To: Rosenthal, Anne[arosenthal@medsfgh.ucsf.edu]

Cc: Chen, Alice[Achen@medsfgh.ucsf.edu]; Azari, Soraya[azaris@medsfgh.ucsf.edu]; Coffa, Diana[DCoffa@fcm.ucsf.edu]; Wlodarczyk, Daniel[DWlodarczyk@php.ucsf.edu]; Tinloy, Elena (DPH)[Elena.Tinloy@sfdph.org]; Hammer,

Hali[HHammer@fcm.ucsf.edu]; Pace, Joseph (DPH)[Joseph.Pace@sfdph.org]; Lam, Rita (DPH)[Rita.Lam@sfdph.org]; Brody, Robert V.[robert.brody@ucsf.edu]; Patel, Swati (DPH)[Swati.Patel@sfdph.org]

From: David Woods[david.woods@sfdph.org]

Sent: Thur 4/25/2013 8:25:00 AM (UTC-07:00)

Subject: RE: From Shawn @ Walgreens: DEA regulations and Walgreen policy on Specific opiates

Thanks Anne and Alice for your responses.

We spoke with a local Walgreens manager and some corporate Walgreens staff members yesterday afternoon. This is a new initiative that they are instituting after conversations their corporate staff have had with the DEA. They appeared to be open to dialog with us about creating a safe and efficient controlled substance Rx prescribing process but also need to ensure it will hold up under scrutiny with the DEA.

We discussed a variety of concerns and questions and even some possible solutions, including standardizing questions asked. We did ask Walgreens to scale back their requests, although we'll have to see how they respond. We will continue to provide Walgreens with your questions, concerns and comments. The specifics you provide may help them see the difficulties this is creating for everyone involved. -dave

David Woods, Pharm.D. Chief Pharmacy Officer Phone: (415) 206-2332 Pager: (415) 327-5183 Fax: (415) 206-2377

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[®] RE: From Shawn @ Walgreens: DEA regulations and Walgreen policy on Specific opiates

RE: From Shawn @ Walgreens: DEA regulations and Walgreen policy on Specific opiates

Rosenthal, Anne

to:

Chen, Alice, Woods, David (DPH), Hammer, Hali, Azari, Soraya, Coffa, Diana, Pace, Joseph (DPH), Wlodarczyk, Daniel, Brody, Robert V.

04/24/2013 10:53 PM

 "Tinloy, Elena (DPH)", "Patel, Swati (DPH)", "Lam, Rita (DPH)"
 CCSF v. Purdue Pharma, et al. 3:18-CV-7591
 Woods Exhibit

 WAG-MDL-02853
 Admitted: 06/08/2022
 11/09/2021

Thanks Dave, Rita, Swati.

I got one of these today from WGs on a patient getting #60/mo of Vicodin. Answers needed to either be handwritten in and faxed, or a whole other document created through eCW and faxed.

It asked:

1. Diagnosis

2. Expected length of therapy

3. Date of last physical and assessment

4. Coordination with other clinicians involved in care and (this part handwritten in) what use of alternative / lesser pain medication for pain control

My concerns / questions:

SF-Opioids02564665 WAG-MDL-02853.00001

1. This is way too much info to spell out for each patient. Many of our providers are not using formal pain assessment templates so the info may not be readily available, and the answer to #4 often takes sleuthing through a mixture of electronic and old paper records. This will take lots of time for providers and result in lots of delay in Rx receipt for patients.

2. What are they going to do with this information anyway? Is the pharmacy actually going to evaluate whether there has been an appropriate effort to coordinate with others and use alternatives and then decide whether to fill on that basis? That doesn't seem to be either their responsibility or their purview.

3. Can we get some more information on what exactly the DEA's expectations from pharmacies will be?

4. Can we work with WGs to scale back their requests to perhaps their first 3 questions?

Thank you!

Anne

Anne Rosenthal, MD Maxine Hall Health Center SF Dept. of Public Health 1301 Pierce St San Francisco, CA 94115 o (415) 292-1300 f (415) 474-3753 arosenthal@medsfgh.ucsf.edu

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From: Chen, Alice

Sent: Wednesday, April 24, 2013 9:46 PM To: Woods, David (DPH); Hammer, Hali; Azari, Soraya; Coffa, Diana; Pace, Joseph (DPH); Wlodarczyk, Daniel; Brody, Robert V. Cc: Tinloy, Elena (DPH); Patel, Swati (DPH); Lam, Rita (DPH); Rosenthal, Anne Subject: Re: From Shawn @ Walgreens: DEA regulations and Walgreen policy on Specific opiates

Hi Dave,

Thanks so much for following up on this.

We were hoping that we could get some clarifications from Walgreens and push them to standardize the practice across stores, as it sounds like different pharmacists are interpreting their mandate differently. Specifically we would like to:

1. Clarify when this information will be requested. For example, will ancillary information be required for someone

who just had a hip replacement, or is this only for longitudinal prescribing of opiates and how is that defined? 2. Standardize the questions asked, so that providers can anticipate and include this rather than having to respond in an ad hoc fashion depending on which Walgreens or which pharmacist on.

3. Minimize the number of questions. If they truly want the entire list of information that Rita outlines below, what I envision is that people will be faxing over pages of information (e.g. The last pain assessment). Are they really prepared to deal with all those faxes? Will they be filing them so they don't burden us - and themselves – with asking for the same information over and over again?

4. Standardize/clarify the frequency with which this information will be requested. It seems unreasonable to ask for all this information with every prescription. Perhaps annually would be sufficient.

I'm cc'ing some of the folks who have been actively involved with our chronic pain/chronic opiate prescribing policies in case I'm missing anything.

Thanks ac

From: David Woods <<u>David.Woods@sfdph.org</u>> Date: Wednesday, April 24, 2013 9:27 AM To: "Chen, Alice" <<u>achen@medsfgh.ucsf.edu</u>> Cc: "Tinloy, Elena (DPH)" <<u>Elena.Tinloy@sfdph.org</u>>, Swati Patel <<u>Swati.Patel@sfdph.org</u>>, "Lam, Rita (DPH)" <<u>Rita.Lam@sfdph.org</u>> Subject: Fw: From Shawn @ Walgreens: DEA regulations and Walgreen policy on Specific opiates

Alice,

I heard that a question came up in ACC about a change in Walgreens policy regarding verifying controlled substance Rx's.

Some of our pharmacists have been in contact with Walgreens about this as well. Please see below for a string of emails discussing this. Is there anything specific that ACC requested that we can help with? -dave

David Woods, Pharm.D. Chief Pharmacy Officer Phone: (415) 206-2332 Pager: (415) 327-5183 Fax: (415) 206-2377

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----- Forwarded by David Woods/DPH/SFGOV on 04/24/2013 09:25 AM -----

Re: From Shawn @ Walgreens: DEA regulations and Walgreen policy on Specific opiates Link

Rita Lam	to:	David Woods	04/23/2013 11:30 AM
Co:			Elena Tinloy, Gloria Wilder, James Gasper

What I can gather from speaking with him is that this may be coming from the DEA to Walgreens Corporate and thus the stores have implemented this policy of verifying the controlled substance prescriptionis valid by the following information requested-

ICD9 code DX/medical condition expected length of treatment Date of last physical and pain assessment use of alternative agents for pain additional comments.

Also, some pharmacist have asked for more information than this. It appears that they are targeting mostly CII, primarily but not limited to methadone, hydromorphone and oxycodone. There is no quantity limit but they will call if there is no history in the system. Also, they will call and verify if the patient is paying cash.

Shawn also mentioned that Safeway and CVS will be implementing a similar policy. After seeing Gloria email, they are looking at stimulants as well.

Rita Lam, PharmD Clinical Pharmacist, Primary Care SFGH/CHN Dept of Pharmaceutical Services 415 206 2327 Office, 415 327 9513 Pager, 415 206 2338 Fax

David Woods/DPH/SFGOV 04/22/2013 05:21 PM	То	Rita Lam/DPH/SFGOV@SFGOV
	сс	elena.tinloy@sfdph.org
	Subject	Re: From Shawn @ Walgreens: DEA regulations and Walgreen policy on Specific opiatesLink

Rita,

Elena mentioned that Alice Chen brought this up in the Ambulatory Care Committee today.

Did Shawn respond with specifics about how the stores are interpreting the guidelines?

David Woods, Pharm.D. Chief Pharmacy Officer Phone: (415) 206-2332 Pager: (415) 327-5183 Fax: (415) 206-2377

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From Shawn @ Walgreens: DEA regulations and Walgreen policy on Specific opiates

Rita Lam	to:	David_Woods, Elena Tinloy, Swati Patel	04/17/2013 10:51 AM		
<u>_</u>		Lenny Chan, Kathleen Liu.	Vivian Lian, Jason Brenner,		
Cc:		Heather Houska			

Rita Lam, PharmD Clinical Pharmacist, Primary Care SFGH/CHN Dept of Pharmaceutical Services 415 206 2327 Office, 415 327 9513 Pager, 415 206 2338 Fax

-----Forwarded by Rita Lam/DPH/SFGOV on 04/17/2013 10:51AM -----

To: Rita Lam <<u>Rita.Lam@sfdph.org</u>> From: "Houghtaling, Shawn" <<u>shawn.houghtaling@walgreens.com</u>> Date: 04/16/2013 10:58PM cc: "Lowe, Ronda" <<u>ronda.lowe@walgreens.com</u>> Subject: Re: DEA regulations and Walgreen policy on Specific opiates

Hello Rita,

Here is the letter that prescribers are getting explaining the regulation. Please feel free to give to your prescribers if necessary.

So far it seems that our generic (5/500) Vicodin stock is fine. I do know that Vicodin (5/300), Vicodin ES and Vicodin HP from AbbVie is the new branded generic that we will most likely be carrying. Have you been seeing supply issues at the general hospital?

Thank you, Shawn call me with any questions- I left a voice mail for you tonight.

Dear Valued Prescriber,

Walgreens wants to ensure that our patients continue to have access to the medications they need while fulfilling our role in reducing the potential abuse of controlled substances. Our intent is to partner with you to ensure that patients receive their appropriate therapy and that the

necessary information to confirm the appropriateness of the prescription is documented to satisfy DEA requirements. This process is designed to protect both you and the pharmacist.

According to Title 21 of the Code of Federal Regulations, section 1306.04, pharmacists are required by the DEA regulations to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose. The regulation states the following:

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Our pharmacists are required to take additional steps when verifying certain prescriptions for controlled substances. This verification process may, at times, require the pharmacist to contact you for additional information necessary to fill the prescription. While the information requested may vary, potential questions could include information about the diagnosis, ICD-9 code, expected length of therapy and previous medications/therapies tried and failed. Privacy laws allow you to share this information with another healthcare professional who is providing care to the patient.

We realize that this process may generate questions and concerns from both you and the patient and we will do our best to respond in a professional and courteous manner. We recognize that sharing appropriate information with our pharmacists may require additional time from you or your office staff and we want to thank you in advance for partnering with us to provide the best care to our patients.

On Apr 16, 2013, at 4:38 PM, "Rita Lam" <<u>Rita.Lam@sfdph.org</u>> wrote:

Ronda, Shawn, I need some clarification. Is this a DEA policy? or Is this a Walgreens policy? I am getting mixed messages from two Walgreens stores.

Rita Lam, PharmD Clinical Pharmacist, Primary Care SFGH/CHN Dept of Pharmaceutical Services 415 206 2327 Office, 415 327 9513 Pager, 415 206 2338 Fax

----- Forwarded by Rita Lam/DPH/SFGOV on 04/16/2013 04:30 PM -----

Rita Lam/DPH/SFGOV

04/16/2013 04:15 PM To Shawn Houghtaling cc

Subject DEA regulations and Walgreen policy on Specific opiates

Hi Shawn,

Can you send a copy of the new DEA regulations and Walgreens policy? This way we can better inform our providers. Thanks. Hope you are doing well.

2nd question-how is the generic vicodin inventory?

Rita Lam, PharmD Clinical Pharmacist, Primary Care SFGH/CHN Dept of Pharmaceutical Services 415 206 2327 Office, 415 327 9513 Pager, 415 206 2338 Fax