

## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and its Drug Enforcement Administration (“DEA”) (collectively, the “United States”), and Okanogan County Public Hospital District No. 3, doing business as Mid-Valley Hospital and Clinic (“Mid-Valley”) through their authorized representatives. The United States and Mid-Valley may be referred to in this Agreement singly as “Party” and collectively as “Parties.”

### Recitals

A. Mid-Valley operates a critical access hospital located in Omak, Washington, that provides inpatient and outpatient services including acute care, emergency services, surgery, obstetrics, orthopedics, and related ancillary services such as laboratory, anesthesia, physical and occupational therapy, radiology, and pharmacy. Mid-Valley has a DEA registration number of A00966347, allowing it to dispense and administer Controlled Substances as prescribed by provider (*i.e.*, Advanced Registered Nurse Practitioner (“ARNP”) or Physician Assistant) and physician members of the medical staff. Mid-Valley uses BD Pyxis MedStation™ automated medication dispensing systems (“Pyxis”) to control staff access to, and dispensing of, medications that require a prescription (“Legend Drugs”) and medications classified as having significant potential for addiction or misuse (“Controlled Substances”) in its acute and outpatient services, including medical services, surgical and obstetrical services, and the Emergency Department. In the typical hospital admissions process, provider or physician orders for each patient’s medications (“Routine Orders”) are entered into the Pyxis. Then, the nurse caring for the patient can access each drug and dose ordered for the patient, and the Pyxis tracks when, by whom, and to whom the drugs are administered. If during hospitalization, a patient requires a medication not previously ordered by the physician or provider, the nurse obtains an order from the physician or provider, then enters the new medication order into the Pyxis so that the medication may be dispensed to the patient. This process is known as an override.

B. In order to protect the public and public health, the Controlled Substances Act, 21 U.S.C. §§ 801 *et seq.*, and implementing regulations promulgated by the DEA (collectively “the CSA”), place duties and responsibilities on medical facilities and professionals (“Registrant(s)”) to ensure that Controlled Substances are prescribed, dispensed, and administered for medically appropriate purposes and in a safe manner. Under the CSA, Registrants are required to keep, on a

current basis, a complete and accurate record of each Controlled Substance received by the Registrant, dispensed for use, and administered to a patient or otherwise disposed of by the Registrant. *See* 21 C.F.R. § 1304.21(a). Registrants who dispense Controlled Substances, including Mid-Valley, are also required to maintain records documenting, *inter alia*, the name of the person to whom each Controlled Substance is dispensed, the date the drug is dispensed, the name or initials of the individual who dispensed or administered the drug, and the number of units or volume dispensed. *See* 21 C.F.R. § 1304.22(c).

C. The CSA also requires that all Registrants provide effective controls and procedures to guard against theft or diversion of Controlled Substances. *See* 21 C.F.R. §1301.74(b). A Registrant is required to notify the DEA of the theft or significant loss of any Controlled Substances within one business day of discovery and to file a complete and accurate DEA Form 106 within 45 days. 21 C.F.R. § 1301.76(b). The DEA Form 106 requires the registrants to identify the number of thefts or losses over the past 24 months and the total quantity of each controlled substance lost or stolen.

D. Beginning in November 2021, Eileen Lombardi was employed by Mid-Valley as a Registered Nurse and ARNP. Lombardi's employment authorized her to have access to all Controlled Substances in Mid-Valley's inpatient and outpatient services and the Emergency Department. Lombardi had previously stolen Controlled Substances at a former employer hospital but had not disclosed her prior conduct to Mid-Valley. Lombardi had, while working for that previous employer hospital, successfully completed the Washington Health Professional Services program offered through the Washington Board of Nursing, which offers nurses with a substance use disorder "an opportunity to safely provide patient care through the monitoring of nurses in a manner that safeguards the public throughout the stages of their recovery and program participation." *See* "Washington Health Professional Services (WHPS)," *available at*: <https://nursing.wa.gov/support-practicing-nurses/support-substance-use>.

E. Shortly after she began working at Mid-Valley, Lombardi began to steal Dilaudid, which is a brand name for hydromorphone HCl ("Dilaudid"). Initially, Lombardi diverted Dilaudid through a process known as "wastage;" that is, pursuant to Routine Orders for a patient, Lombardi dispensed Dilaudid contained in a 1 mg or 2 mg vial from the Pyxis for a *bona fide* patient. Then, she withdrew the prescribed dose of the Dilaudid contained in the dispensed vial, *e.g.*, 0.5 mg, into a syringe and set that syringe aside for the patient, took another syringe from her

pocket, withdrew the remaining Dilaudid from the vial (which, under Mid-Valley policy, was supposed to be disposed of, or “wasted,” by emptying the vial into the sink) and put that syringe in her pocket. She then took the stolen Dilaudid home at the end of her shift (“Waste Thefts”).

F. Later in her employment, Lombardi began to enter overrides into the Pyxis to obtain access to additional Controlled Substances, which she then diverted to her own personal use. In entering the overrides, Lombardi sometimes used the names of real patients, many of whom had already been discharged from the hospital; additionally, she created fictitious patients and entered orders for Dilaudid through the override process. While a nurse might typically note in the patient record the reason for an override—*e.g.*, “patient complains of increased pain”—Lombardi entered no notes in the patient record to explain her overrides. Mid-Valley typically had a cumulative total of fewer than one override per week from all nurses; however, the number of overrides entered when Lombardi was working was consistently significantly higher than those entered by other staff. Lombardi also often volunteered to work extra shifts, which Lombardi admitted later was so she could have more access to steal Controlled Substances. Lombardi admitted to DEA investigators that she diverted 2-3 units of 1 mg/ml Dilaudid every shift she worked at Mid-Valley. Lombardi admitted that she diverted about half the drugs she stole through the use of overrides for fictitious or discharged patients (“Override Thefts”), and half through Waste Thefts of amounts designated as waste after administration of Dilaudid to *bona fide* patients.

G. Finally, information obtained during Mid-Valley’s own investigation indicated that Lombardi appeared to use a third method to obtain more Dilaudid; that is, by originating orders for the drug as an ARNP member of the Medical Staff (which is permissible for ARNPs in Washington) and diverting one-half to three-quarters of the amount of Dilaudid she ordered through Waste Thefts. In these thirty-seven (37) instances, Lombardi ordered 2 mg/ml vials of Dilaudid for patients who each received either 0.25 mg or 0.5 mg of Dilaudid, resulting in 1.75 mg or 1.5 mg per vial stolen by Lombardi.

H. Pyxis machines produce Override reports for all Overrides entered into the system. Mid-Valley pharmacy technicians (nonprofessional, technical staff who assist in the pharmacy) printed off these reports regularly and placed them on the counter for review; however, the Pharmacy Director, who was a Registered Pharmacist licensed by the Washington Board of Pharmacy, filed them away without reviewing them. As a result, no one at Mid-Valley reviewed the records for discrepancies in dispensing and administration of Controlled Substances, which

enabled Lombardi to continue diverting Dilaudid for two years. During the period of Lombardi's employment, Mid-Valley also generally maintained readily retrievable records for the administration of Controlled Substances for only ninety (90) days.

I. In mid-2023, a billing audit was begun at Mid-Valley as part of its compliance monitoring program. In the course of this audit, the reviewer noticed that financial records indicated Mid-Valley was paying to resupply more Dilaudid than was being charged to patients and alerted Mid-Valley management of the discrepancy. Mid-Valley immediately contracted with an outside pharmacy compliance company to conduct further investigation of records and patient charts to determine the cause(s) of the discrepancy. On October 23, 2023, the consultant, working with senior Mid-Valley management and clinical staff, determined that the discrepancy was caused by Lombardi's thefts of Dilaudid.

J. On December 6, 2023, Mid-Valley filed a DEA Form 106 and reported suspected employee theft. The form listed the first date of theft as October 23, 2023, and stated the number of thefts in the past 24 months was 1. The Form 106 also listed the stolen controlled substance was Hydromorphone 1 mg/ml, and the total quantity stolen as 1,260 mg. This number was estimated by Mid-Valley's Pharmacy Director by taking the number of Dilaudid Overrides entered by Lombardi over the previous ninety (90) days and multiplying it by five; thus, the amount initially reported was an estimate only.

K. The Mid-Valley investigation showed that Lombardi stole Dilaudid through Overrides, both for actual patients and for fictitious or previously discharged patients, totaling 898 mg of Dilaudid. Additionally, Lombardi stole 469 mg of Dilaudid through Waste Thefts, including the amounts stolen through her ARNP-originated orders and Routine Orders. The total amount of Dilaudid stolen by Lombardi, as determined through the investigation, including through Overrides, Routine Orders, and Waste Thefts, is thus 1,367 mg.

L. Mid-Valley has cooperated with the United States' investigation and has taken proactive steps to address the conduct described above to ensure that it does not recur. Those steps are further set forth in detail in the separate Memorandum of Agreement (MOA) between DEA and Mid-Valley.

M. Mid-Valley acknowledges that the facts set forth above in these recitals are true and accurate. Mid-Valley further acknowledges and understands that it had, and continues to have, the obligation to comply with the Controlled Substance Act, Chapter 21, United States Code, and the

regulations promulgated thereunder. Mid-Valley represents that it will comply with these obligations from this point forward, and further represents that it has taken additional steps to ensure its compliance with those requirements going forward.

N. The United States contends that it has certain civil and administrative claims under the Controlled Substances Act, Chapter 21, United States Code, and its implementing regulations against Mid-Valley, as further set forth in Recitals A through K above. Mid-Valley's conduct described above, and the United States' claims and allegations that Mid-Valley violated 21 U.S.C. § 842(a)(5) and regulations promulgated thereunder, and that therefore are liable for an assessment of civil penalties for each violation pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5, are hereinafter referred to as the "Covered Conduct."

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

#### Terms of Agreement

1. Mid-Valley shall pay the United States \$15,000 (the Settlement Amount). Payment in full shall be made within twenty-one (21) days of the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney for the Eastern District of Washington.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims), and conditioned upon Mid-Valley's full payment of the Settlement Amount under this Agreement, the United States releases Mid-Valley from any civil or administrative monetary claim the United States has for the Covered Conduct under the Controlled Substances Act, and its implementing regulations.

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

- 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, including mandatory or permissive exclusion from Federal health care programs;
- 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; and
- f. Any liability of individuals not a party to this Agreement.

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

5. Mid-Valley releases the United States and its agencies, officers, agents, employees, and servants, from any claims (including for attorneys' fees, costs, and expenses of any kind and however denominated) that Mid-Valley 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.

6. Mid-Valley 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. §§ 1395-1395k and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Mid-Valley, in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and investigation(s) of the matters covered by this Agreement;

- (3) Mid-Valley's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payments Mid-Valley makes to the United States pursuant to this Agreement;

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).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Mid-Valley, and Mid-Valley 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 Mid-Valley to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Mid-Valley further agrees that within 90 days of the Effective Date of this Agreement Mid-Valley shall identify to applicable Medicare and TRICARE Medicare Administrative Contractors ("MACs") 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 Mid-Valley 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. Mid-Valley agrees that the United States, at a minimum, shall be entitled to recoup from Mid-Valley 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 Mid-Valley on the effect

of inclusion of Unallowable Costs (as defined in this Paragraph) on Mid-Valley's cost reports, cost statements, or information reports.

7. 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.

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

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

10. 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 Washington. 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.

11. This Agreement constitutes the complete agreement between the Parties regarding Mid-Valley's liability for the Covered Conduct. The Parties acknowledge that Mid-Valley and the DEA have also entered into a Memorandum of Understanding as part of Mid-Valley's corrective actions. This Agreement may not be amended except by written consent of the Parties.

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

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

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

15. This Agreement is binding on Mid-Valley's successors, transferees, heirs, and assigns.


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

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

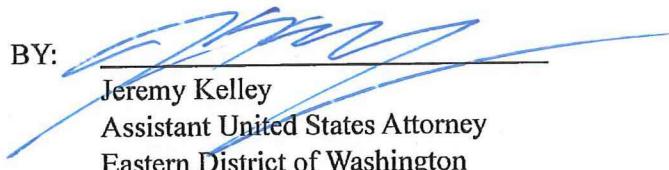


THE UNITED STATES OF AMERICA

DATED: 10/15/2024

BY:   
Dan Fruchter  
Assistant United States Attorney  
Eastern District of Washington

DATED: 10/15/2024

BY:   
Jeremy Kelley  
Assistant United States Attorney  
Eastern District of Washington

MID-VALLEY PUBLIC HOSPITAL DISTRICT NO. 3

DATED: 10/14/2024

BY: Christina G. Wagar

Interim Chief Executive Officer/Superintendent  
Okanogan County Public Hospital District No.  
3, d/b/a Mid-Valley Hospital and Clinic

DATED: 10/15/2024

BY: Rick Mount

Rick Mount  
Paine Hamblen, P.S.  
Counsel for Okanogan County Public  
Hospital District No. 3, d/b/a Mid-Valley  
Hospital and Clinic