

## 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, the Drug Enforcement Administration (“DEA”), and the Department of Labor (collectively, the “United States”); and Injured Workers Pharmacy LLC (“IWP”). The United States and IWP are each referred to herein as a “Party” and collectively as the “Parties.”

### RECITALS

A. IWP is a mail-order pharmacy that is located at 300 Federal St, Andover, Massachusetts. IWP dispenses and ships prescription drugs, including controlled substances, across the United States, primarily to workers who have been injured on the job. IWP is a pharmacy registered with the DEA.

B. The DEA is the Department of Justice component agency primarily responsible for enforcing the Controlled Substances Act (“CSA”), 21 U.S.C. § 801, et seq., and is vested with the responsibility of investigating violations of the CSA.

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

D. The Department of Labor’s Office of Worker Compensation Programs administers workers compensation claims under the Federal Workers Compensation Act. Each pharmacy submitting claims for payment to the Department of Labor pursuant to that Act “signifies that the service for which reimbursement is sought was performed as described, necessary, appropriate and properly billed in accordance with accepted industry standards.” 20 C.F.R. § 10.801(d). In 2018, the Department of Labor began requiring pharmacies to pre-

adjudicate federal workers compensation prescription claims electronically through a pharmacy benefit manager. The Department of Labor required pre-adjudication to curtail opioid abuse among injured federal workers.

E. Each DEA registrant is required to conduct its operations in accordance with the CSA and the regulations promulgated thereunder. Under the CSA, a prescription “must 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(a). The prescriber has a responsibility for proper prescribing, “but a corresponding responsibility rests with the pharmacist who fills the prescription.” *Id.*

F. Beginning in or around June 2018, the United States and the Attorney General for the Commonwealth of Massachusetts (the “Massachusetts AG”) began investigating, among other things, IWP’s processes and documentation relating to the dispensing of controlled substances. The two investigations proceeded in parallel until June 2020, when IWP resolved the Massachusetts AG’s investigation by settling with the Massachusetts AG for \$11 million and agreeing to permanent injunctive relief in a stipulated consent judgment (the “Massachusetts AG Consent Judgment”). The settlement with the Massachusetts AG concerned IWP’s dispensing practices from 2008 to 2019. The United States’ investigation concerned IWP’s dispensing practices, as discussed further below, from 2014 through 2019.

G. Prior to and in connection with the Massachusetts AG Consent Judgment, IWP implemented changes to its policies and procedures concerning dispensing controlled substances, including opioids.

H. IWP admits, acknowledges, and accepts its responsibility for the following facts:

a. Between January 1, 2014, and July 31, 2019, IWP received numerous

prescriptions with “red flags,” including high doses of opioids, early refills, and “Holy Trinities.” A Holy Trinity occurs when an opioid, a benzodiazepine, and a muscle relaxant are prescribed simultaneously to a patient. “Red flags” may indicate a prescriber issued a prescription for a reason other than a legitimate medical purpose, such as abuse or diversion. Pharmacists must review and resolve such “red flags” before filling any prescription. When IWP received prescriptions with “red flags” between January 1, 2014, and July 31, 2019, IWP pharmacists did not always resolve the “red flags” before filling those prescriptions. Even though IWP implemented process improvements beginning in 2017, IWP pharmacists did not have a consistent process or documentation with respect to resolving “red flags.”

b. IWP dispensed medications to injured federal workers and submitted claims for payment to the Department of Labor. Between December 12, 2017, and September 26, 2019, the Department of Labor’s pharmacy benefit manager issued drug utilization review (“DUR”) alerts for 1,456 claims for federal workers’ prescriptions for issues such as drug interactions, potential allergic reactions, and therapeutic duplication of opioids. A DUR helps pharmacists ensure that prescribed drugs are appropriate and medically necessary. To clear those DUR rejections and ultimately receive payment from the Department of Labor, IWP’s non-pharmacy, claims employees routinely submitted override codes representing that IWP had consulted with prescribers about the DUR alerts. The IWP claims employees, who lacked clinical pharmacy experience and training, submitted the overrides without consulting with IWP pharmacists. Because IWP pharmacists were not aware of the rejections, they did not consult with prescribers in response to the DUR alerts received from the Department of Labor, as represented by IWP claims employees. The foregoing conduct set out in subparagraphs (a) through (b) of Paragraph H is referred to below as the “Covered Conduct.”

I. In May 2020, IWP self-disclosed to the Department of Labor that the DUR alerts issue affected 821 claims and offered to repay 256 of them.

J. The United States contends that it has certain civil and administrative claims for civil monetary penalties, injunctive relief, and administrative remedies against IWP under the CSA and its implementing regulations based upon the Covered Conduct. Such civil and administrative claims under the CSA include violations of 21 U.S.C. §§ 827(a)(3), 842(a)(1), 843(a)(2), and the following implementing regulations: 21 C.F.R. §§ 1301.19(b), 1301.71(a), 1304.21(a), 1306.04(a), 1306.05(a), 1306.06, and 1307.02.

K. The United States also contends that it has certain federal civil claims against IWP for submitting or causing the submission of false claims for payment to the Department of Labor.

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

#### TERMS AND CONDITIONS

1. IWP shall pay to the United States the sum of Ten Million Dollars (\$10,000,000), plus interest at a rate of 3.6% per annum from February 13, 2023 (“Settlement Amount”), of which \$318,341.40 is restitution. Within fifteen (15) calendar days of the Effective date of this agreement, IWP shall pay One Million Two Hundred Fifty Thousand Dollars (\$1,250,000), plus interest accrued.

a. Over a period of five years, IWP will pay the remaining Eight Million, Seven Hundred Fifty Thousand Dollars (\$8,750,000), plus interest at 3.6% per annum, pursuant to the payment schedule attached at Exhibit A. If a prepayment occurs under either paragraph 1.d or paragraph 7 of this Agreement, the parties agree that the principal balance will be adjusted

accordingly and that the computation and allocation of interest set forth in Exhibit A will be adjusted consistent with the remaining principal balance.

b. Interest shall accrue on the unpaid Settlement Amount as indicated in Exhibit A. Collectively the Settlement Amount and interest received by the United States shall be referred to as the “Settlement Payments.”

c. If IWP or any of its affiliates is sold, merged, or transferred, or a significant portion of the assets of IWP or of any of its affiliates is sold, merged, or transferred into another non-affiliated entity, IWP shall promptly notify the United States, and all remaining payments owed pursuant to the Agreement shall be accelerated and become immediately due and payable.

d. The Settlement Amount may be prepaid, in whole or in part, without penalty or premium.

e. IWP shall pay the Settlement Payments, or any portion thereof, by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the District of Massachusetts.

2. No later than five business days after the Effective Date of this agreement, IWP and the DEA will enter into the Corrective Action Plan (“CAP”).

3. Subject to the exceptions in Paragraph 4 (concerning reserved claims) and Paragraph 5 (injunctive relief) below, and conditioned upon the United States’ receipt of the Settlement Amount, and upon IWP complying with Paragraph 2, the United States releases IWP, its predecessors, its current and former parents, divisions, subsidiaries, successors, and assigns from any civil or administrative monetary claim the United States has for the Covered Conduct under Controlled Substances Act; the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program

Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

4. Notwithstanding the release given in Paragraph 3 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, or any administrative remedy, 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;
- g. Any liability for failure to deliver goods or services due; and
- h. Any liability for personal injury or property damages or for other consequential damages arising from the Covered Conduct.

5. The United States reserves the right to seek injunctive relief pursuant to 21 U.S.C. § 843(f) if IWP fails to pay the Settlement Amount, or fails to comply with the obligations of the CAP.

6. IWP has provided financial disclosures and supporting documents (“Financial Disclosures”) to the United States, and the United States has relied on the accuracy and completeness of those Financial Disclosures in reaching this Agreement. IWP warrants that the

Financial Disclosures are complete, accurate, and current as of the Effective Date of this Agreement. If the United States learns of asset(s) in which IWP had an interest of any kind as of the Effective Date of this Agreement (including, but not limited to, promises by insurers or other third parties to satisfy IWP's obligations under this Agreement) that were not disclosed in the Financial Disclosures, or if the United States learns of any false statement or misrepresentation by IWP on, or in connection with, the Financial Disclosures, and if such nondisclosure, false statement, or misrepresentation changes the estimated net worth set forth in the Financial Disclosures by One Million Dollars (\$1,000,000) or more, the United States may at its option: (a) rescind this Agreement and reinstate its suit or file suit based on the Covered Conduct or (b) collect the full Settlement Amount in accordance with the Agreement plus one hundred percent (100%) of the net value of IWP's previously undisclosed assets. IWP agrees not to contest any collection action undertaken by the United States pursuant to this provision and agrees that it will immediately pay the United States the greater of (i) a ten-percent (10%) surcharge of the amount collected in the collection action, 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, pursuant to this paragraph rescinds this Agreement, IWP waives and agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 120 calendar days of written notification to IWP that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on the Effective Date of this Agreement.

7. In the event IWP receives proceeds from any insurance policy on account of the Settlement Amount in this Agreement or the Covered Conduct at any time before the Settlement

Amount has been paid in full, IWP agrees to remit those insurance proceeds to the United States within fifteen (15) days, and that amount shall be credited against future payments, with the schedule of remaining payments to be adjusted as described in paragraph 1.a. IWP need not remit to the United States more insurance proceeds than necessary to pay the Settlement Amount in full. This paragraph does not apply to IWP's receipt of proceeds from any insurance policy on account of its legal expenses.

8. IWP waives and shall not assert any defenses it may have to any criminal prosecution 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.

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

10. IWP agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of IWP, and 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 and any criminal investigation(s) of the matters covered by this Agreement;
- (3) IWP's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment IWP makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by IWP, and IWP shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, IWP shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by IWP or any of its subsidiaries or affiliates from the United States. IWP agrees that the United States, at a minimum, shall be entitled to recoup from IWP any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine IWP's books and records and to disagree with any calculations submitted by IWP or

any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by IWP, or the effect of any such Unallowable Costs on the amount of such payments.

11. The obligations imposed upon IWP pursuant to this Agreement are in addition to, and not in derogation of, all requirements imposed upon IWP 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.

12. IWP agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, IWP 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. IWP 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.

13. The Settlement Amount and Settlement Payments represent the amount the United States is willing to accept in compromise of its civil claims arising from the Covered Conduct due solely to IWP's financial condition as reflected in the Financial Disclosures referenced in Paragraph 6.

a. In the event that IWP fails to pay the Settlement Amount as provided in the payment schedule set forth in Paragraph 1 above and in Exhibit A, IWP shall be in Default of IWP's payment obligations ("Default"). The United States will provide a written Notice of

Default, and IWP 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 Agreement up to the date of payment. Notice of Default will be delivered to IWP, or to such other representative as IWP shall designate in advance in writing. If IWP 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).

14. In the event of Uncured Default, IWP 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 IWP for the claims that would otherwise be covered by the releases provided in Paragraph 4 above, with any recovery reduced by the amount of any payments previously made by IWP 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 IWP 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, IWP 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, IWP 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 IWP 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. IWP 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.

15. In exchange for valuable consideration provided in this Agreement, IWP acknowledges the following:

a. IWP 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 IWP, 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 IWP 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 any of IWP's payments or 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, IWP 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 IWP's debts, or to adjudicate IWP as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for IWP or for all or any substantial part of IWP's assets:

(i) the United States may rescind the releases in this Agreement and bring any civil and/or administrative claim, action, or proceeding against IWP for the claims that would otherwise be covered by the releases provided in Paragraph 4 above; and

(ii) the United States has an undisputed, noncontingent, and liquidated allowed claim against IWP in the amount of Eleven Million Two-Hundred Twenty-Six Thousand Sixty-Two Dollars and Seventy-One Cents (\$11,226,062.71), plus first payment handshake interest, per Paragraph 1, 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. IWP agrees that any civil and/or administrative claim, action, or proceeding brought by the United States under Paragraph 17.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. IWP 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). IWP 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 IWP that the releases have been rescinded pursuant to this paragraph, except to the extent such defenses were available on the Effective Date.

16. This Agreement is intended to be for the benefit of the Parties only.

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

18. Each Party represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

19. 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 District of Massachusetts. This Agreement shall be deemed to have been drafted by all Parties to this Agreement and, therefore, shall not be construed against any Party for that reason in any subsequent dispute.

20. The Agreement contains the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties. Forbearance by the United States from pursuing any remedy or relief available to it under this Agreement shall not constitute a waiver of rights under this Agreement.

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

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

23. This Agreement is binding on IWP's successors, transferees, heirs, and assigns.

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


25. The Parties may execute this Agreement via facsimile and/or by portable document format (.pdf), both of which shall be deemed the equivalent of an original signature.

26. This Agreement shall become effective on the date of the signature of the last signatory to the Agreement ("Effective Date" of this Agreement).

SIGNATURES TO FOLLOW ON NEXT PAGE

THE UNITED STATES OF AMERICA

DATED: 6/27/2023

BY: 

BRIAN M. LAMACCHIA  
JESSICA J. WEBER  
Assistant U.S. Attorneys  
United States Attorney's Office  
District of Massachusetts

DATED: 6/13/2023

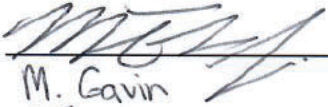
BY: 

JENNIFER VALDIVIESO  
Deputy Director for Program and  
System Integrity  
Division of Federal Employees', Longshore  
and Harbor Workers' Compensation  
Office of Workers' Compensation Programs  
United States Department of Labor



INJURED WORKERS PHARMACY LLC

DATED: 6/23/23

BY:   
M. Gavin  
CEO

DATED: 6/23/2023

BY: 

ERIC P. CHRISTOFFERSON  
BRIAN H. BENJET  
DLA Piper LLP  
Counsel for Injured Workers Pharmacy LLC

**Exhibit A**

<b>Year</b>	<b>Payment #</b>	<b>Due Date</b>	<b>Principal</b>	<b>Interest</b>	<b>Payment</b>	<b>Balance</b>
						\$10,000,000.00
0	1	Effective Date of Agreement	\$1,250,000.00	Handshake interest to be calculated per Para. 1 based on payment date	\$1,250,000.00, plus handshake interest	\$8,750,000.00
1	2	One year after First Payment	\$935,000.00	\$315,000.00	\$1,250,000.00	\$7,815,000.00
2	3	Two years after First Payment	\$968,660.00	\$281,340.00	\$1,250,000.00	\$6,846,340.00
3	4	Three years after First Payment	\$1,003,531.76	\$246,468.24	\$1,250,000.00	\$5,842,808.24
4	5	Four years after First Payment	\$1,039,658.90	\$210,341.10	\$1,250,000.00	\$4,803,149.34
5	6	Five years after First Payment	\$4,803,149.34	\$172,913.38	\$4,976,062.71	\$0.00
		TOTAL	\$10,000,000.00	\$1,226,062.72, plus handshake interest	\$11,226,062.71, plus handshake interest	

## **Attachment 1 - Corrective Action Plan**

This Corrective Action Plan (“CAP”) between the Injured Worker’s Pharmacy (“IWP”) and the U.S. Drug Enforcement Administration (“DEA”) memorializes the policies and procedures that IWP and the DEA (jointly, the “Parties”) have agreed upon to advance IWP’s efforts to ensure compliance with the Controlled Substances Act (the “Act”) and to enhance IWP’s ability to prevent, detect, and address drug diversion. IWP is registered with the DEA as a Retail Pharmacy authorized to handle Schedule II-V controlled substances under DEA [REDACTED].

1. This CAP is incorporated by reference at paragraph 2 of the Settlement Agreement between IWP and the United States executed contemporaneously with this CAP (the “Settlement Agreement”).
2. This CAP pertains to the “Covered Conduct” described in Recital H of the Settlement Agreement and in the United States’ contentions in Recital I of the Settlement Agreement.
3. DEA agrees to take no further administrative action against IWP, along with their respective directors, officers, managers, employees, successors and assigns related to the Covered Conduct. However, should IWP violate this CAP, IWP understands that DEA may institute further administrative action, including but not limited to seeking revocation of IWP’s DEA registration for any new violation, as well as for the Covered Conduct. DEA may also seek injunctive relief to enforce the terms of the CAP pursuant to 21 U.S.C. § 843 (f), as stated in Paragraph 5 of the Settlement Agreement.
4. The period of this CAP shall be five (5) years, starting on the Effective Date of the Settlement Agreement.

5. Whenever this CAP requires notice to the DEA, the persons to be notified will be Taylor McCarty [REDACTED] and Heather Danner-Ryan [REDACTED]. Whenever this CAP requires notice to IWP, the persons to be notified will be Jayne Kresac [REDACTED] [REDACTED] and Brian Benjet [REDACTED].

Either party may change the name and/or contact information of its contact person(s) by so notifying the other party's contact person(s).

6. Prior to, in connection with, and following the Massachusetts AG Consent Judgment, IWP has implemented several changes to their controlled substance handling procedures, including, but not limited to, the following:

- a. In 2018, IWP released a High-Risk Prescribing Regimens Standard of Procedure ("SOP"), which requires pharmacists to conduct a thorough review of prescriptions that are identified as part of a high-risk drug combination. As later amended, this SOP requires the Pain Management Specialty Pharmacist to contact the prescribers of the identified high-risk prescriptions to confirm awareness and accuracy of the prescribed dosages and treatment plan.
- b. In 2020, IWP implemented an Initial High-Risk Opioid Prescription Policy and Procedure, which expands the clinical checks conducted prior to initial dispensing, by including a process for documenting the authenticity of high-risk prescriptions before dispensing the medication and a process for providing specific counseling to patients regarding alternatives to high-risk prescriptions. IWP also implemented training regarding the identification of initial high-risk opioid prescriptions, the review process, and the documentation process. In

addition, IWP implemented an At-Risk Patient Process that requires holistic review of patient profiles for high-risk medications.

- c. IWP has implemented other new and revised pharmacy policies and procedures.

IWP has provided the DEA with copies of its current policies and procedures that pertain to:

- i. At-Risk Patient Chronic Pain Counseling
- ii. CII Room Operation
- iii. Controlled Substance Inventory
- iv. Controlled Substances Workflow (CIII-CV)
- v. Drug Utilization Review (DUR)
- vi. Clinical Intervention: High Risk Prescribing Regimens
- vii. Initial High-Risk Opioid Prescriptions
- viii. Naloxone Standing Order
- ix. New At-Risk Patient Auditing Procedure
- x. PDMP Query
- xi. Prescription Authentication Practices
- xii. Processing Pharmacist Responsibilities & Preserving Pharmacist's Judgement
- xiii. Professional License Verification (MedPro)
- xiv. Receipt of Pharmaceutical Inventory
- xv. Pharmacy Record Retention
- xvi. Pharmacy Risk Evaluation and Mitigation Strategy (REMS)
- xvii. Schedule II Narcotic Non-Contiguous States
- xviii. PMSP Program Provider Monitoring

7. Since 2017, IWP has either hired new personnel or created new positions including: a Chief Compliance Officer that reports to the Board of Directors as well as the Chief Executive Officer, Pain Management Specialty Pharmacist, replacing its Chief Executive Officer, and hiring new executive and clinical leadership. IWP's new Chief Compliance Officer has since designed and implemented a new compliance program.
8. IWP agrees that it will continue utilizing the changes that it undertook, as those changes are listed out in paragraph 6 in order to address the Covered Conduct, and to remain in compliance with Title 21 of the Code of Federal Regulations.

9. During the CAP Period, IWP:
- a. Agrees to abide by all federal, state and local statutes and regulations relating to controlled substances.
  - b. Agrees to allow DEA personnel to enter the registered location at any time during regular business hours, without prior notice, and without requiring DEA to obtain an administrative inspection warrant, search warrant, or other means of entry, in order to verify compliance with the Controlled Substances Act (Title 21 United States Code §801, et seq.), its implement regulations, and this CAP.
  - c. Agrees to maintain complete and accurate records relating to controlled substances, and to maintain copies of these records for a period of five years, from the effective date of this CAP, which will be available to DEA for inspection and copying, and inventories as required by 21 C.F.R. § 1304.04(a), except that, during the CAP Period only, the time period for which records and inventories must be maintained is extended to five (5) years from the date of such records or inventories.
  - d. Agrees to be truthful and accurate in all information that it submits to the DEA and that any notifications, as required by this CAP and DEA rules and regulations, are timely submitted.
  - e. Agrees that if any state agency or entity conducts an inspection or any investigation of IWP by seeking any records or documents from IWP, IWP hereby gives its unrestricted consent to the state agency or entity to share

any and all reports, documents, evidence and information of whatever nature or kind with the DEA.

- f. Agree to continue implementing SOP's to ensure compliance with its obligations under 21 CFR 1306.04(a).
- g. Agrees to maintain SOPs to ensure compliance with its obligations under 21 CFR § 1306.04(a).
- h. Agrees that it shall maintain SOPs to ensure the pharmacy complies with the requirements of 21 CFR § 1306.05, including by ensuring prescriptions contain all the required information.
- i. Agrees to maintain, on a current basis, a complete and accurate record of each controlled substance received, sold, delivered, dispensed or otherwise disposed of, as required by 21 CFR § 1304.21(a).
- j. Agrees that only IWP pharmacists will make clinical determinations relating to Drug Utilization Review ("DUR") alerts for prescriptions that are flagged for issues such as drug interactions, potential allergic reactions, dangerous drug combinations and therapeutic duplication of opioids, to ensure that the prescribed drugs are appropriate and medically necessary prior to filling.
- k. Agrees to emphasize the identification of potential safety concerns, red flags, and potentially illegitimate prescriptions.
- l. Agrees to not make any decision relating to a pharmacist's performance review, compensation, promotion, work hours, hiring, or termination that relies in whole or in part on dispensing rates, whether measured individually or in aggregate. This restriction shall not be interpreted to limit IWP's ability

to reassign pharmacists to different responsibilities based on operational considerations, or to prohibit employment decisions based upon non-performance (e.g., absenteeism, failure to complete essential job responsibilities) or significant underperformance, as compared to peers and taking into account best dispensing practices.

- m. Agrees to provide controlled substance training to all new employees who handle controlled substances or records related to controlled substances. This training shall be conducted within one week of hire. This training shall include, but not be limited to the following: (1) the proper handling, recordkeeping, security, and storage procedures for controlled substances (2) how to identify and handle prescription red flags to ensure patient safety and prescription legitimacy (3) how to identify potentially dangerous medication combinations (4) current CDC prescription guidelines and (5) controlled substance abuse and prevention.
- n. Agrees to provide controlled substance training to all current employees who handle controlled substances or records related to controlled substances. This training shall be conducted at least, but not limited to, annually. This training shall include, but not be limited to the following: (1) the proper handling, recordkeeping, security, and storage procedures for controlled substances (2) how to identify and handle prescription red flags to ensure patient safety and prescription legitimacy (3) how to identify potentially dangerous medication combinations (4) current CDC prescription guidelines and (5) controlled substance abuse and prevention.



- o. Agrees to maintain a drug diversion team consisting of employees in compliance, pharmacy, security and operations roles. This drug diversion team shall be tasked with establishing, maintaining, and, if appropriate, advancing various diversion controls throughout IWP.
- p. Will send a copy of this CAP, in its entirety, to the Massachusetts Department of Public Health Drug Control Program, within ten days of the full execution of this Agreement.
- q. At least once every 12 months following the Effective Date of the Settlement Agreement, IWP will conduct a self-evaluation to review compliance with all requirements of the Act, this CAP and its corresponding commitments to maintain SOPs and a compliance program directed at IWP's obligations under the Act. At the completion of each evaluation, the Pharmacy Manager of Record and/or the Chief Compliance Officer will certify that he/she has completed the evaluation and document any corrective action to be taken. IWP will retain the letters of certification, and make them available to the DEA upon request, for two years following the expiration of this CAP.
- r. IWP will promptly and thoroughly investigate all thefts, significant losses, and other potential diversions of controlled substances. IWP will establish protocols to reduce the number of in-transit losses of controlled substances and will promptly report all such thefts, significant losses, and other diversions to DEA. DEA is aware that IWP has additional reporting duties to licensure boards, and all other relevant agencies.

10. IWP will comply at all times with the Act and the regulations issued thereunder. To the extent that any requirements in the Act or regulations are greater than those imposed by this CAP, the stricter requirements will apply.
11. Each Party and signatory to this CAP represents that it/he/she freely and voluntarily enters into this CAP without any degree of duress or compulsion.
12. This CAP is intended for the benefit of the Parties only; it does not create any rights or benefits for third parties.
13. This CAP is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this CAP is the United States District Court for the District of Massachusetts. This CAP shall be deemed to have been drafted by both Parties and shall not, therefore, be construed against either Party in any subsequent dispute.
14. This CAP and the Settlement Agreement constitute the complete agreement between the DEA and IWP relating to the matters addressed herein. This CAP may be amended only by a writing signed by both DEA and IWP.
15. The undersigned signatories represent and warrant that it is fully authorized to execute this CAP on behalf of the parties.
16. This CAP may be executed in two counterparts, each of which constitutes an original and both of which constitute one and the same agreement.
17. This CAP is binding on IWP's successors, transferees, and assigns.


**SIGNATURES TO FOLLOW ON NEXT PAGE**

**On Behalf of IWP:**



\_\_\_\_\_  
Brian H. Benjet  
DLA Piper LLP (US)  
Counsel for Injured Workers Pharmacy LLC

Date: 6-23-2023



\_\_\_\_\_  
Michael Gavin  
Chief Executive Officer  
Injured Workers Pharmacy LLC

Date: 6/23/23

**On Behalf of the United States Department of Justice,  
Drug Enforcement Administration:**

**BRIAN**  
**BOYLE**

Digitally signed by  
BRIAN BOYLE  
Date: 2023.06.23  
17:46:30 -04'00'

\_\_\_\_\_  
Brian D. Boyle  
Special Agent in Charge  
Drug Enforcement Administration  
New England Field Division

Date: \_\_\_\_\_

**MARK**  
**RUBBINS**

Digitally signed by  
MARK RUBBINS  
Date: 2023.06.23  
15:28:24 -04'00'

\_\_\_\_\_  
Mark J. Rubbins  
Diversion Program Manager  
Drug Enforcement Administration  
New England Field Division

Date: \_\_\_\_\_