixth Street Drugs shall maintain effective controls against diversion consistent with the CSA.
4. Within 30 days following the effective date of this MOA, a complete physical inventory of controlled substances pursuant to the CSA will be conducted at Sixth Street Drugs. Further, Sixth Street Drugs will provide the DEA with an electronic copy of a physical count for all controlled substances at Sixth Street Drugs.
5. Sixth Street Drugs will hire an external auditor to conduct unannounced audits of five (5) highly abused Schedule II-V controlled substances randomly chosen by the auditor at Sixth Street Drugs. The audits will be conducted every six months following the effective date of this MOA and will review compliance with applicable requirements of the CSA and this MOA. These audits will encompass both an accountability and required record review as follows:

- a. A controlled substance accountability of the five (5) highly abused Schedule II-V controlled substances, the information to include the name, strength, and number of dosage units for each controlled substance; and the date for each dispensation. Any discrepancies or deficiencies found by the audits will be resolved within (30) days and documented on the audit report. The results of the controlled substance accountability report will be submitted electronically to the DEA within 45 days after the audit, in an Excel format, to include any discrepancies found during the audit, and any actions taken in response to these discrepancies.
  - b. A review of receiving and dispensing records, utilized to complete the controlled substance accountability, to verify compliance with applicable requirements of the CSA and this MOA. The review will also include the pharmacies actions to resolve red flags relating to the dispensing pharmacists corresponding responsibility as required by Title 21 Code of Federal Regulations §1306.04(a) 05(f). The findings of this review will be submitted electronically to the DEA within 45 days after the audit, in an Excel format, to include any discrepancies found during the record review, any actions taken in response those discrepancies.
    - i. Sixth Street Drugs is required to implement the Diversion Response Team (DRT) as recommended by the third-party auditor.
    - ii. Sixth Street Drugs shall ensure security controls and procedures are in place to prevent controlled substances from being diverted. Every six months following the effective date of this MOA, Sixth Street Drugs shall provide DEA an account of every reported suspicious controlled substance incident, in electronic format, within 30 days of the close of the six-month time period. The report must include the reason for the initiated investigation; what actions did Sixth Street Drugs take; and, what remedial or corrective measures were implemented.
    - iii. Sixth Street Drugs shall investigate and document any theft of controlled substances, or any significant loss. If a theft of a controlled substance or any significant loss occurs, Sixth Street Drugs shall report the theft or significant loss in compliance with the CSA.
6. Within 30 days following the effective date of this MOA, Sixth Street Drugs 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. Sixth Street Drugs shall, at minimum, create and/or implement the following:

- a. Employee orientation materials designed to educate Sixth Street Drugs employees or those individuals that will have access to controlled substances at the pharmacy as part of their official duties, on the potential of drug diversion in the workplace.
  - b. Annual employee training module designed to prevent drug diversion and create awareness of the necessity for the safe handling of controlled substances to be delivered to all employees who have regular access to controlled substances at Sixth Street Drugs. 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.
  - c. Within 60 days following the effective date of this MOA, Sixth Street Drugs shall provide documentation, that all employees of Sixth Street Drugs and other individuals who have access to controlled substances at Sixth Street Drugs were trained pursuant to the above training.
7. Notify the State of Michigan Department of Licensing and Regulatory Affairs and DEA of any licensed employee who has been discharged and/or resigned from employment at Sixth Street Drugs due to the diversion of controlled substances.
8. Sixth Street Drugs shall allow DEA representatives to perform unannounced inspections without an Administrative Inspection Warrant.
9. Sixth Street Drugs shall not, after the effective date of this MOA, hire as an employee who has access to controlled substances, any person 1) who 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, Sixth Street Drugs determines that the person is unfit for the position or 2) who Sixth Street Drugs 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 Sixth Street Drugs desires to employ an individual at Sixth Street Drugs, otherwise prohibited by this provision, Sixth Street Drugs must request, pursuant to the CSA, a waiver from DEA.
10. If Sixth Street Drugs wishes to change/modify any of the conditions of this MOA, Sixth Street Drugs shall notify the DEA of the proposed change/modification. DEA will respond, in writing, prior to any proposed change/modification.

For any part of this MOA that requires reporting to DEA, Sixth Street Drugs shall submit documents in electronic format to [SIXTHSTREET.COMPLIANCE@dea.gov](mailto:SIXTHSTREET.COMPLIANCE@dea.gov).

For SIXTH STREET DRUGS INC.:

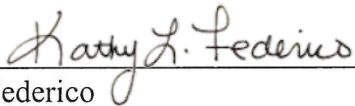


Chris Podges  
President

Date: 5/25/22

For the DRUG ENFORCEMENT ADMINISTRATION:

Kathy L. Federico, Diversion Program Manager, DEA Detroit Field Division, acknowledges and states she has read the foregoing and agrees with the contents thereof; and 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.



Kathy L. Federico  
Diversion Program Manager  
Detroit Field Division

Date: 05-26-2022