

July 5, 2015

Office of Special Counsel
John U. Young, Attorney, Disclosure Unit
U.S. Office of Special Counsel
1730 M Street, NW, Suite 218
Washington, DC 20036-4505

Re: OSC File No. DI-14-3389

Dear Mr. Young:

Please allow this letter to serve as my comments on the Report of Investigation provided to me on June 23, 2015. I note that the investigation was flawed in that the additional allegations were that there were numerous other medications on special drug request at the facility, not specifically and only to Mental Health. I noted that the investigation was next to a sham and made no effort to review practices in the pharmacy here beyond what was brought in the specific allegations. Just as in the first report of the Medical Inspector, there was, for example, no assessment of whether other drugs or classes of drugs had been changed due strictly to cost concerns. There was no review of other drugs used in various other departments of the Beckley facility which were on the controlled list and, as clearly shown on a previous e-mail sent to your office, the Chief of Pharmacy was apparently unable to identify the drugs on the restricted list, dates they were placed on restriction, or why they are on it. This would certainly give even an untrained professional the appearance of ineptness and malfeasance of office and position.

Spreadsheets were given to the Medical Inspectors, to substantiate that the pharmacy did in fact know of specific VANF medications that were being restricted at Beckley and thus, withheld from use for our Veterans' care and treatment. The report indicated, "Neither the mental health prescribing providers nor the pharmacists we interviewed were aware of the existence of a list of mental health medications requiring an RDR before the medication could be dispensed. The Medical Center Pharmacy Service could create such a list of mental health medications for providers by running a report at any time, but we were told they had not done so." Attached emails from Ms. Rappold allege that she did not know what medications were on the list, and could not find out. This would contradict earlier testimony given to the Medical Inspectors (see email inserts below)

"In November 2014, subsequent to the original VA site visit, the Medical Center Pharmacy Service initiated a review of all medications requiring an RDR (hereafter, Pharmacy Review) to see whether inclusion of each medication on the list was still appropriate. Medications no longer being restricted were to be removed from the list. The results of the Pharmacy Review were approved on May 13, 2015."

It is important to see the vast lists of medications that had been on Special Drug Request and were on routine denial for Veteran Care. This list is furnished at the end of this response. The Medical Inspectors did not bother to question any reason or valid intent for having any of these medications on SDR restrictions.

Of the witnesses interviewed, only 3 Primary Care providers were on the roster. That excluded about 10 more potential witnesses. There were numerous Mental Health providers listed, who would know nothing about restricted medications for Primary Care and other specialty clinics, including the Emergency Department. One Mental Health provider was overheard bragging by coworkers that she did not cooperate and "told the inspectors nothing." (Dees). One pharmacist who has been at the facility for nearly 30 years was intentionally

excluded from the witness list, giving suspect that the witness list was specially prepared to get the results desired. This pharmacist had valuable information to give to the Medical Inspectors which would substantiate the allegations set forth.

It was written in the report, "If a request is disapproved, instructions for appeal to the Medical Centers COS for final decision are also provided,". Providers have been told at New Employee Orientation by Ms. Rappold to not waste their time appealing to the COS, as any decision she makes would be upheld by him as a rubber stamp. This important fact was omitted from the report.

Emails regarding requests for lists of medications on SDR at Beckley (read bottom to top):

From: Rappold, Brenda F. BECVAMC
Sent: Thursday, February 12, 2015 4:32 PM
To: MARTIN, RUSSELL L. BECVAMC
Cc: Hopkins, Thomas E BECVAMC; McGraw, Karin(BECVAMC); Legg, Debra L BECVAMC; Moye, Allen R. BECVAMC; BERRYMAN, JOHN D. BECVAMC; Cole, Elizabeth K. BECVAMC; Miklos, Melissa BECVAMC
Subject: RE: information request

The Veterans Administration National Formulary (VANF) is our medical center's formulary. You can access the formulary on the tools bar in Computerized Patient Record System (CPRS). Some of the medications are marked on the VANF as having "Criteria for Use". We require a Special Drug Request (SDR) for these medications to insure providers follow the Criteria for Use. There are also other medications that require SDR at our medical center, which is in accordance with VHA Handbook 1108.08, VHA Formulary Management Process. An excerpt from the VHA Handbook 1108.08, VHA Formulary Management Process, the following is provided:

Restrictions to prescribing can be established for VANF items that require close monitoring to ensure appropriate use. For example, in the case of anti-infectives, facility level restrictions intended to prevent resistance are permissible. **Restrictions may include evidence-based guidelines or prescribing privileges for providers with specific expertise.** Restrictions are not to be based solely on economics, nor are they to be so limiting as to prevent patients with legitimate medical needs from receiving these medications and supplies.

In response to your questions:

1. What is the exact criteria that determines the need for special drug request requirement? **The National Pharmacy Benefits Management/Veterans Integrated Service Network Pharmacist Executives/Medical Advisory Panel (PBM/VPE/MAP) Group determines that some medications need to be ordered under specific**

circumstances and develop Criteria for Use documents, clinical recommendations, etc. These documents can be found at the PBM website:

<https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx>

2. Who is authorized to make that determination? The aforementioned group, PBM/VPE/MAP makes the national decision. Locally, the P&T Committee would consider special drug requests and make recommendations to CEB for consideration.

3. What system is in place to review past decisions and ensure the status should not be changed now to remove SDR? As new information is produced in the literature, the Criteria for Use or clinical recommendations may change, but there is not specific time frame in which this may happen. The literature is continually being reviewed by the PBM/VPE/MAP. Locally, the CPSs review SDRs for which they are responsible for addressing and make requests to P&T to consider making a recommendation to CEB to remove the SDR requirement. The more SDR requirements that are removed results in less work for providers and pharmacy. We are making every effort to decrease the number of local SDR requirements.

4. Why would our system be different from the national formulary, that one is easy to review/reproduce and likely easy to update? Our system is not different from the VANF. The VANF is our formulary.

5. Why are there not “templates” sent to Tomi Lilly on ALL SDR’s. Pharmacy has tried to provide templates for the one most commonly used ones and has always been willing to develop one if a provider requests.

6. Why don’t the P&T minutes reflect an accurate list of all drugs that are non formulary? There is no requirement to have a non-formulary list. By exclusion, if a medication is not listed on the VANF, it is non-formulary.

Again, as for the information itself being requested, this is not something that I have that is maintained or reasonably available. Please see below from the master agreement.

Master Agreement,

Section 5 - Information

If the Union makes a request under 5 USC 7114(b)(4), the Department agrees to provide the Union, upon request, with information that is normally maintained, reasonably available, and necessary for the Union to effectively fulfill its representational functions and responsibilities. This information will be provided to the Union within a reasonable time and at no cost to the Union.

If the information I provided does not make sense, or you have additional questions, I would be happy to sit down and discuss this with you.

Respectfully,

Brenda Rappold

From: MARTIN, RUSSELL L. BECVAMC

Sent: Tuesday, February 03, 2015 12:57 PM

To: Rappold, Brenda F. BECVAMC

Cc: Hopkins, Thomas E BECVAMC; McGraw, Karin(BECVAMC); Legg, Debra L BECVAMC; Moye, Allen R. BECVAMC; BERRYMAN, JOHN D. BECVAMC; Cole, Elizabeth K. BECVAMC; Miklos, Melissa BECVAMC

Subject: RE: information request

Asking for a list of drugs that have been deemed non formulary at this facility would NEVER be unlawful. I am positive you as Pharmacy Chief are aware I am a provider, fully credentialed to order the meds on the very list I ask about. Further, the email clearly identifies me as the Vice President for professionals unit of AFGE which means the bargaining unit personnel I represent would be all of the hospital staff members who also have access to the meds requested, and all of whom are responsible for ordering in the correct manner.

As to whether the information is ever maintained or available is also questionable. If our Chief of the Pharmacy, the very person who processes each drug and determines through (hopefully) specific criteria whether the drug should be formulary or not, and who then sends the information to the computer personnel to make the necessary changes in the computer ordering system after clearing the

changes through multiple committees and other personnel is not able to then regurgitate the list, I would be very concerned. This is the same person who should be able to answer 'why' the medication was placed on local restriction, and to any changes in the status of any drug that would affect the decision such as whether the price dropped, whether the drug went generic, whether the current standards of care have changed, and now recommend a particular drug for use, etc. etc. How can we hold the hospital providers accountable to correctly manage special drug requests when necessary if a list cannot be provided as to which drugs fall in that category?

Further, I would be concerned if our Pharmacy Chief has no tracking system in place to prove that a particular drug was routed through the appropriate groups and approved to be made locally restricted, by the local mechanism vs. personal choice and for what particular reason these medications should be restricted to veterans in need of care at Beckley VA Medical Center by our professionals who are held accountable by Federal Law for caring properly for these veterans and who are represented by AFGE.

In light of such a refusal, I believe that the request should not only be answered immediately but also perhaps there should be more answers provided to the union as the specifics of the complete program.

1. What is the exact criteria that determines the need for special drug request requirement
2. Who is authorized to make that determination
3. What system is in place to review past decisions and ensure the status should not be changed now to remove SDR
4. Why would our system be different from the national formulary, that one is easy to review/reproduce and likely easy to update
5. Why are there not "templates" sent to Tomi Lilly on ALL SDR's.
6. Why don't the P&T minutes reflect an accurate list of all drugs that are non formulary?

Please provide the above information along with the originally requested information as required by regulation by COB February 10 2015.

Thanks

Russell Martin PA-C

Vice President for professionals unit

AFGE 2198

Sent: Monday, February 02, 2015 11:28 AM

To: MARTIN, RUSSELL L. BECVAMC

Subject: RE: information request

Mr. Martin,

I have reviewed your request but I have to regretfully deny your request based on your failure to provide an adequate reason for the requested information for me to make a determination under 5 USC 7114 (b) (4) as to it being lawful for me to provide. As for the information itself being requested, this is not something that I have that is maintained or reasonably available. Please see below from the master agreement.

Master Agreement,

Section 5 - Information

If the Union makes a request under 5 USC 7114(b)(4), the Department agrees to provide the Union, upon request, with information that is normally maintained, reasonably available, and necessary for the Union to effectively fulfill its representational functions and responsibilities. This information will be provided to the Union within a reasonable time and at no cost to the Union.

Respectfully,

Brenda Rappold

From: MARTIN, RUSSELL L. BECVAMC
Sent: Tuesday, January 27, 2015 11:32 AM
To: Rappold, Brenda F. BECVAMC
Cc: Miklos, Melissa BECVAMC
Subject: information request

AFGE 2198 is requesting the following information for use in representing the bargaining unit. As it is likely a fair amount of data, please respond via email as to the number of days necessary to obtain the information. Thanks

Russell Martin Vice President for professionals unit

AFGE 2198

Name of every current medication at Beckley VA that the Beckley VA P&T placed on SDR, date it was put on SDR and reason(s) for SDR. Date to be reviewed.

Medication	Date on SDR	Reason(s) for SDR	Review Date
A) ---	----	---	---

The following is a copy from emails sent to the Beckley VA hospital staff regarding medications that have recently miraculously been removed from Special Drug Request status –

From: Rappold, Brenda F. BECVAMC

Sent: Thursday, June 18, 2015 2:01 PM

To: VHABECHOSPITAL STAFF; VHABECPHARMACISTS; VHABECPHARMACY TECHNICIANS; VHABECP&T; VHABECNURSING ADMINISTRATION

Subject: Removal of the Special Drug Request Requirement for Some Medications, as approved by the CEB

As approved by the Clinical Executive Board (CEB), the Special Drug Request requirement for the following items/medications have been removed. The medical center drug file has been edited accordingly. Thanks.

Acamprosate Ca 333mg EC tab
Acetaminophen 160mg/5ml Alcohol-Free Liquid
Acyclovir injection 500mg
Aluminum Chloride Hexahydrate 20% topical solution
Appliance Deodorant Solution
Atropine Injection 0.4mg/ml (20ml vial)
Bandage elastic (Coban)
Benzoyl Peroxide 5% Lotion
Betamethasone Dipropionate Cream 0.05% (15Gm/tube)
Betamethasone Dipropionate 0.05% Cream
Betamethasone Dipropionate 0.05% Ointment
Bromocriptine oral, by mouth (PO)
Bumetanide PO
Bumetanide Injection
Buprenorphine/Naloxone
Buprenorphine
Cadexomer Iodine 0.9% Topical Gel
Calcium citrate with Vitamin D
Chlorhexidine Gluconate 4% Topical Liquid
Clarithromycin 500mg tablet
Clindamycin Phosphate 1% Lotion
Clindamycin Phosphate 2% Vaginal Cream
Clomiphene Citrate 50mg tablets
Clomipramine PO
Clotrimazole 1% topical solution
Cromolyn NA 5.2mg 200D Nasal Inhl
Cromolyn Sodium 10mg/ml Inhalant Solution, 2ml vial
Depend underwear, maximum, men
Depend underwear, maximum, women
Desipramine Hydrochloride PO
Dextroamphetamine 5mg Immediate Release (IR)
Docusate NA 283mg Rectal Enema
Dressing, Melgisorb, Ca Alginate Rope
Enalapril PO
Ergocalciferol (Vitamin D2) 50,000 International Unit Capsule
Estrogen 0.625/medroxyprogesterone 5mg (Premphase®)
Estradiol 0.05 mg/day (Climara®) Patch
Estradiol PO

Felodipine PO
Fluconazole Injection
Fluocinonide 0.01% Topical solution
Fluocinonide 0.1% Topical Cream
Fluoxetine Hydrochloride 20mg/5ml solution
Fluticasone Propionate 50mcg 120 dose Nasal Inhaler
Formoterol Fumarate 12mcg inhaler capsule
Hydrocortisone 2.5% lotion
Hydrocortisone 2.5% Cream
Ibuprofen 100mg/5ml suspension
Incontinent Liner Depend Guards #10544
Insulin syringe 0.5ml 31 Gauge 5/16 inch
Insulin syringe 1.0 ml 31 Gauge 5/16 inch
Insulin, Aspart, Human 70/30 Novolog injection
Ipratropium Bromide Nasal Spray
Ketorolac Tromethamine 0.5% Ophthalmic Solution
Lancet, Softclix Device
Levetiracetam Injection
Levonorgestrel
Lidocaine 2.5/Prilocaine 2.5% Cream
Lidocaine Injection 2%
Losartan PO
Lovastatin PO
Medical Adhesive H#7730
Midodrine PO
Minoxidil PO
Montelukast Na 10mg tablet
Nifedipine (Eqv-CC) Sustained Action (SA) PO
Ofloxacin 0.3% Otic solution
Oxybutynin Chloride SA tablet
Pantoprazole Na 40mg injection
Potassium Chloride SA Capsule
Potassium Citrate SA Tablet
Prempro® Tab, 28 Pack
Proctosol® HC 2.5%
Propofol 10mg/ml 20ml
Reclipsen® Tab, 28
Salicylic Acid 17% solution, topical
Skin Prep, No Sting Wipe
Sulfacetamide Sodium 10/Sulfur 5%
Sulfasalazine Entab 500mg
Triamcinolone Acetonide 0.025%
Vitamin E 500 International Units Capsule
Zeasorb® Powder

Brenda Rappold, R.Ph.
Chief, Pharmacy
200 Veterans Avenue
VAMC Beckley, WV 25801
Phone: 304-255-2121, Ext 4213
Fax: 304-256-5456

Continued....

From: Rappold, Brenda F. BECVAMC

Sent: Thursday, June 25, 2015 1:00 PM

To: VHABECHOSPITAL STAFF; VHABECPHARMACISTS; VHABECNURSING ADMINISTRATION; VHABECP&T

Subject: SDR removed for some medications for specific providers

The **Clinical Executive Board** has recently approved the removal of the Special Drug Request (SDR) requirement for some drugs for some specialists, as noted in the list below. The drug file has been amended to reflect these changes.

Drug	Service that <u>Does Not Need</u> SDR to Prescribe
Anagrelide PO	Oncology
Aripiprazole PO	Mental Health
Argatroban Injection	Cardiology
Artificial Tears Preservative Free	Optometry
Benoxinate/Fluorescein Ophthalmic Solution	Optometry
Betaxolol Ophthalmic Solution	Optometry
Bevacizumab	Oncology
Bicalutamide	Oncology
Bortezomib	Oncology
Calcipotriene 0.005% Topical Cream	Dermatology
Cladribine injection	Oncology
Cyclopentolate Ophthalmic Solution	Optometry
Dexamethasone/Neo/Poly Ophthalmic Ointment	Optometry
Dexamethasone/Tobramycin Ophthalmic solution	Optometry
Dexamethasone/Tobramycin Ophthalmic ointment	Optometry
Dipyridamole Injection	Cardiology
Echothiophate Iodide Ophthalmic Solution	Optometry
Estramustine PO	Oncology
Etoposide Injection	Oncology
Flecainide PO	Cardiology
Flurbiprofen Ophthalmic Solution	Optometry
Gemcitabine Injection	Oncology
Gentamicin Ophthalmic Ointment	Optometry, may authorize refills
Hepatitis A Injection	Gastroenterology (GI)
Hepatitis B Immune Globulin	Gastroenterology
Hydrocortisone/Pramoxine Rectal Foam	Gastroenterology
Hydrocortisone Acetate Rectal Foam	Gastroenterology

Ifosfamide Injection	Oncology
Imatinib PO	Oncology
Irinotecan Injection	Oncology
Levobunolol Ophthalmic Solution	Optometry
Mesna Injection	Oncology
Methazolamide PO	Optometry
Methimazole PO	Endocrinology
Metoprolol Succinate SA	Cardiology
Mitoxantrone Injection	Oncology
Multivit/Oph Antiox/Lutein	Optometry
Sodium (Na) Carboxymethylcellulose	Optometry
Oxaliplatin Injection	Oncology
Propafenone PO	Cardiology
Ribavirin PO	Gastroenterology
Rituximab Injection	Oncology
Sotalol	Cardiology
Tetracaine Ophthalmic Solution	Optometry
Timolol Ophthalmic Gel	Optometry
Ursodiol PO	Gastroenterology

*Brenda Rappold, R.Ph.
Chief, Pharmacy
200 Veterans Avenue
VAMC Beckley, WV 25801
Phone: 304-255-2121, Ext 4213
Fax: 304-256-5456*

See list of medications that remain on SDR that the Medical Inspector never looked at.

In conclusion, while I have great respect for the OSC, I have much criticism for the Medical Inspectors who conducted this investigation. No orally transcribed testimony was furnished by the Medical Inspectors to corroborate their conclusions, although transcription/court reporting services were on site and operating for this entire investigation. The Medical Inspectors (hereinafter MI) raise eyebrows when they rubber-stamp allegations as “UNSUBSTANTIATED” yet do not furnish witness testimony to show how they arrived at their conclusion. The first allegation was mis-worded as it inferred just Mental Health, instead of the entire hospital being affected. The use of restricting medication dispense quantities could be justified for safety, however none of this was ever proven by Beckley Pharmacy officials. In fact, I know of a patient who receives 90 day supplies of potentially deadly tricyclic antidepressants from another provider, which would be a clear patient danger. There was no indication that proper minutes of Beckley Pharmacy P&T or the Clinical Executive Board were kept, or reviewed by the MI team which could have been a critical piece to this investigation. There is no evidence that emails or other communications were examined for collusion among Beckley officials. Mysteriously the pharmacy did not know what medications were on SDR, and an Excel Spreadsheet had been circulated with numerous SDR medications, yet incredulously none where on there “solely for costs”? One might wonder what they were on there for in the first place. Interestingly, dozens of

medications have been removed from the SDR restrictions in recent weeks. Amazing to say the least! Testimony was allegedly given to the Medical Inspectors that the COS would rubber-stamp denials for meds. This was not addressed in this investigation, but would appear criminal in nature with abuse of power, position and authority. In short, this investigation is a sham, and I conclude a cover-up to protect VA management. It is a disgrace to the American public, taxpayers and more importantly to our Veterans. I do not have any problem exposing these corrupt government officials, including those that have helped cover-up the wrong-doing at the Beckley VA Medical Center. Again, I request to remain anonymous as provided by statute of law, however I hope this report can be made fully public, especially in the hands of those who can take corrective actions, so that there will be accountability within the VA for its abuse, injustice and malpractice to our nation's deserving veterans.