KAMALA D. HARRIS Attorney General of California	
JANICE K. LACHMAN	
Supervising Deputy Attorney General KRISTINA T. JARVIS	
Deputy Attorney General	
State Bar No. 258229 1300 I Street, Suite 125	
P.O. Box 944255	
Sacramento, CA 94244-2550 Telephone: (916) 324-5403	
Facsimile: (916) 327-8643 Attorneys for Complainant	
Allorneys for Complainant	
BEFORE THE BOARD OF PHARMAC	V
DEPARTMENT OF CONSUMER	RAFFAIRS
STATE OF CALIFORN	A
In the Matter of the Accusation Against:	Case-No5709
PLUMAS DISTRICT HOSPITAL,	ACCUSATION
dba PLUMAS DISTRICT HOSPITAL PHARMACY	
DOUGLAS LAFFERTY, ADMINISTRATOR DAN CARL LEGRADY, PHARMACIST-IN-CHARGE	
1065 Bucks Lake Road Quincy, California 95971	
- •	
Hospital Pharmacy Permit No. HPE 32553 (Eff. 1/9/86- 2/9/16)	
Drug Ŕoom Permit No. DRE 32553 (Eff. 2/9/16)	
DARLENE DANO	
7112 Regard Way Sacramento, California 95842	
Pharmacist License No. RPH 35371,	
CHERYL ANN MUSSELL P.O. Box 982	
Quincy, California 95971	
Pharmacy Technician Registration No. TCH 135012,	
and	
RAYMOND MIRANDA DURO	
3218 Diamond Ridge Drive Reno, Nevada 89523	- -
Pharmacist License No. RPH 61786	
Respondents.	
	J

Complainant alleges:

PARTIES

Virginia Herold ("Complainant") brings this Accusation solely in her official capacity 1. 3 as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs. 4 2. On or about January 9, 1986, the Board issued Hospital Pharmacy Permit Number 5 HPE 32553 to Plumas District Hospital ("Respondent PDH"), doing business as Plumas District 6 Hospital Pharmacy. On or about July 18, 2011, Douglas Lafferty became the administrator. The 7 hospital pharmacy permit was in full force and effect at all times relevant to the charges brought 8 herein and was cancelled on or about February 9, 2016. On or about February 9, 2016, the Board 9 issued Drug Room Permit Number DRE 32553 to Respondent PDH, doing business as Plumas 10 District Hospital Pharmacy. On or about February 9, 2016, Jeffrey Monaghan became the 11 consultant pharmacist for the Drug Room Permit. The following licensed pharmacists were the 12 pharmacists-in-charge of record for Respondent PDH during the time periods indicated below. 13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

1

2

Pharmacist-in-Charge

Date Associated

Date Disassociated

Mark LeRoy November 9, 2012 September 30, 2013 Darlene Dano October 25, 2013 November 27, 2013 Viktoria Zaita February 11, 2014 June 24, 2014 Karen L. Schad September 24, 2014 July 9, 2015 Michael Demetrius Farros July 9, 2015 October 12, 2015 Douglas Milton Mclaskey October 12, 2015 October 30, 2015 Dan Carl LeGrady October 30, 2015 November 9, 2015 Andrew Diesh November 9, 2015 November 29, 2016 **Richard Foster** November 29, 2016 February 9, 2016

3. On or about August 11, 1980, the Board issued Pharmacist License Number RPH 35371 to Darlene Dano ("Respondent Dano"). The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2018, unless renewed.

4. On or about September 5, 2013, the Board issued Pharmacy Technician Registration Number TCH 135012 to Cheryl Ann Mussell ("Respondent Mussell"). The pharmacy technician registration was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2016, unless renewed.

1	5. On or about October 15, 2008, the Board issued Pharmacist License Number RPH				
2	61786 to Raymond Miranda Duro ("Respondent Duro"). The pharmacist license was in full force				
3	and effect at all times relevant to the charges brought herein and will expire on May 31, 2018,				
4	unless renewed.				
5	JURISDICTION/STATUTORY AND REGULATORY PROVISIONS				
6	6. This Accusation is brought before the Board under the authority of the following				
. 7	laws. All section references are to the Business and Professions Code ("Code") unless otherwise				
8	indicated.				
9.	7. Code section 4300 states, in pertinent part:				
10	(a) Every license issued may be suspended or revoked.				
11 12	(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:				
13	(1) Suspending judgment.				
14	(2) Placing him or her upon probation.				
15 16	(3) Suspending his or her right to practice for a period not exceeding one year.				
17	(4) Revoking his or her license.				
18	(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper				
19	8. Code section 4300.1 states:				
20 21 22 23	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.				
24	9. Code section 4301 states, in pertinent part:				
25 26 27	The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:				
28					
	3				
If	(PLUMAS DISTRICT HOSPITAL PHARMACY) ACCUSATION				

(PLUMAS DISTRICT HOSPITAL PHARMACY) ACCUSATION

1	(c) Gross negligence.
2	
3	(g) Knowingly making or signing any certificate or other document that
4	falsely represents the existence or nonexistence of a state of facts.
5	
6	(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.
. 7	
8	(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
9 10	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.
11	••••
12	(q) Engaging in any conduct that subverts or attempts to subvert an
13	investigation of the board
14	10. Code section 4059.5, subdivision (a), states:
15 16 17	Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.
18	11. Code section 4113 states, in pertinent part:
19 20	(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.
21	· · · · · · · · · · · · · · · · · · ·
22 23	(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
24	pharmacy.
25	(d) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to
26 27 28	take over as the pharmacist-in-charge. The proposed replacement pharmacist-in- charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board
	4
	(PLUMAS DISTRICT HOSPITAL PHARMACY) ACCUSATI

٠

1 - J.

â

1	12. Code section 4115 states, in pertinent part:		
23	(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.		
5	(b) This section does not authorize the performance of any tasks specifie		
6 7	(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist		
8	13. Code section 4329 states:		
9 10 11	Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor.		
12	14. Code section 4322 states, in pertinent part:		
13 14 15	Any person who fraudulently represents himself or herself to be registered, is guilty of a misdemeanor, and upon conviction thereof shall be punished by a fine not exceeding five thousand dollars (\$5,000), or by imprisonment not exceeding 50 days, or by both that fine and imprisonment.		
16	15. Title 21, Code of Federal Regulations ("CFR"), section 1304.11, subdivision (c),		
17 18	states: Biennial inventory date. After the initial inventory is taken, the registrant		
19 20	shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.		
21	16. Title 21, CFR, section 1305.05, subdivision (a), states:		
22 23	A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for		
24 25	each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. The power of attorney must be available for inspection together with other order records.		
26	17. Title 21, CFR, section 1305.12, subdivision (d), states:		
27 28	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		
	5		
	(PLUMAS DISTRICT HOSPITAL PHARMACY) ACCUSATIO		

signing the DEA Form 222, must also be inserted in the signature space.



1

2

3

4

5

6

7

8

9

10

.11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

18. Title 16, Code of California Regulations ("CCR"), section 1714, subdivision (b),

states:

Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

19. Title 16, CCR, section 1718 states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

20. Title 16, CCR, section 1735.2 states, in pertinent part:

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

21. Title 16, CCR, section 1735.3 states, in pertinent part:

. . . .

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

(4) The identity of the pharmacist reviewing the final drug product.

22. Title 22, CCR, section 70263, states, in pertinent part:

. . . .

. . . .

(a) All hospitals having a licensed bed capacity of 100 or more beds shall have a pharmacy on the premises licensed by the California Board of Pharmacy. Those hospitals having fewer than 100 licensed beds shall have a pharmacy license issued by the Board of Pharmacy pursuant to Section 4029 or 4056 of the Business and Professions Code.

(c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or his or her representative and the administrator or his or her representative.

(f) Supplies of drugs for use in medical emergencies only shall be immediately available at each nursing unit or service area as required.

(3) The supply shall be inspected by a pharmacist at periodic intervals specified in written policies. Such inspections shall occur no less frequently than every 30 days. Records of such inspections shall be kept for at least three years.

(n) The hospital shall establish a supply of medications which is accessible without entering either the pharmacy or drug storage room during hours when the pharmacist is not available. Access to the supply shall be limited to designated registered nurses. Records of drugs taken from the supply shall be maintained and the pharmacist shall be notified of such use. The records shall include the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. The pharmacist shall be responsible for maintenance of the supply and assuring that all drugs are properly labeled and stored. The drug supply shall contain that type and quantity of drugs necessary to meet the immediate needs of patients as determined by the pharmacy and therapeutics committee.

COST RECOVERY

23. Code section 125.3 provides, in pertinent part, that a 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.

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

DRUG CLASSIFICATIONS

24. "Remicade" is a brand name for infliximab, and is indicated for the treatment of

rheumatoid arthritis. Infliximab is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

Inspection of January 14, 2014

25. On or about January 14, 2014, Board inspectors H. and P. went to Plumas District Hospital ("PDH") to conduct an inspection of the pharmacy. The inspectors knocked on the pharmacy door and were greeted by Respondent Mussell ("Mussell"). The inspectors asked for the pharmacist-in-charge ("PIC"). Mussell stated that the pharmacist would be back in a couple of minutes. Inspector P. asked Mussell where the pharmacist was, and she indicated that he was at another hospital inspecting their drug room. Mussell identified the pharmacist as Raymond Duro (Respondent Duro; "Duro").

26. The inspectors observed Mussell checking in a drug order from Cardinal Health, and 10 saw liquid lorazepam, a Schedule III controlled substance, on the counter. The inspectors asked 11 Mussell if she had signed for the order and she said yes. 12

27. 13 Mussell stated she needed to make a call, and shortly thereafter Chief Nursing Officer Dan Schuessler ("Schuessler") arrived at the pharmacy. The inspectors asked him when a 14 15 pharmacist was last in the pharmacy. Schuessler stated that Douglas Lafferty ("Lafferty") would know, and called him. When Lafferty arrived, he stated he did not think they needed a 16 17 pharmacist in the pharmacy all of the time because PDH had applied for a drug room license. Mussell said she had called Duro and he would be there soon. 18

28.The inspectors requested and obtained copies of various pharmacy records, including compounding worksheets/logs and a written policy and procedure for controlled substances. The compounding worksheets showed that Mussell had compounded the drug Remicade without pharmacist supervision.

29. Inspector P. asked for a copy of the biennial inventory for controlled substances. No biennial inventory was available at the pharmacy. The inspectors then asked for the 24 compounding self-assessments for PIC's Mark LeRoy ("LeRoy") and Respondent Dano ("Dano"). Mussell could not find the documents.

8

27

Ш

19

20

21

22

23

25

26

1

2

3

4

5

6

7

8

9

30. Duro arrived at the pharmacy approximately two hours after the inspection began. Duro told the inspectors that he was not a staff pharmacist, but "remotely verified" the prescriptions sent to him by the hospital when there was no pharmacist on duty.

PDH's timesheets for Dano from September 20, 2013 to November 27, 2013, and for 31. Mussell from October 1, 2013 to January 3, 2014 showed that Mussell worked in the pharmacy when there was no pharmacist on duty approximately 11 times in October 2013, 7 times in November 2013, and 22 times in December 2013; and from January 2, 2014 to January 14, 2014. Mussell also worked in the pharmacy approximately 11 times in October 2013 and 12 times in November 2013, when Dano was present for only part of the day.

32. The inspectors issued an inspection report and provided a copy to Duro. The report stated that "[u]nder no circumstances is the pharmacy to be operated without a licensed pharmacist. No keys in possession of anyone other than by security - for access of the Pharmacist only." Inspector P. asked Mussell if she understood she could never work in the pharmacy without the supervision of a licensed pharmacist. Mussell stated that she understood.

33. Respondent Dano was contacted about the inspection, and stated that she guit 15 working in the pharmacy in late November 2013, but had failed to notify the Board of her 16 disassociation. 17

18

19

20

21

22

23

27

28

1

2

3

4

5

6

 $\overline{7}$

8

9

10

11

12

13

14

Inspection of September 23, 2014

34. On or about September 23, 2014, Inspector P. returned to the pharmacy to conduct an inspection and found Mussell working without pharmacist supervision. Schuessler came to the pharmacy, and said Karen Schad ("Schad") would be the new PIC and that she had been filling in at the pharmacy working half days.

35. Copies of the pharmacy's perpetual inventory log for hydromorphone 2 mg/ml showed that on September 22, 2014, 50 vials of the drug had been sent to the medical/surgical 24 unit. Mussell stated that the nurses had access to the pharmacy after hours. PDH's policies and 25 procedures state that entry into the narcotics cabinet is restricted to registered pharmacists and 26 that Schedule III, IV, and V controlled substances were stored in a locked cabinet in the pharmacy.

36. Schuessler asked Mussell if she had the keys to the narcotics cabinet. Mussell took keys off of a wall hook and handed them to the inspector. The inspector asked Mussell if the keys on her wrist ring were to the pharmacy. Mussell said yes. The inspector had Mussell give her the keys.

. 5

1

2

3

4

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

37. DEA 222 forms (order form for schedule I and II controlled substances) had been signed by pharmacists Michael Shimoide ("Shimoide"), Viktoria Zaita ("Zaita"), and Duro. Mussell had signed the delivery logs on the line indicated for a pharmacist to sign and had left the pre printed "RPH" on that line intact without indicating that she was not in fact a pharmacist. It is the pharmacist's responsibility to receive the drugs from the delivery driver and to sign the DEA forms and invoices. Mussell claimed that these duties had been delegated to her. However, PDH had no Power of Attorney ("POA") forms.

38. The nurses employed at PDH had access to a night locker to obtain needed medications, as well as access to the pharmacy. PDH maintained a Pharmacy Entry Log as well as a night locker list showing the medications stored in the locker. In and between August 2014 and September 2014, nursing staff had entered the pharmacy approximately 21 times to obtain medications that were available in the night locker as well as candy and chocolate.

39. The nurses employed at PDH had access to the pharmacy because the key to the pharmacy is locked in the medication cart, to which all nurses have access.

40. On or about September 25, 2014, Inspector P. requested documents from Cardinal Health for the time period from January 1, 2014 through September 24, 2014, including power of attorney forms for any pharmacists who were granted authority by the hospital's DEA registrant to order Schedule II controlled substances on behalf of the pharmacy, and all signed delivery logs for deliverics made to PDH. Schuessler was the registrant for PDH, and there were no power of attorney forms.

41. On or about September 30, 2014, Inspector P. returned to PDH with a consultant from the California Department of Public Health. The consultant conducted an inspection of the pharmacy. The consultant and the inspector interviewed nurse M. M. who stated that she had access to the pharmacy and that the pharmacy keys were stored in the Emergency Department

(ED). Floor surveys were obtained that had been conducted between May 28, 2014, and August 28, 2014. The surveys had been completed by Mussell who sometimes had a nurse sign off on them. Floor surveys are required to be conducted by a pharmacist.

42. On or about August 20, 2015, Duro was interviewed and he stated that he had never worked for or in the pharmacy except for the day of the first inspection on January 14, 2014.

43. PDH submitted a change of PIC on August 11, 2014, to remove Zaita and add
Shimoide. This change was not approved because the form was signed by unauthorized person.
On September 30, 2014, the Board received a change of PIC from PDH to remove Shimoide and add Schad. The change was approved on October 15, 2014. PDH had gaps in PIC coverage from November 28, 2013 to February 10, 2014, and from June 25, 2014 to September 23, 2014.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

44. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (c), in that Respondent PDH committed acts or omissions constituting gross negligence, as follows:

a. On and between October 1, 2013 and January 14, 2014, Respondent PDH authorized or permitted Respondent Mussell, a pharmacy technician, to work in the pharmacy without the direct supervision and control of a pharmacist; to perform the duties of a pharmacist, including signing for deliveries of controlled substances and dangerous drugs and compounding the drug Remicade; and/or to take charge of or act as supervisor, manager and/or pharmacist-in-charge of the pharmacy. Further, on and between May 28, 2014 and August 28, 2014, Respondent PDH authorized or permitted Respondent Mussell to conduct monthly inspections of the floor stock (supplies of drugs for use in medical emergencies) at the nursing units and service areas without a pharmacist's license. In addition, on or about September 23, 2014, Respondent PDH authorized or permitted Respondent Mussell to work in the pharmacy without pharmacist supervision and/or perform the duties of a pharmacist despite being admonished on January 14, 2014, that the pharmacy was not to be operated without a licensed pharmacist.

28 ///

b. On and between November 28, 2013 and February 10, 2014, and June 25, 2014 and
 September 23, 2014, Respondent PDH failed to designate a pharmacist-in-charge of the
 pharmacy.

c. In and between January 2014 and September 2014, Respondent PDH authorized or permitted Respondent Mussell to sign for additional deliveries of dangerous drugs and controlled substances when, in fact, Respondent Mussell was not a licensed pharmacist.

d. Respondent PDH failed to maintain the pharmacy and its facilities, space, fixtures and/or equipment so that drugs were safely and properly secured in that Respondent Mussell and the nursing staff were allowed access to the pharmacy without a pharmacist present and had access to the keys to the pharmacy. Further, on or about September 23, 2014, Respondent Mussell had access to the keys to the pharmacy and the locked narcotics cabinet.

SECOND CAUSE FOR DISCIPLINE

(Failure to Notify Board of Disassociation of PIC)

45. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent PDH violated Code section 4113, subdivision (d), as follows:

a. Respondent PDH failed to notify the Board within 30 days of the disassociation of pharmacist-in-charge Viktoria Zaita in that Zaita left her employment at PDH on approximately June 24, 2014, yet the Board was not notified of the disassociation until August 11, 2014.

b. Respondent PDH failed to notify the Board within 30 days of the disassociation of pharmacist-in-charge Dano in that Dano left her employment at PDH on November 27, 2013, yet the Board was not notified of the disassociation until January 16, 2014.

THIRD CAUSE FOR DISCIPLINE

(Receipt of Dangerous Drugs by Unauthorized Person)

46. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent PDH violated Code section 4059.5, subdivision (a), as follows: Respondent PDH authorized or permitted Respondent

28

]]]

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

1	Mussell to receive and/or sign for dangerous drugs and controlled substances as set forth above			
2	when, in fact, Respondent Mussell was not a licensed pharmacist.			
. 3	FOURTH CAUSE FOR DISCIPLINE			
4	(Signature of DEA 222 Forms by Unauthorized Persons)			
5	47. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant			
6	to Code section 4301, subdivisions (j) and (o), in that Respondent PDH violated Title 21, CFR,			
7	sections 1305.05, subdivision (a), and 1305.12, subdivision (d), as follows: Respondent PDH			
8	authorized or permitted pharmacists Shimoide, Zaita, and Duro to sign DEA 222 forms upon			
9	delivery or receipt of Schedule II controlled substances when, in fact, none of the pharmacists had			
10	been granted power of attorney to sign the DEA forms.			
11	FIFTH CAUSE FOR DISCIPLINE			
12	(Failure to Complete Biennial Inventory)			
13	48. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant			
14	to Code section 4301, subdivision (o), in that Respondent PDH violated Title 21, CFR, section			
15	1304.11, subdivision (c), as follows: On or before January 14, 2014, Respondent PDH failed to			
16	complete or have available at the pharmacy a biennial inventory of all stocks of controlled			
17	substances on hand at the pharmacy.			
18	SIXTH CAUSE FOR DISCIPLINE			
19	(Failure to Provide Supervision of Pharmacy Technician)			
20	49. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant			
21	to Code section 4301, subdivision (o), in that on and between October 1, 2013 and January 14,			
22	2014, and on or about September 23, 2014, Respondent PDH violated Code section 4115, as			
23	follows: Respondent PDH authorized or permitted Respondent Mussell, a pharmacy technician,			
24	to work in the pharmacy without the direct supervision and control of a pharmacist and to			
25	perform the duties of a pharmacist, as set forth in paragraph 44 above.			
26	///			
27				
28	///			

SEVENTH CAUSE FOR DISCIPLINE (Failure to Supervise Sterile Compounding Conducted by Pharmacy Technician) 50. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent PDH violated Title 16, CCR, sections 1735.2, subdivision (i), and 1735.3, subdivision (a)(4), as follows: Respondent PDH authorized	
50. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent PDH violated Title 16, CCR, sections	
to Code section 4301, subdivision (o), in that Respondent PDH violated Title 16, CCR, sections	
to Code section 4301, subdivision (o), in that Respondent PDH violated Title 16, CCR, sections	
or permitted Respondent Mussell, a pharmacy technician, to compound Remicade for consumer J.	
G. on January 6, 2014, for consumer S. J. on September 16, 2013, October 30, 2013, and	
December 20, 2013, and for consumer L. S. on October 18, 2013, and December 27, 2013,	
without pharmacist supervision.	
EIGHTH CAUSE FOR DISCIPLINE	
(Failure to Maintain Pharmacy, Fixtures, and Equipment	
So that Drugs Were Safely and Properly Secured)	
51. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant	
to Code section 4301, subdivision (o), in that Respondent PDH violated Title 16, CCR, section	
1714, subdivision (b), by failing to maintain the pharmacy and its facilities, space, fixtures and/or	
equipment so that drugs were safely and properly secured, as set forth in paragraph 44(d) above.	
NINTH CAUSE FOR DISCIPLINE	
(Failure to Perform Monthly Inspections of Floor Stock)	
52. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant	
to Code section 4301, subdivision (o), in that on and between May 28, 2014 and August 28, 2014,	
in that Respondent PDH violated Title 22, CCR, section 70263, subdivision (f)(3), as follows:	
Respondent PDH authorized or permitted Respondent Mussell, a pharmacy technician, to conduct	
monthly inspections of the floor stock at the nursing units and service areas when, in fact,	
Respondent Mussell was not a licensed pharmacist. Further, on and between June 28, 2013 and	
March 7, 2014, Respondent PDH failed to ensure that at least one pharmacist took part in or was	
made a part of the hospital's pharmacy and therapeutics committee.	
///	
///	
14	

.

ş

2 Y.----

TENTH CAUSE FOR DISCIPLINE

(Unlawful Access to Hospital Pharmacy after Hours)

53. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that in and between August 2014 and September 2014, Respondent PDH violated Title 22, CCR, section 70263, subdivision (n), by allowing the nursing staff to access the pharmacy when it was closed.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Self-Assessment)

54. Respondent PDH is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent PDH violated Title 16, CCR, section 1735.2, subdivision (j), as follows: Respondent PDH failed to ensure that pharmacists-in-charge Mark LeRoy and Respondent Dano had completed compounding self-assessments, as set forth in paragraph 29 above.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Notify Board of Disassociation as PIC)

55. Respondent Dano is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent Dano violated Code section 4113, subdivision (d), by failing to notify the Board within 30 days of disassociating as the pharmacistin-charge for PDH, as set forth in paragraph 45(b) above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Receipt of Dangerous Drugs by Unauthorized Person)

56. Respondent Dano is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent Dano violated Code section 4059.5, subdivision (a), as follows: On or about December 31, 2013, Respondent Dano, as pharmacist-in-charge of record for PDH, authorized or permitted Respondent Mussell to receive and/or sign for dangerous drugs and/or controlled substances when, in fact, Respondent Mussell was not a licensed pharmacist.

28 ///

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Provide Supervision of Pharmacy Technician)

57. Respondent Dano is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent Dano violated Code section 4115, as follows: On and between October 25, 2013 and January 14, 2014, Respondent Dano, as pharmacist-in-charge of record for PDH, authorized or permitted Respondent Mussell, a pharmacy technician, to work in the pharmacy without Respondent Dano's direct supervision and control and to perform the duties of a pharmacist, including, but not limited to, signing for deliveries of controlled substances and dangerous drugs from suppliers and compounding the drug Remicade as set forth in paragraph 50, above.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Supervise Sterile Compounding Conducted by Pharmacy Technician)

58. Respondent Dano is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent Dano violated Title 16, CCR, sections 1735.2, subdivision (i), and 1735.3, subdivision (a)(4), as follows: Respondent Dano, as pharmacist-in-charge of record for PDH, failed to supervise sterile compounding conducted by Respondent Mussell, a pharmacy technician, as set forth in paragraph 50 above.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Pharmacy, Fixtures, and Equipment

So that Drugs Were Safely and Properly Secured)

59. Respondent Dano is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent Dano violated Title 16, CCR, section 1714, subdivision (b), as follows: On and between October 25, 2013 and January 14, 2014, Respondent Dano, as pharmacist-in-charge of record for PDH, failed to maintain the pharmacy and its facilities, space, fixtures and/or equipment so that drugs were safely and properly secured in that Respondent Dano knew, or should have known, that Respondent Mussell had access to 'the keys to the pharmacy and the locked narcotics cabinet.

28 ///

1	SEVENTHEENTH CAUSE FOR DISCIPLINE				
2	(Failure to Complete Compounding Self-Assessment)				
3	60. Respondent Dano is subject to disciplinary action for unprofessional conduct pursuant				
4	to Code section 4301, subdivision (o), in that Respondent Dano violated Title 16, CCR, section				
5	1735.2, subdivision (j), as follows: Respondent Dano failed to complete a compounding self-				
6	assessment within 30 days of becoming the pharmacist-in-charge for Respondent PDH as set				
7	forth in paragraph 29, above.				
8	EIGHTEENTH CAUSE FOR DISCIPLINE				
9	(Failure to Complete Biennial Inventory)				
10	61. Respondent Dano is subject to disciplinary action for unprofessional conduct pursuant				
11	to Code section 4301, subdivision (o), in that Respondent Dano violated Title 21, CFR, section				
12	1304.11, subdivision (c), as follows: On or before January 14, 2014, Respondent Dano failed to				
13	complete or have available at the pharmacy a biennial inventory of all stocks of controlled				
14	substances on hand at the pharmacy.				
15	NINETEENTH CAUSE FOR DISCIPLINE				
16	(Working as a Pharmacy Technician without Pharmacist Supervision)				
17	62. Respondent Mussell is subject to disciplinary action for unprofessional conduct				
18	pursuant to Code section 4301, subdivision (o), in that Respondent Mussell violated Code section				
19	4115 by working as a pharmacy technician at Plumas District Hospital Pharmacy without the				
20	direct supervision and control of a pharmacist, as set forth in paragraph 44(a) above.				
21	TWENTIETH CAUSE FOR DISCIPLINE				
22	(Engaging in Practice as a Pharmacist without a License)				
23	63. Respondent Mussell is subject to disciplinary action for unprofessional conduct				
24	pursuant to Code section 4301, subdivision (o), in that Respondent Mussell violated Code section				
2,5	4329 by taking charge of or acting as supervisor, manager, or pharmacist-in-charge of PDH				
26	Pharmacy and compounding or dispensing prescriptions or furnishing dangerous drugs without a				
: 27 i	pharmacist's license, as follows:				
28	///				
	17				

a. Respondent Mussell signed for deliveries of controlled substances and dangerous drugs from suppliers, compounded the drug Remicade without pharmacist supervision, and conducted monthly inspections of the floor stock at the nursing units and service areas, as set forth in paragraph 44(a) above. Further, on or about September 23, 2014, Respondent Mussell worked in the pharmacy without pharmacist supervision and/or performed the duties of a pharmacist despite having been directly admonished prior to that date that Respondent Mussell could never work in the pharmacy without the supervision of a licensed pharmacist

b. Respondent Mussell had access to the keys to the pharmacy and the locked narcotics
 cabinet, as set forth in paragraph 44(d) above.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Fraudulent Representation)

64. Respondent Mussell is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent Mussell violated Code section 4322 by fraudulently representing herself to be a licensed pharmacist, as follows: On and between December 31, 2013 and September 23, 2014, Respondent Mussell signed delivery logs as the "Rph" (pharmacist) upon receipt of dangerous drugs and controlled substances when, in fact, Respondent Mussell was not a licensed pharmacist.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Knowingly Signing Documents Containing False Representations)

65. Respondent Mussell is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondent Mussell knowingly made or signed documents that falsely represented the existence or nonexistence of a state of facts, as set forth in paragraph 64 above.

TWENTY-THIRD CAUSE FOR DISCIPINE

(Subverting or Attempting to Subvert an Investigation of the Board)

66. Respondent Duro is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (q), in that Respondent Duro engaged in conduct that subverted or attempted to subvert an investigation of the Board, a follows: On or about August 20, 2015,

18

1

2

3

4

5

6

7

8

Respondent Duro stated that he had never worked for or in the pharmacy except for the day of the inspection on January 14, 2014. In fact, Respondent Duro worked in the capacity as pharmacist for PDH when he signed DEA 222 forms on December 31, 2013 and January 28, 2014, to order Schedule II controlled substances on behalf of the pharmacy. Further, Respondent Duro signed a Cardinal Health delivery log on January 2, 2014, showing that he received a delivery of the controlled substances fentanyl, hydromorphone, and morphine.

TWENTH-FOURTH CAUSE FOR DISCIPLINE

(Aiding or Abetting Violations of the Pharmacy Law

and State Laws Governing Pharmacy)

67. Respondent Duro is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (o), in that Respondent Duro assisted in or abetted Respondent Mussell, a pharmacy technician, in violating Code section 4115, as follows: On or about December 31, 2013 and January 2, 2014, Respondent Duro was present in the pharmacy, as set forth in paragraph 66 above. Respondent Duro knew, or should have known, that on those dates during times that he was not in the pharmacy, Respondent Mussell was working in the pharmacy alone without the direct supervision and control of a pharmacist.

TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Signature of DEA 222 Forms by Unauthorized Persons)

68. Respondent Duro is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent Duro violated Title 21, CFR, sections 1305.05, subdivision (a), and 1305.12, subdivision (d), as follows: Respondent Duro signed DEA 222 forms upon delivery or receipt of Schedule II controlled substances when, in fact, he had not been granted power of attorney to sign the DEA forms, as set forth in paragraph 47 above.

<u>PRAYER</u>

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:

28 || ///

1

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

1	1.	Revoking or suspending Hospital Pharmacy Permit Number HPE 32553 and Drug			
2	Room Per	Room Permit Number DRE 32553, issued to Plumas District Hospital, doing business as Plumas			
3	District He	District Hospital Pharmacy;			
4	2. Revoking or suspending Pharmacist License Number RPH 35371, issued to Darlene				
5	Dano;				
6	3.	Revoking or suspending Pharmacy Technician Registration Number TCH 135012,			
. 7	issued to Cheryl Ann Mussell;				
8	4.	4. Revoking or suspending Pharmacist License Number RPH 61786, issued to Raymond			
9	Miranda D	'uro;			
10	5.	Ordering Plumas District Hospital, doing business as Plumas District Hospital			
11	Pharmacy,	Darlene Dano, Cheryl Ann Mussell, and Raymond Miranda Duro to pay the Board of			
12	Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to				
13	Business a	Business and Professions Code section 125.3; and			
14	6	Taking such other and further action as deemed necessary and proper.			
15		11/4/16 Digina Kedd			
16	DATED: _				
17		VIRGINIA HEROLD Executive Officer			
18		Board of Pharmacy Department of Consumer Affairs State of California			
19		Complainant			
20					
21					
22					
23					
24					
25					
26					
27					
28	SA201610012	21			
-		20			
]]		(PLUMAS DISTRICT HOSPITAL PHARMACY) ACCUSATION			

į

Contraction of the second