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**California State Board of Pharmacy**

1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834  
Phone (916) 574-7900  
Fax (916) 574-8618  
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
GOVERNOR EDMUND G. BROWN JR.

**Date: March 16, 2012**

**To: Enforcement Committee**

**Subject: Agenda Item 1- Presentation and Discussion on the on the Use of Off-Shore Entities to Input Patient Treatment and Refill Authorization for California Pharmacies**

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Last year, the board directed a pharmacy to stop using an off shore data entry service to input patient data.

After this order, the board received a request from an attorney representing the pharmacy and requested an appearance before the board to more fully discuss this matter. This written request follows this page.

This meeting is the first opportunity for the committee to hear this appeal. Board AG Liaison Joshua Room will assist the committee in discussing this issue.

Note: The remainder of the meeting will be involved with e-pedigree issues.

HOOPER, LUNDY & BOOKMAN, P.C.

HEALTH CARE LAWYERS

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November 22, 2011

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FILE NO. 79038-903

VIA FACSIMILE

Ms. Virginia K. Herold  
Executive Officer  
California State Board of Pharmacy  
1625 North Market Blvd., #N219  
Sacramento, CA 95834

Re: Inspection Report and Cease and Desist Order re:  
Pharmacy's Use of Off-Site Data Entry Services

Dear Giny:

On November 8, 2011, Skilled Nursing Pharmacy (PHY 49972) ("SNP") was inspected and issued an inspection report which included a Cease and Desist Order related to its use of an offsite data entry service. (A copy is attached for your convenience). SNP currently contracts with Critical Entry Data Systems ("CEDS") for back office data entry of refill prescription orders. SNP contracted with CEDS for such services based on their belief that the use of the CEDS services is fully compliant with the California State Board of Pharmacy's ("Board") rules and regulations.

In response to the Inspection Report and the Inspector's request, SNP has developed and submitted a plan of correction setting forth the actions taken and/or to be taken to cease the use of the CEDS services. However, since SNP believes the use of the CEDS service is integral to the ongoing viability of their business and that sufficient policies and procedures can be put in place to ensure such services do not violate the Board's rules and regulations, we are

Ms. Virginia K. Herold  
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Page 2

concurrently submitting this letter to request that the Board approve SNP's continued use of the CEDS services.

SNP and many other independent pharmacies are increasingly challenged by the reimbursement cutbacks being imposed by many payors. Medi-Cal for example in some instances pays below cost. Additionally, competition with national pharmacy chains that have access to rebates not offered to smaller pharmacies and the ever changing industry requirements such as short cycle dispensing etc. have forced independent pharmacies to tighten their belts and search for new methods of cutting costs that do not negatively impact or hamper clinical services in any way.

The second largest expense line item on SNP's financial statement is labor costs. In large part, SNP's profitability today is based on controlling labor costs. During SNP's research of cost cutting methods used by other pharmacies throughout the country, it was introduced to CEDS which is a data entry company that operates like a back office (see description of processes below) to help substantially control costs. For example, a single computer operator employed at the pharmacy location costs \$17-22 per hour plus benefits, while a contracted remote operator costs \$8-10 per hour and does not require the provision of additional benefits. If pharmacy reimbursement continues to be cut, and short cycle mandates by payors goes into effect, SNP is not sure it will be able to survive without instituting creative ways to save on costs.

SNP strongly believes that the procedures and controls it has put in place (see CEDS: Refill Labels Preparation Procedures attached) addresses and is in-line with the Board's rules and regulations. In fact, the procedure for in-house processing and remote processing is almost identical with respect to pharmacist review and supervision of every order. The only difference is that in this case the unlicensed personnel perform the physical data entry offsite.

Process for use of CEDS services:

1. Initial Orders: Initial orders are received by and processed by the pharmacy only. CEDS services are not used for initial orders.
2. Refill Orders: Based on an initial order faxed directly to the pharmacy by facility staff (e.g. skilled nursing facility), the pharmacy dispenses the first 30 day supply of ordered medications. Three days before the initial 30 day supply is exhausted the facility staff fax refill paperwork to the pharmacy. Faxes are received by the pharmacy electronically and pharmacy in-house staff code the electronic documents so that they are placed in an electronic cue for CEDS. CEDS staff then access the electronic refill documentation and input data into the label creating program which is then accessed by pharmacy in-house staff (licensed pharmacists or pharmacy techs) who review and print the hard copy labels. A licensed pharmacy tech then attaches the label to the meds and a pharmacist then reviews the labels, the meds and the original

Ms. Virginia K. Herold  
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prescription documentation to ensure accuracy. Pharmacist then releases the labeled meds for delivery to the facility.

As described above, CEDS staff perform ONLY those tasks that are specifically permitted to be performed by non-licensed personnel. Title 16, Section 1793.3(a) of the California Code of Regulations states that non-licensed persons may type prescription labels and/or enter prescription information into a computer record system. Additionally, at the direction of a licensed pharmacist, non-licensed persons may receive refill authorizations. However, the responsibility for the accuracy of such information and the prescription dispensed remains with the licensed pharmacist who initials the prescription record. The procedures instituted by SNP ensures that all data entry performed by CEDS staff is monitored and reviewed by a licensed pharmacist at all times and in all ways complies with the requirements of 16 CCR Section 1793.3.

On or about June 17, 2011, I contacted the Board's supervising inspector, Robert Ratcliff, to discuss the use of offsite data entry. During that conversation Inspector Ratcliff informed me that this was an issue the Board was looking into but had not yet developed any specific regulations to address such services. Inspector Ratcliff also mentioned that if the pharmacy did utilize such services they would have to ensure they complied with existing regulations such as those addressing non-licensed personnel, pharmacist supervision and document retention. Based on this conversation SNP developed the above procedures which do comply with these requirements.<sup>1</sup>

The current cease and desist order states that the use of the CEDS services violates 16 CCR Section 1764 and Civil Code Section 56.10 as an unauthorized disclosure of prescription. However, Section 1764 states that such disclosure is not unauthorized if the disclosure is to a person duly authorized by law to receive such information and Section 56.10(3) specifically states "the information may be disclosed to a person or entity that provider billing, claims management, medical data processing, or other administrative services for providers of health care." (*emphasis added*) Therefore, SNP argues that the use of CEDS for data processing and other administrative services is not a violation of the provisions cited. In fact, the use of such services is specifically permitted by these provisions.

I cannot stress how important this type of program is to SNP and other similarly situated independent pharmacy providers. We are told by CEDS that other states have processes in place

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<sup>1</sup> Additionally, CEDS informed SNP that in April of 2007 CEDS met with a few members of the Board to discuss the services they were providing to California pharmacies and the Board did not object or instruct them to cease such services at that time. See CEDS letter to Ben Mandelbaum (owner/officer of SNP) attached.

Ms. Virginia K. Herold

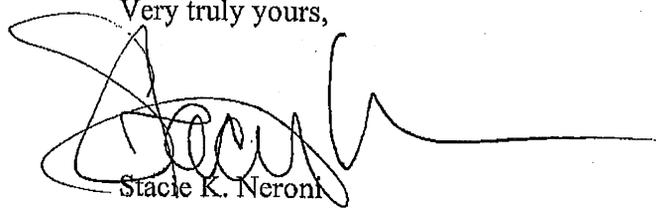
November 22, 2011

Page 4

that allow for the use of such data entry services. Therefore, SNP respectfully requests that the Board consider allowing SNP's continued use of the CEDS services under their existing procedures; or, in the alternative, the Board's guidance in setting up an alternative but acceptable process and/or procedure for the use of the CEDS services.

Thank you very much for your consideration and please do not hesitate to contact me if you have any questions.

Very truly yours,

A handwritten signature in black ink, appearing to read "Stacie K. Neroni", with a long horizontal line extending to the right.

Stacie K. Neroni

SKN

Enclosure

CC: Robert Ratcliff, Chief Supervising Inspector

**HOOPER, LUNDY & BOOKMAN, P.C.**

**HEALTH CARE LAWYERS**

1875 CENTURY PARK EAST, SUITE 1600  
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**FACSIMILE TRANSMITTAL SHEET**

<b>DATE:</b>	November 22, 2011	<b>PAGES</b> (Incl. cover sheet):	15
<b>RECIPIENT</b>	Virginia Herold California State Board of Pharmacy	<b>PHONE</b>	(916) 574-7900
		<b>FAX NO.</b>	(916) 574-8618
<b>FROM:</b>	Stacie K. Neroni		
<b>REFERENCE:</b>	Skilled Nursing Pharmacy		
<b>MESSAGE:</b>			

This message is intended only for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone and return the original message to us at the above address via the U.S. Postal Service. Thank you.

**PLEASE CALL US IMMEDIATELY  
IF THERE ARE ANY PROBLEMS DURING THIS TRANSMISSION:**

**OPERATOR:** Barbara Webster, (310) 551-8114  
**CLIENT NAME:** Skilled Nursing  
**FILE NO.:** 79038-903

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 \* P. 01 \*  
 \* TRANSACTION REPORT \*  
 \* NOV-22-2011 TUE 11:50 AM \*  
 \* FOR: \*  
 \* SEND \*  
 \* DATE START RECEIVER TX TIME PAGES TYPE NOTE M# DP \*  
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 \* 618# \*  
 \* TOTAL : 2M 45S PAGES: 15 \*  
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**HOOPER, LUNDY & BOOKMAN, P.C.**  
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STATE AND CONSUMER SERVICES AGENCY  
 DEPARTMENT OF CONSUMER AFFAIRS  
 GOVERNOR EDMUND G. BROWN JR.

### INSPECTION REPORT

Pharmacy  Hospital Pharmacy \_\_\_\_\_ Clinic \_\_\_\_\_ Exempt Hospital \_\_\_\_\_ Wholesaler \_\_\_\_\_ Hypodermic \_\_\_\_\_

Date: 11/8/2011 Inspector: Anna Yamada

Firm: SKILLED NURSING PHARMACY Phone: (626) 820-5800

Address: 16666 E JOHNSON DR #C City: INDUSTRY Zip: 91745

Ownership: CORPORATION

Permit #: PHY49972 Permit Exp: 12/1/2011 DEA#: FS1632593 DEA Exp: 2/29/2012

Date of Self Assessment Form: 6/30/2011 Other Permit #: LSC99563 Date of DEA Inventory: 6/22/2011

Hours M-F: 24 hours Hours Saturday 24 hours Hours Sunday: 24 hours

PIC \_\_\_\_\_ Administrator \_\_\_\_\_

RPH Consultant \_\_\_\_\_

Staff	RPH Name:	License #:	Staff Name:	License #:
	<u>MARIA CHRISTINE M TANA</u>	<u>INT27655</u>	<u>MCLELLAN T NGUYEN</u>	<u>TCH108818</u>
	<u>NERMINE IBRAHIM-INTERI</u>	<u>RPH63780</u>	<u>EDGAR F GARCIA</u>	<u>TCH40169</u>
	<u>AN M VONG-PENDING PIC A</u>	<u>RPH52872</u>	<u>KATY Q GUAN</u>	<u>TCH108100</u>
	<u>ALI R SEDGHI</u>	<u>RPH46550</u>	<u>ANNA HUGO</u>	<u>TCH82774</u>
	<u>ARSENIA U MAMARIL</u>	<u>RPH47467</u>	<u>IN KYUNG LEE</u>	<u>TCH28521</u>
	<u>MICHAEL J LASTRA</u>	<u>RPH41217</u>	<u>CHUONG H LIJONG</u>	<u>TCH59837</u>
	<u>CECILIA C YU</u>	<u>RPH60869</u>	<u>TOMAS M MACARANAS</u>	<u>TCH14105</u>
	<u>KHANH-LINH T TRAN</u>	<u>RPH60461</u>	<u>LINH T PHAM</u>	<u>TCH79720</u>
	<u>RICHARD M LU</u>	<u>RPH54432</u>	<u>CLAIRE B SARMIENTO</u>	<u>TCH96587</u>
	<u>JANICE P SO-CHAN</u>	<u>RPH50218</u>	<u>CLAIRE B SARMIENTO</u>	<u>TCH96587</u>
	<u>YONG A SOK</u>	<u>RPH44253</u>	<u>JRMA S LANDIG</u>	<u>TCH10240</u>
			<u>LARISA LIVANU</u>	<u>TCH45977</u>
			<u>SHAUNA S MCCAFFREY</u>	<u>TCH93447</u>
			<u>STACY MORALES</u>	<u>TCH78681</u>
			<u>ERNEST CLEIN VI D PONCE</u>	<u>TCH106345</u>
			<u>MARY GANT (COMPLIANCE</u>	<u>MANAGER</u>
			<u>FRED CASILLAS (DISPATCH</u>	<u>MANAGER</u>
			<u>FRANCISCO ROMAN</u>	<u>TCH62979</u>
			<u>ANNA RODRIGUEZ (FLOOR</u>	<u>TCH75088</u>
			<u>ROGER ESCOBAR (FLOOR</u>	<u>TCH51298</u>
			<u>SONNY BERNABE (CS TCH)</u>	<u>TCH63090</u>
			<u>TIMOTHY R BEAVERS</u>	<u>TCH96921</u>
			<u>JAYRALD R DELA PENNA</u>	<u>TCH71442</u>
			<u>CYNTHIA L FRIAS</u>	<u>TCH31517</u>
			<u>BRANDON T HANSON</u>	<u>TCH110641</u>
			<u>THUY K NGUYEN</u>	<u>TCH112312</u>



**INSPECTION REPORT**

JOSELYTO V RECINTO TCH60516  
ALODIA A VALDEZ TCH79741

Reference

1	CCR 1764	<p>Unauthorized disclosure of prescriptions.</p> <p>In that, on or about 4/7/07, Skilled Nursing Pharmacy disclosed C.M. personal prescription information to her employer without her consent.</p>
2	CCR 1764	<p>Unauthorized disclosure of prescriptions.</p> <p>as it relates to CC 56.10: In that, Skilled Nursing Pharmacy contracted with CEDS to provide offsite data entry of the pharmacy's prescriptions, however, the prescriptions were being processed on an unlicensed premise.</p>

*cc. 56.10*

**Inspector Remarks:**

Here today with Inspector DeBora White.

Large closed door long term care pharmacy servicing about 120 facilities (majority SNF as well as assisted living facilities) with over 120,000 patients. Here today for annual LSC inspection and complaint investigation.

Routine inspection conducted by Inspector White on separate inspection report.

Skilled Nursing Pharmacy contracted with CEDS (Critical Entry Data Systems) to provide offsite data entry of the pharmacy's prescriptions and these prescriptions were processed by data processors located in another country at an unlicensed premise.

**Cease and desist order:**

Skilled Nursing Pharmacy shall immediately cease and desist engaging in the practice of the pharmacy's prescription being processed in an unlicensed premise (ie via CEDS) until the pharmacy is able to provide written documentation from the Board which allowed such activity.

**For investigation:**

BOP received complaint from C.M. alleging pharmacy violated her HIPAA rights by releasing her prescription information to her employer without her consent. C.M. also alleged the pharmacy incorrectly dispensed several of her prescriptions and filled her methadone prescription without obtaining the original prescription. The investigation substantiated the pharmacy released C.D.'s information without her consent.

Official receipt#330330 issued for the items received.

In order to complete investigation, pending PIC Vo to fax to Inspector Yamada at 626-446-2291 the following:

1. Written statement and plan of correction addressing the use of CEDS within 14 days
2. Written statement addressing C.M.'s complaint within 14 days
3. Mail original RX#680983 methadone 10mg, 578456 trazodone 50mg, and 804997 Ambien 10mg for C.M. to Inspector Yamada at PO Box 2465, Monrovia, CA 91017 within 72 hours

**Licensee Remarks:**



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STATE AND CONSUMER SERVICES AGENCY  
 DEPARTMENT OF CONSUMER AFFAIRS  
 GOVERNOR EDMUND G. BROWN JR.

**INSPECTION REPORT**

I have reviewed, discussed, understand and received a copy of this form .

Pharmacist (sign) \_\_\_\_\_

Pharmacist (print) An Tong

Inspector (sign) \_\_\_\_\_

Owner(sign) \_\_\_\_\_

Inspector (print) Anna Yanaki

Owner(print) \_\_\_\_\_

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

(626-446-2066)

**CEDS: REFILL LABELS PREPARATION**  
**For Skilled Nursing Pharmacy**  
**ACCESS AND PROCESSING PROCEDURES**  
**(TRIAGED REFILL REQUEST DOCUMENTS ONLY)**

- A. Log in to the Pharmacy Application System: RESCOT by assigned Username and Password

Go To: Order Processing Menu

- B. Log in to the Integrated Central Fax Software: DOCUTRACK  
(to view electronic image of Refill request document)

- C. In DOCUTRACK,

Go To: CEDS REFILL Que.

(Access by CEDS operators is limited only to this QUE)

- a. Open document in the order: First In First Out
- b. Associate original prescription to the refill request document

- D. Process a Refill by creating a new refill label and assign new Rx Date

- E. Process all refill order requests, except:

- 1. CONTROLLED 2 MEDS (C2 MEDS)
- 2. NON-COVERED MEDS (Medicaid and Part D Non-Formulary)
- 3. OVER THE COUNTER MEDS (OTC)
- 4. TOO SOON TO FILL REQUEST
- 5. EMERGENCY KIT request
- 6. INFUSION THERAPY med or IV Compounded med

- F. Exception orders or documents containing items E, above, are image copied then

Move To: RPH CLARIFICATION QUE.

(Built-in programming features prevent further processing and completion of refill orders that require clinical assessment, data values, formulary substitution, or justification of a non-formulary). Orders copied to this QUE are accessed by in-house RPh for review and to provide critical data values, and ultimately to complete the label preparation process.

- G. All other Refill processing issues, that are not Exception items, are image copied then

Move To: CEDS CLARIFICATION QUE.

(The incomplete labels are accessed, reviewed and resolved by in-house QA Pharmacy Technicians.)

H. CEDS operators to enter Refill quantities according to established

**SNP PARAMETERS:** (Accuracy enforced by the QA Pharmacy Technicians who review completed labels for day supply and quantities prior to printing.)

<u>Pay Types</u>		<u>Day Supply and Quantity</u>
HMO/MED-A/VA	-	Brand meds -7days; Generic meds- 14days
MED-D /CALX-routine meds	-	Up to cycle date
MED-D/CALX- PRN meds	-	30 TABS
HOSPICE	-	Brand meds-7 days; Generic meds- 14days
PRIVATE	-	30 DAYS SUPPLY

I. CEDS operators to notify QA Pharmacy Technicians when labels are ready to print for review then printing. Label counts are recorded and confirmed to prevent missing labels.

J. SNP QA Pharmacy Technicians review all labels prior to printing for :

1. Correctness of quantity
2. Correctness of day supply
3. Number of labels (ex: BID order must have 2 labels, or TID must have 3 labels)

Approved labels are printed by the SNP QA Pharmacy Technicians and distributed to other Pharmacy Technicians to pull products from stock and fill accordingly.

Marvin J. Mickow Jr.

President

Mr. Ben Mandelbaum  
President  
Skilled Care Pharmacy  
16666 East Johnson Road  
City of Industry, CA 91745

915 Middle River Drive, Suite 313  
Fort Lauderdale, FL 33304  
Office: 954-566-9884, Ext. 3  
Cell: 954-643-2808  
Fax: 954-252-3732  
mmickow@cedsr.com  
www.cedsrx.com

Dear Mr. Mandelbaum:

Please accept this correspondence as an outline of our April meeting with a few select Board of Pharmacy individuals.

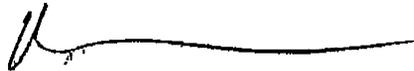
In general, we felt the meeting was productive, and encouraged by the questions posed to CEDS (Critical Entry Data Systems). We did a very thorough presentation of our various services, and had a lengthy discussion. The personnel from the board said very little about legality of our services, so that leads me to believe there were no legal issues of concern at this meeting.

My interpretation of the meeting results were to continue on the course we are on. Specifically, there are no regulations violated by our services, and after we presented all services, the people we met with told us we could continue on our current path, that this is more of a pharmacy business decision.

Find attached our list of people at this meeting, and our notes, as well as questions and answers provide.

I hope this is helpful.

Sincerely,



Marvin Mickow  
President/CEO  
CEDS (Critical Entry Data Systems)

Marvin J. Mickow Jr.

President

915 Middle River Drive, Suite 313  
Fort Lauderdale, FL 33304  
Office: 954-566-9884, Ext. 3  
Cell: 954-643-2808  
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California State Board of Pharmacy Presentation  
Board of Pharmacy Offices  
Sacramento, CA  
April 17, 2007

The following is intended to serve as an outline of this meeting and what was discussed. We have tried to make this letter as accurate as possible. The meeting was not recorded, and so the information is gathered from our notes and collective memory.

State Board Members Present:

Virginia Herold  
Executive Officer  
California State Board of Pharmacy

Robert N. Radcliff, Pharm. D.  
Supervising Inspector  
California State Board of Pharmacy

Joseph Wong, Pharm.D.  
Inspector  
California State Board of Pharmacy

CEDS Employees Present:

Marvin Mickow  
President / CEO

Derek Taylor, Pharm. D.  
Director, Client Services

Arnold Pena  
Account Manager

Dave Carroll, Pharm. D.  
California CEDS Consultant

Marvin J. Mickow Jr.

President

915 Middle River Drive, Suite 313  
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mmickow@cedsr.com  
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1. Introduction – Marvin Mickow
  - a. Explained that we are meeting with the board to explain who CEDS is, what services CEDS provides and how CEDS integrates with the current practices of long-term-care pharmacy.
  - b. Introduced CEDS Employees
2. Presentation Part 1 – Dave Carroll.
  - a. Explanation of current long-term-care pharmacy operations in the state of California.
  - b. Gave details of how various data entry functions are currently being performed.
  - c. Discussed current utilization of remote connections to perform data entry functions off-site.
3. Presentation Part 2 – Derek Taylor
  - a. Trained by on-site staff to follow the same operating protocols currently employed by the pharmacies
  - b. Constant communication with the pharmacy via Instant Messaging, E-mail, scheduled weekly conference calls, and account managers constantly available for immediate troubleshooting.
  - c. Large variety of functions we perform for the clients at their request.
  - d. CEDS initial training of the operators before being assigned to any client.
  - e. Security precautions employed by CEDS to maintain maximum protection of information.

During the presentation, several questions were asked by the pharmacy board members and they were discussed with the CEDS employees. Here is a list of issues mentioned and the points addressed that we feel relate to CEDS directly.

**Question:** How does pharmacist in charge verify the entry from CEDS?

**Answer:** If the work requires verification (new orders for example), the order is verified by the pharmacist just as it is currently done by on-site operators. If the work does not require the verification of the pharmacist (billing for example), a member of the on-site staff in that department reviews the work from CEDS until they are comfortable with their accuracy and production. At that point, they work in that function independently (same as currently done by on-site staff).

Marvin J. Mickow Jr.

President

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- Question:** How do you ensure that the DUR's are caught by the pharmacist? If the operators do not notify the pharmacist, this could put the patient at risk.
- Answer:** Agreed. Most computer systems allow the Pharmacist in Charge to select the permissions of operators, specifically who can override DURs, Allergies, etc... In addition, all operators are instructed clearly on the importance of these interactions and are instructed to stop processing any order with any warning immediately and relay to the pharmacist.
- Question:** How are the orders relayed to the operators and how is it determined who is assigned to the document?
- Answer:** All information stays on-site and is shared by both on-site and remote operators. The document management system only allows 1 operator to work on a document at a time.
- Question:** One of the main concerns of the board is prescription errors. What kind of tracking have you done, and how does CEDS accuracy compare?
- Answer:** CEDS is in constant communication with the clients to determine accuracy, and requests to correct any errors. We have not had any error from a CEDS operator be dispensed to our knowledge. All of our clients so far have reported much better accuracy with our operators (once they are trained) than from their current on-site staff.
- Question:** Why are pharmacies hiring CEDS? Are there truly labor shortages or is this decision being made to eliminate current employees in favor of "the bottom line"?
- Answer:** The decision to hire or fire staff is made by the client, but so far, our operators have not been hired to replace any current on-site staff. Our clients have great difficulty getting the staffing to pharmacy growth, and are using CEDS to help with the increased workload.
- Question:** Because there is no pharmacy license for a clerical labor service, the pharmacy board does not have the ability to regulate your operation. CEDS is currently ahead of regulations at this moment. This issue has

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been brought up by the state board a few years back in anticipation of this type of service, but has not yet been addressed by the board. If licensing scheme was created, would you be licensed knowing possible revocation or penalties if you did not meet certain standards?

Answer: Yes, we would be very happy to comply with this type of licensure. It would legitimize what we do, and it would also require that CEDS and any competitors maintain the highest standards of order entry.

As the discussion was finishing, Marvin Mickow presented the following offer to the state board and this was how they replied:

Marvin: In order to get a better picture of how CEDS works with the clients and our quality, CEDS could get permission from current clients in the state of California and provide the board with their contact information as a reference.

Virginia: That is not necessary. The members of the board in this meeting feel we have gathered enough information on CEDS as a company and how you operate to move forward with this issue. The state board is happy to see you have spent your time to come in and meet with us to work together on this new aspect of pharmacy. We do not feel we need to contact any current clients, because you have been forthright in the information you have presented. At this point any pharmacy using CEDS is doing so as a business decision. We will present the information we have gathered from this meeting and depending on how it is received, we may bring it to an upcoming state board meeting. These are held about every 3 months. We will let you know as this moves forward.

#### CEDS Impressions of the Meeting:

After this initial meeting, CEDS feels that the state board is aware of our operation, the types of services we provide and that we are currently servicing pharmacies in California. At no time did they tell us to stop moving forward in California. The board of pharmacy is interested in pursuing pharmacy specific licensure for companies like CEDS in order to maintain safety and quality standards. While this and any other decisions are being addressed, CEDS is comfortable continuing to service clients.

**Herold, Virginia@DCA**

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**From:** Stacie K. Neroni [SNERONI@HEALTH-LAW.COM]  
**Sent:** Wednesday, January 25, 2012 4:29 PM  
**To:** Herold, Virginia@DCA  
**Subject:** RE: Use of Off-Site Data Entry Services  
**Importance:** High

Dear Giny,

Attached please find the letter I previously sent to you regarding the use of off-site data entry services by a licensed California pharmacy. Skilled Nursing Pharmacy ("SNP") would like to request that this issue be added to the next enforcement committee meeting agenda. I believe that meeting is currently scheduled for March 21, 2012. SNP would like the opportunity to discuss these types of services with the Board in the hopes of possibly developing a process under which the Board would allow the use of such services in the future. A representative of SNP and I (and possibly a representative of CEDS) would like to attend the meeting to discuss the issue. Thank you very much for your consideration and please let me know if there is anything I can provide in advance to assist the board in reviewing this issue.

*Stacie K. Neroni*

[sneroni@health-law.com](mailto:sneroni@health-law.com)

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**From:** Herold, Virginia@DCA [mailto:Virginia.Herold@dca.ca.gov]  
**Sent:** Tuesday, January 24, 2012 4:14 PM  
**To:** Stacie K. Neroni  
**Subject:** RE: Use of Off-Site Data Entry Services

I suggest you submit some written material describing the process. You may have already done this, and if you have just resend.

1/25/2012

Virginia Herold

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**From:** Stacie K. Neroni [mailto:SNERONI@HEALTH-LAW.COM]  
**Sent:** Tuesday, January 24, 2012 3:48 PM  
**To:** Herold, Virginia@DCA  
**Subject:** RE: Use of Off-Site Data Entry Services

Thank you! Was this email all I needed to get on the agenda or should I submit something more formal to you?  
 S.

*Stacie K. Neroni*  
[sneroni@health-law.com](mailto:sneroni@health-law.com)

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**From:** Herold, Virginia@DCA [mailto:Virginia.Herold@dca.ca.gov]  
**Sent:** Tuesday, January 24, 2012 3:47 PM  
**To:** Stacie K. Neroni  
**Cc:** Ratcliff, Robert@DCA  
**Subject:** RE: Use of Off-Site Data Entry Services

It will be enforcement, and perhaps on March 21, which is the next meeting.

Virginia Herold

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**From:** Stacie K. Neroni [mailto:SNERONI@HEALTH-LAW.COM]  
**Sent:** Tuesday, January 24, 2012 3:45 PM  
**To:** Herold, Virginia@DCA  
**Cc:** Ratcliff, Robert@DCA  
**Subject:** RE: Use of Off-Site Data Entry Services

Hi Giny, just pestering you. Hope you aren't too impacted by the move. Can you let me know which meeting I should request to be added to the agenda and how to go about submitting such a request (see below)? Thanks.

1/25/2012

S

*Stacie K. Neroni*

[sneroni@health-law.com](mailto:sneroni@health-law.com)

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**From:** Stacie K. Neroni  
**Sent:** Monday, January 09, 2012 3:34 PM  
**To:** 'Virginia\_Herold@dca.ca.gov'  
**Cc:** 'Ratcliff, Robert@DCA'  
**Subject:** Use of Off-Site Data Entry Services

Hi Giny,

My client Skilled Nursing Pharmacy would like the opportunity to address the Board regarding the off-site data entry services we have been discussing recently. Can I request that the topic be added to the agenda for the next meeting so that the client (and/or I) are able to present the issue? If so, which meeting is more appropriate, the enforcement meeting or the legislation meeting? Thanks. Stacie.

*Stacie K. Neroni*

[sneroni@health-law.com](mailto:sneroni@health-law.com)

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