

FOR IMMEDIATE RELEASE

North Suburban Regional Human Rights Authority Report of Findings HRA #16-100-9012 Elgin Mental Health Center

Introduction

The North Suburban Regional Human Rights Authority (HRA) opened this investigation regarding Elgin Mental Health Center (hereafter referred to as Center), Forensic Treatment Program after receiving a complaint of alleged rights violations. The complaint accepted for investigation was that a physician ordered a non-formulary medication and the consumer is not being provided with a therapeutic substitution.

The rights of consumers receiving services at the Center are protected by the Illinois Mental Health and Developmental Disabilities Code (405 ILCS 5). Medicaid is governed by the federal Centers for Medicare and Medicaid (CMS); the Healthcare and Family Services (HFS) administers the Medicaid program in Illinois.

Consumers receiving services at EMHC's Forensic Treatment Program have been remanded by Illinois County Courts to the Illinois Department of Human Services (DHS) under statutes finding them Unfit to Stand Trial (UST) and Not Guilty by Reason of Insanity (NGRI). Placement evaluations determine the most appropriate inpatient or outpatient setting for forensic treatment based on a number of factors including age, gender, mental health diagnosis, and security need. Unless a person is specifically ordered to receive services in an outpatient setting, court ordered referrals under state forensic statutes call for placement in a secure inpatient setting. The Forensic Treatment Program has 344 beds.

Methodology

Relevant policies were reviewed as were sections of the consumer's record with authorization. The HRA met with the Director of Pharmacy and the consumer's Primary Care Physician to discuss the allegations. This issue was also discussed with the consumer whose rights were alleged to have been violated both in person and via telephone.

Findings

The consumer's whose rights were alleged to have been violated reported that in May 2015 he had prostate removal surgery that was conducted off-site. During a follow-up consultation in September 2015, the surgeon told the consumer that it is customary and advisable to begin taking Viagra three months following the surgery for increased blood flow to the surgical area. The consumer stated that when the medication was ordered by his Center physician, he was advised that the medication is non-formulary and that there is no substitution. The consumer stated that he would be willing to purchase the medication with his own money.

According to the clinical record, the consumer was remanded to the Center in January 1999. Medical Diagnoses as of January 2016 were as follows: Chronic Otitis Externa, both ears; Persistent Folliculitis; Chronic HSV-1 of Penis; External Hemorrhoids; History of Left Knee Bursitis; Post-Surgical Prostate Removal (5/2015).

Radical prostatectomy (prostate removal) is surgery to remove all of the prostate gland and some of the tissue around it. It is done to treat prostate cancer. Risks of this procedure are: problems controlling bowel movements (bowel incontinence); problems controlling urine (urinary incontinence); erection problems (impotence); injury to the rectum; and urethral stricture (tightening of the urinary opening due to scar tissue).

The chart showed that after the surgery, the consumer received off-site follow-up appointments. During the September follow-up appointment, the Urology Registered Nurse recommended Viagra 100 mg daily due to the consumer complaining of erectile dysfunction. The chart contained a physician's order dated September 9, 2015 that ordered Viagra daily for rehabilitation; the physician wrote that a #9705 form was filed. Also contained in the chart are copies of the follow-up consultation reports. A few weeks after the surgery, it was noted that the consumer was doing well post-op, his catheter was removed and Kegel exercises were explained. The next report, dated June 23, 2015, noted that the consumer was doing well post-op, his pain was well controlled, his stress urinary incontinence was improving, he is doing Kegel exercises and he complained of erectile dysfunction. Viagra was not listed as a prescribed medication.

The physician explained to the HRA that upon hearing that the medication was recommended, he completed a #9705 form, requesting a non-formulary medication. The physician stated that this was merely a recommendation and not a medication order from the surgeon. The physician stated that the non-formulary medication was subsequently denied. The next scheduled off-site post-surgery appointment was scheduled for April 5, 2016. The HRA obtained prescription documents from this appointment. One pharmacy prescription documented that the consumer had a "radical prostatectomy for prostate cancer and they have prescribed Viagra 25 mg. to be taken 8x a month for penile rehabilitation". The other order was written for Sildenafil (Viagra) PRN (as needed) 25 mg. 4 to 5 hours prior to sexual activity. Once again, the consumer maintains to the HRA that the purpose of the medication is for rehabilitation not sexual activity.

The Director of Pharmacy said that the original order for the Viagra was to treat incontinence and that CMS would not approve that medication. The consumer was then given three options: Kegel exercises, and two different types of medication for the incontinence. It was stated that nothing in the Viagra literature supports the claim that the consumer needs this as a postoperative treatment. It was stated that the CMS does not provide medication that is used for sexual activity. It was further stated that the pharmacy had requested education regarding the benefits of this mediation for post-operative prostate surgery, but they have not received that education. The Director stated that the consumer would not be allowed to personally purchase the mediation, because then it would be considered a formulary medication – meaning it would be have to be entered into the computer data and thus be a possible option for others.

The Director provided the HRA with copy of the Center's medication policy which states that medication orders "shall be limited to medications that are needed to treat the patient condition." Also provided was the Illinois Department of Human Services Sexual Activity in Mental Health Facilities policy which states that "sexual activity between an individual and an employee, part-time employee, temporary employee, contractor, subcontractor, employee of a contractor or volunteer is prohibited at all times and is considered abuse. In addition, sexual activity between persons who are inpatients at a state-operated mental health facility is prohibited." Also supplied was Viagra information, which stated that the medication helps the man get and keep an erection only when he is sexually stimulated; an erection will not occur by just taking the medication. The literature did not say that the medication could be used for incontinence. The Director also offered that there are other means for the consumer to treat erectile dysfunction such as a mechanical pump.

According to the American Cancer Society web-site, "The major possible side effects of radical prostatectomy are urinary incontinence (being unable to control urine) and erectile dysfunction (impotence; problems getting or keeping erections). These side effects can also occur with other forms of prostate cancer treatment. Incontinence can be treated. Even if your incontinence can't be corrected completely, it can still be helped. Most doctors feel that regaining potency is helped along by trying to get an erection as soon as possible once the body has had a chance to heal (usually several weeks after the operation). Some doctors call this penile rehabilitation. Medicines (see below) may be helpful at this time. There are several options for treating erectile dysfunction:

- **Phosphodiesterase-5 (PDE5) inhibitors** such as sildenafil (Viagra), vardenafil (Levitra), and tadalafil (Cialis) are pills that can help with erections. These drugs won't work if both nerves that control erections have been damaged or removed. Common side effects of these drugs are headache, flushing (skin becomes red and feels warm), upset stomach, light sensitivity, and runny or stuffy nose. Rarely, these drugs can cause vision problems, possibly even blindness. Some other drugs such as nitrates, which are drugs used to treat heart disease, can cause problems if you are taking a PDE5 inhibitor, so be sure your doctor knows what medicines you take.
- Alprostadil is a man-made version of prostaglandin E1, a substance naturally made in the body that can produce erections. It can be injected almost painlessly into the base of the penis 5 to 10 minutes before intercourse or placed into the tip of the penis as a suppository. You can even increase the dosage to prolong the erection. You might have side effects, such as pain, dizziness, and prolonged erection, but they are not usually serious.
- Vacuum devices are another option to create an erection. These mechanical pumps are placed over the penis. The air is sucked out of the pump, which draws blood into the penis to produce an erection. The erection is maintained after the pump is removed by a strong rubber band placed at the base of the penis. The band is removed after sex.
- **Penile implants** might restore your ability to have erections if other methods don't help. An operation is needed to put them inside the penis. There are several types of penile implants, including those using silicone rods or inflatable devices."

The HRA examined Medicaid covered medication on the HFS website and found that neither Viagra nor its generic is a Medicaid covered medication.

Conclusion

Pursuant to Section 2-102(a) of the Illinois Mental Health and Developmental Disabilities Code, "A recipient of services shall be provided with adequate and humane care and services in the least restrictive environment, pursuant to an individual services plan." The consumer was offered a therapeutic substitution for the post-operative side effect of incontinence. Medication was also ordered post-operative surgery that was non-formulary; a request for the medication was denied; no therapeutic substitution would be available to treat the erectile dysfunction. It is concluded that consumer rights have not been violated.

RESPONSE

Notice: The following page(s) contain the provider response. Due to technical requirements, some provider responses appear verbatim in retyped format.



Bruce Rauner, Governor

James T. Dimas, Secretary

Division of Mental Health – Region 2 Elgin Mental Health Center

RECOVERY IS OUR VISION Recovery is a Personal Journey of Hope, Healing, Growth, Choice, and Change

May 24, 2016

Ms. Patricia Getchell, Chairperson North Suburban Regional Human Rights Authority 9511 Harrison Street, W-300 Des Plaines, IL 60016-1565

Re: HRA #16-100-9012

Dear Ms. Getchell:

Thank you for your thorough review. We are happy to hear these allegations were unsubstantiated. We pride ourselves on providing excellent medical care to all our patients.

Please feel free to include our response with any public release of your Report of Findings.

Sincerely,

Meredith Kiss, M.A. Hospital Administrator

MK/JP/aw