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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **CUSTOM MADE PHARMACY, INC., DBA SPECIALTY COMPOUNDING PHARMACY; ROMINA TABIBZADEH; MARZIEH ESMAEILI** **13322 Riverside Dr.** **Sherman Oaks, CA 91423** **Pharmacy Permit No. PHY 48534;** **and** **ROMINA SADIGHIM** **18375 Ventura Blvd., #141** **Tarzana, CA 91356** **Pharmacist License No. RPH 52145;** **and** **MARZIEH ESMAEILI** **P.O. Box 8461** **Northridge, CA 91327** **Pharmacist License No. RPH 67584;** Respondents.	Case No. 5691 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (the "Board"), Department of Consumer Affairs.

2. On or about February 15, 2007, the Board issued Pharmacy Permit Number PHY 48534 to Custom Made Pharmacy, Inc., dba Specialty Compounding Pharmacy; Romina Tabibzadeh; Marzieh Esmaeili ("Respondent Specialty"). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein. Respondent Specialty's Pharmacy Permit was expired on December 31, 2015, and was cancelled on February 24, 2016. Respondent Romina Sadighim ("Respondent Sadighim")[1] was the Pharmacist-in-Charge of Respondent Specialty from August 20, 2012, to November 16, 2014. Respondent Marzieh Esmaeili ("Respondent Esmaeili") was the Pharmacist-in-Charge of Respondent Specialty from November 17, 2014, to October 18, 2015.

3. On or about September 12, 2000, the Board issued Pharmacist License Number RPH 52145 to Respondent Sadighim. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2018, unless renewed.

4. On or about August 16, 2012, the Board issued Pharmacist License Number RPH 67584 to Respondent Esmaeili. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board, Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 118, subdivision (b), of the Code provides that the suspension/expiration/surrender/cancellation of a license shall not deprive the

[1] Romina Sadighim is also known as Romina Tabibzadeh. All references to Respondent Sadighim are to the same individual.

Board/Registrar/Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

7. Section 4300 of the Code states:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper. . . ."

8. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

9. Section 4402(a) of the Code provides that any license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period.

STATUTORY PROVISIONS

9. Section 4040 of the Code states in pertinent part:

"(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

"(1) Given individually for the person or persons for whom ordered that includes all of the following:

". . . .

"(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6."

10. Section 4301 of the Code states:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

". . . .

"(b) Incompetence.

". . . .

"(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

". . . .

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency. . . ."

12. Section 4063 of the Code states:

"No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed."

12. Section 4113 of the Code states:

"(a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

". . . .

"(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. . . ."

18. Section 4306.5 of the Code states:

"Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services. . . ."

REGULATORY PROVISIONS

11. California Code of Regulations, title 16, section 1717, states in pertinent part:

". . . .

"(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself.

"All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. . . ."

12. California Code of Regulations, title 16, section 1717.3, states:

"(a) No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank.

"(b) A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug,

that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.

"(c) 'Preprinted multiple checkoff prescription blank,' as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug i.e., a 'checkoff,' indicates a prescription order for that drug."

13. California Code of Regulations, title 16, section 1735.3, states:

"(a) For each compounded drug product, the pharmacy records shall include:

". . . .

"(6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code. . . ."

14. California Code of Regulations, title 16, section 1761, states in pertinent part:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription."

15. Code of Federal Regulations, title 21, section 1305.12, states in pertinent part:

"(a) A purchaser must prepare and execute a DEA Form 222 simultaneously in triplicate by means of interleaved carbon sheets that are part of the DEA Form 222. DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.

". . . .

"(d) Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a Form 222 under § 1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space. . . ."

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COST RECOVERY PROVISION

16. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FACTS

17. On or about December 11, 2014, the Board received a complaint from the National Benefit Integrity Medicare Drug Integrity Contractor ("NBI MEDIC") that Respondent Specialty was identified as an outlier in a Compounding Pharmacy Risk Score Project. NBI MEDIC conducted an investigation whereby it analyzed prescription drug event ("PDE") data from the Integrated Data Repository ("IDR") for retail independent pharmacies nationwide from January 1, 2010, through October 23, 2012. NBI MEDIC used specified criteria[2] to identify questionable billing for compound drugs. NBI MEDIC was able to identify that the pharmacies investigated were dispensing bulk powders that were previously excluded by the Federal Drug Administration and billing for the capsule which is approved. Respondent Specialty was the 18th highest pharmacy by PDE count for the identified compound drugs.

18. As a result of the complaint filed by NBI MEDIC, the Board initiated an investigation into Respondent Specialty's activities. As part of the investigation, on August 12, 2015, a Board investigator conducted an inspection of Respondent Specialty's facility at 1332 Riverside Drive, Sherman Oaks, CA 91423. Respondent Specialty's pharmacist-on-duty assisted the Board investigator during the inspection.

19. As part of the inspection, the investigator reviewed Respondent Specialty's compounding logs and determined the logs contained inaccurate manufacturer lot numbers and expiration dating of oxycodone powder. Copies of compound oxycodone capsules were

[2] The three criteria were: (1) using the Compound Code 2, indicating the prescription is a compound drug; (2) using the Dispensing Fee of $7.50 or less, indicating they are bilign for compounding drugs but not actually dispensing them; and (3) Drug names Baclofen, Cyclobenzaprine HCL, Diclofenac Potassium, Diclofenac Sodium, Gabaentin, Ketoprofen, and Ketamine HCL.

compared to the oxycodone powder perpetual log and determined to have old lot numbers recorded on them. The oxycodone powder perpetual log included the following relevant entries regarding lot number 110275/B:

TABLE 1

Date	Type of Entry	Amount Purchased (GM)[3] (If a Purchase Entry)	Purchase Lot (If a Purchase Entry)	Dispensed Amount (GM) (If a Dispense Entry)	Balance (GM)
12/19/2014	Dispense			1.905	11.815
12/19/2014	Purchase	200	110275/B		211.815
12/24/2014	Dispense			2.88	208.935
1/16/2015	Dispense			12.02	196.915
1/16/2015	Dispense			21.605	175.31
1/23/2015	Dispense			2.885	172.425
2/10/2015	Dispense			18.01	154.415
2/23/2015	Dispense			2.89	151.525
3/10/2015	Dispense			18.013	133.512
3/11/2015	Dispense			21.6	111.912
3/23/2015	Dispense			2.88	109.032
4/9/2015	Dispense			21.6	87.432
4/9/2015	Dispense			18	69.432
4/22/2015	Dispense			2.88	66.552
5/8/2015	Dispense			18	48.552
5/8/2015	Dispense			21.6	26.952
5/21/2015	Dispense			2.89	24.062
6/4/2015	Purchase	100	115743/B		124.062
6/4/2015	Dispense			21.602	102.46
6/5/2015	Dispense			21.678	80.782
6/5/2015	Dispense			18.019	62.763
6/24/2015	Dispense			2.88	59.883
7/3/2015	Dispense			21.6	38.283
7/3/2015	Dispense			18	20.283
7/21/2015	Dispense			2.88	17.403
7/31/2015	Purchase	100	120475/F		117.403
7/31/2015	Dispense			21.602	95.801
7/31/2015	Dispense			18.001	77.8

[3] "GM" is the abbreviation for gram.

8/10/2015	Dispense			6.3	71.5

The supply of Oxycodone Hydrochloride Powder from lot number 110275/B had only 24.062 GM of powder remaining on May 21, 2015. On June 4, 2015, Respondent Specialty added 100 GM of powder by adding lot number 115743/B to the supply, bringing the total balance to 124.062 GM.

20. The relevant compound lots are as follows:

TABLE 2

Date Made	Compound Lot No.	Oxycodone Hydrochloride Powder Lot No. Used	Oxycodone Quantity Used	Recorded Expiration Date of Oxycodone Hydrochloride Powder Used
7/22/2015[4]	07222015@5	110275/B	2.88 GM	3/30/2017
7/31/2015	07312015@7	110275/B	18 GM	3/30/2017
7/31/2015	07312015@8	110275/B	21.6 GM	3/30/2017
8/10/2015	08102015@1	110275/B	6.3 GM	3/30/2017

The compounding worksheets for the Compound Lots outlined in Table 2 state that the compound lots contain Oxycodone Hydrochloride Powder from lot number 110275/B. However, as of the manufacture date of the Compound Lots identified in Table 2, there was no remaining stock or sufficient quantity of lot number 110275/B to be used in compounding the lots. Thus, each of the lots outlined in Table 2 state that they utilized Oxycodone Hydrochloride Powder in lot number 110275/B, although they utilized oxycodone hydrochloride powder from another lot (either lot number 115743/B or lot number 120475/F). Also, the expiration date of the Oxycodone Hydrochloride Powder was incorrectly recorded as March 30, 2017. The correct expiration date was April 30, 2017 for compound lots using Oxycodone Hydrochloride Powder from lot number 115743/B. The correct expiration date was July 31, 2017 for compound lots using Oxycodone Hydrochloride Powder from lot number 120475/F.

[4] The compounding worksheets lists this date as July 22, 2015. The perpetual log lists this date as July 21, 2015.

21. During the inspection on August 12, 2015, the investigator also discovered two DEA 222 order forms – stamped as form numbers 170535888 and 170535889 – that were pre-signed without any actual order recorded on them. Respondent Specialty's pharmacist-on-duty informed the investigator that the pharmacist-in-charge will sometimes sign the form in advance in case staff needs to order some items when she is gone. At this time, Respondent Esmaeili was the Pharmacist-in-Charge of Respondent Specialty.

22. On or about August 31, 2015, Respondent Esmaeili provided the Board's investigator with copies of requested prescriptions filled by Respondent Specialty. Several prescription document forms were multiple check-off prescription blanks where the prescriber simply checked a box next to the medication he or she wanted to prescribe, signed, and dated the prescription. The prescriber did not write in the medication, quantity, or directions. A review of those prescriptions revealed that Respondent Specialty filled three preprinted, multiple check-off prescription blanks without converting them to verbal prescriptions:

Table 3

Date Filled	Prescription No.	Controlled Substance	Pharmacist-in-Charge
6/20/2012	196257	Ketamine	W. F.
6/20/2012	196260	Ketamine	W. F.
8/19/2013	212896	Ketamine	Respondent Sadighim

23. The Board investigator also discovered that on or about May 22, 2012, Respondent Specialty received a refill authorization from Dr. M. S. The prescription Respondent Specialty provided to the Board is not signed by the prescribing physician. The prescription also lacks any documentation of verbal authorization from the prescribing physician. Respondent Specialty filled this prescription on May 22, 2012.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating Statutes Applicable to Pharmacy – Respondent Specialty)

24. Respondent Specialty's Pharmacy Permit is subject to disciplinary action pursuant to section 4301, subdivision (j), in that Respondent Specialty exhibited unprofessional conduct by failing to comply with the provisions of the following sections of the Business & Professions code:

(a) Sections 4040, subdivision (a)(1)(F) and 4063: On or about May 22, 2012, Respondent Specialty filled prescription number 194948, which lacked the prescriber's authorization. No verbal documentation of the refill authorization was written on the prescription, and no prescriber's signature was located on the prescription.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating California Regulations Applicable to Pharmacy -- Respondent Specialty)

25. Respondent Specialty's Pharmacy Permit is subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondent Specialty exhibited unprofessional conduct by failing to comply with the provisions of the California Code of Regulations, title 16, as follows:

(a) Section 1735.3, subsection (a)(6): From about July 22, 2015, through about August 10, 2015, in relation to the compound lots outlined in Table 2, above, Respondent Specialty failed to record the accurate manufacturer lot number of ingredients on the compounding log. The perpetual log indicated the manufacturer lot number recorded on these compounded products had been deleted prior to compounding.

(b) Section 1717.3: From about June 20, 2012, through about August 19, 2013, in relation to the prescriptions outlined in Table 3, above, Respondent Specialty filled controlled substance prescriptions pursuant to improper preprinted multiple check-off prescription blanks.

(c) Section 1761, subsection (a): On or about May 22, 2012, Respondent Specialty filled prescription number 194948, which lacked the prescriber's authorization. No verbal documentation of the refill authorization was written on the prescription, and no prescriber's signature was located on the prescription.

Complainant realleges paragraphs 18-24, above, as if fully set forth herein.

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THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating Federal Regulations Applicable to Pharmacy -- Respondent Specialty)

26. Respondent Specialty's Pharmacy Permit is subject to disciplinary action pursuant to section 4301, subdivision (o), in that Respondent Specialty exhibited unprofessional conduct by failing to comply with the provisions of the Code of Federal Regulations, title 21, as follows:

(a) Section 1305.12, subsections (a) and (d): On or about August 12, 2015, Respondent Specialty maintained two DEA 22 Forms – stamped as form numbers 170535888 and 170535889 – that were pre-signed by the Pharmacist-in-Charge but without the date or the ordered controlled substances.

Complainant realleges paragraphs 18-24, above, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating California Regulations Applicable to Pharmacy -- Respondent Sadighim)

27. Respondent Sadighim's Pharmacist License is subject to disciplinary action pursuant to sections 4301, subdivision (o), and 4113, subdivision (c), in that Respondent Sadighim exhibited unprofessional conduct by failing to comply with the provisions of the California Code of Regulations, title 16, as follows:

(a) Section 1717.3: On or about August 19, 2013, Respondent Specialty filled controlled substance prescription number 212896 pursuant to a preprinted, multiple check-off prescription blank. Respondent Sadighim was the Pharmacist-in-Charge on August 19, 2013.

Complainant realleges paragraphs 18-24, above, as if fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating California Regulations Applicable to Pharmacy -- Respondent Esmaeili)

28. Respondent Esmaeili's Pharmacist License is subject to disciplinary action pursuant to section 4301, subdivision (o), and 4113, subdivision (c), in that Respondent Esmaeili exhibited

unprofessional conduct by failing to comply with the provisions of the California Code of Regulations, title 16, as follows:

(a) Section 1735.3, subsection (a)(6): From about July 22, 2015, through about August 10, 2015, in relation to the compound lots outlined in Table 2, above, Respondent Specialty failed to record the accurate manufacturer lot number of ingredients on the compounding log. The perpetual log indicated the manufacturer lot number recorded on these compounded products had been deleted prior to compounding. Respondent Esmaeili was the Pharmacist-in-Charge during the compounding of these capsules.

Complainant realleges paragraphs 18-24, above, as if fully set forth herein.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violating Federal Regulations Applicable to Pharmacy -- Respondent Esmaeili)

29. Respondent Esmaeili's Pharmacist License is subject to disciplinary action pursuant to section 4301, subdivision (o), and 4113, subdivision (c), in that Respondent Esmaeili exhibited unprofessional conduct by failing to comply with the provisions of the Code of Federal Regulations, title 21, as follows:

(a) Section 1305.12, subsections (a) and (d): On or about August 12, 2015, Respondent Specialty maintained two DEA 22 Forms – stamped as form numbers 170535888 and 170535889 – that were pre-signed by the Pharmacist-in-Charge but without the date or the ordered controlled substances. Respondent Esmaeili was the Pharmacist-in-Charge on August 12, 2015.

Complainant realleges paragraphs 18-24, above, as if fully set forth herein.

DISCIPLINE CONSIDERATIONS

30. To determine the degree of discipline, if any, to be imposed on Respondent Specialty, Complainant alleges that on or about March 17, 2014, in a prior action, the Board issued Citation Number CI 2012 56942 and ordered Respondent Specialty to pay a fine of $500.00 for violating section 4115, subdivision, (f)(1), of the Code. That Citation is now final and is incorporated by reference as if fully set forth.

31. To determine the degree of discipline, if any, to be imposed on Respondent Specialty, Complainant alleges that on or about September 17, 2013, in a prior action, the Board issued Citation Number CI 2012 55459 with no civil penalty for violating California Code of Regulations, title 16, section 1716. That Citation is now final and is incorporated by reference as if fully set forth

32. To determine the degree of discipline, if any, to be imposed on Respondent Specialty, Complainant alleges that on or about August 31, 2011, in a prior action, the Board issued Citation Number CI 2009 43694 and ordered Respondent Specialty to pay a fine of $2,750.00 for violating California Code of Regulations, title 16, section 1716.2, subdivisions (a)(3) & (4), and Health and Safety Code, section 111330. That Citation is now final and is incorporated by reference as if fully set forth.

33. To determine the degree of discipline, if any, to be imposed on Respondent Sadighim, Complainant alleges that on or about March 17, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 60377 and ordered Respondent Sadighim to pay a fine of $500.00 for violating section 4115, subdivision (f)(1), of the Code. That Citation is now final and is incorporated by reference as if fully set forth.

34. To determine the degree of discipline, if any, to be imposed on Respondent Sadighim, Complainant alleges that on or about September 17, 2013, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 58171 and ordered Respondent Sadighim to pay a fine of $750.00 for violating California Code of Regulations, title 16, section 1716. That Citation is now final and is incorporated by reference as if fully set forth.

35. To determine the degree of discipline, if any, to be imposed on Respondent Esmaeili, Complainant alleges that on or about March 17, 2014, in a prior action, the Board of Pharmacy issued Citation Number CI 2013 60378 and ordered Respondent Esmaeili to pay a fine of $500.00 for violating section 4115, subdivision (f)(1), of the Code. That Citation is now final and is incorporated by reference as if fully set forth.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 48534, issued to Custom Made Pharmacy, Inc., dba Specialty Compounding Pharmacy; Romina Tabibzadeh; Marzieh Esmaeili;

2. Revoking or suspending Pharmacy License Number RPH 52145, issued to Romina Sadighim;

3. Revoking or suspending Pharmacist License Number RPH 67584, issued to Marzieh Esmaeili;

4. Ordering Respondents Specialty, Romina Sadighim, and Marzieh Esmaeili to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

5. Taking such other and further action as deemed necessary and proper.

DATED: 3/11/18

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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