FOR IMMEDIATE RELEASE

North Suburban Regional Human Rights Authority
Report of Findings
HRA #15-100-9011

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 reported was that the pharmacy department has restricted consumers from using personal meal replacements/protein shakes.

The rights of consumers are protected by the Illinois Mental Health and Developmental Disabilities Code (405 ILCS 5).

Recipients 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 315 beds.

Methodology

To pursue this investigation, the HRA requested center policy specific to the allegation, and met with pharmacy personnel to discuss the allegation.

Findings

It was reported that some consumers purchase meal replacement/protein shakes and that these items were stored in the consumer's personal bin. During specific times of the day, the item would be given to the consumer by a staff member for consumption. The protein shakes were powder products; the consumer would mix the powder with water to make the shake. It was stated that pharmacy implemented a "no personal supplement" rule and thus consumers can no longer have these items.

At the site visit, the Director of Pharmacy stated that dietary-type supplements/non-formulary/herbal medications are not allowed for the following reasons: these medications are not entered into the computerized patient profile which leads to possible risks (e.g. drug-drug interactions of new orders) for the patient and all healthcare professionals treating him/her

including Nursing, Pharmacy, and Physicians. It was further stated that non-formulary items are not on the MAR (Medication Administration Record) nor are they unit-dose packaging which can lead to errors. It was explained that the Pharmacy Department receives recall information for items purchased from their wholesalers; recall information about items not purchased by the Center is limited and/or not available. A further concern is the corruption of the packages, in that packages can be easily altered or replaced with other substances, and the Center cannot verify expiration dates. It was stated that the Center does provide some dietary supplements; for example, omega fish oil, multivitamins.

The Center's Medication policy states that "any medication brought into the hospital (by courier or any other means) shall be sent to the Pharmacy Service with a Medication Received at Hospital form attesting to the contents. This shall serve as a receipt for the medication, the Pharmacy Services shall identify the medication and determine appropriate disposition. An EMHC physician may write a physician's order for the specific medication. Providing it is appropriate for the patient to receive and in the Pharmacist's judgement suitable for consumption, it may be dispensed to the patient upon discharge, or to the patient care unit to give as instructed on the bottle."

The HRA also received the following written information from pharmacy personnel that was provided to unit staff members; the staff members were to share this information with consumers. The statement qualified that the "the use of herbals or dietary supplements is not endorsed by the State Central P & T [Pharmacy and Therapy] committee. Only formulary medications that have been approved by Central P & T will be allowed in the facilities. Herbals and supplements are not allowed at EMHC due to the following concerns: the physician and pharmacist must check herbal medications and/or supplements for potential interactions with other mediations(s). Checking reference tests for drug-disease state interactions, drug-drug interactions information, is time consuming and may lead to incomplete/conflicting information. New interactions are continually being discovered. The treatment team must be informed of medications they are prescribing, dispensing and administering. Non-formulary/Herbal medications are not entered into the computerized patient profile. This leads to additional labor for nursing and possible risk (e.g. drug-drug interactions of new orders) for the patient and all healthcare professionals treating him/her including Nursing, Pharmacy, and Physicians. Non-Formulary Items are not on the MAR nor are they unit dose packaging. This can lead to errors. Recall information for items not purchased by EMHC is limited and/or not available. Pharmacy receives recall information for items purchased from our wholesaler. This means there is a legal concern. Adulteration of Package: Some vehicles and/or dosage forms easily altered or can be replaced with other substances. Some packages are easy to 'reseal.' Medications for consideration should be in a prescription vial filled by a pharmacy with identifications listed. Stability and Expiration date: The expiration date can be verified. The storage of the medication cannot be verified."

According to the Food and Drug Administration, "Congress defined the term 'dietary supplement' in the Dietary Supplement Health and Education Act (DSHEA) of 1994 as a "*product taken by mouth that contains a 'dietary ingredient' intended to supplement the diet. The 'dietary ingredients' in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of 'foods,"'not drugs, and requires that every supplement be labeled a dietary supplement. Dietary supplements may not be risk-free under certain circumstances. If you are pregnant, nursing a baby, or have a chronic medical condition, such as, diabetes, hypertension or heart disease, be sure to consult your doctor or pharmacist before*

purchasing or taking any supplement. If you plan to use a dietary supplement in place of drugs or in combination with any drug, tell your health care provider first. Many supplements contain active ingredients that have strong biological effects and their safety is not always assured in all users. If you have certain health conditions and take these products, you may be placing yourself at risk. Taking a combination of supplements or using these products together with medications (whether prescription or OTC drugs) could under certain circumstances produce adverse effects, some of which could be life-threatening. Be alert to advisories about these products, whether taken alone or in combination. For example: Coumadin (a prescription medicine), ginkgo biloba (an herbal supplement), aspirin (an OTC drug) and vitamin E (a vitamin supplement) can each thin the blood, and taking any of these products together can increase the potential for internal bleeding. Combining St. John's Wort with certain HIV drugs significantly reduces their effectiveness. St. John's Wort may also reduce the effectiveness of prescription drugs for heart disease, depression, seizures, certain cancers or oral contraceptives."

Also discussed were nutritional supplements. Pharmacy personnel stated that patients can obtain nutritional supplements with the approval of the physician and the dietary department. However, sometimes there is a fine-line between the dietary and nutritional supplement. The Pharmacy Department supplied the HRA with written materials that addressed both nutritional and dietary facts/guides. Examples showed a low-carb time released protein blend powder and an egg while protein powder; both products fall under the FDA's definition of a dietary supplement. Examples of nutritional supplements included meal bars, and protein shake powders. Thus, a patient might order a protein shake thinking it is a nutritional supplement, when it fact it is a dietary supplement. It was stated that all nutritional type supplements must be approved by the dietary department.

The Center's Nourishments & Snacks policy states that "nourishment requests for individual patients should be submitted on the Diet Prescription/Dietitian Referral form."

The Nutrition Labeling and Education Act of 1990 (NLEA) provides the FDA with specific authority to require nutrition labeling of most foods regulated by the Agency; and to require that all nutrient content claims (i.e., 'high fiber', 'low fat', etc.) and health claims be consistent with agency regulations. Regulations implementing the NLEA labeling provisions were issued on January 6, 1993, with technical amendments published on August 18, 1993. Dietary supplements must be labeled as such and must not be represented for use as a conventional food or as the sole item of a meal or the diet. One way to distinguish dietary supplements from conventional foods is by looking at the nutrition information on the label of the product. Conventional foods must have a "Nutrition Facts" panel on their labels, but dietary supplements must have a "Supplement Facts" panel.

Conclusion

Pursuant to the Illinois Mental Health and Developmental Disabilities Code, Section 2-104, "every recipient who resides in a mental health or developmental disabilities facility shall be permitted to receive, possess and use personal property and shall be provided with a reasonable amount of storage space therefor, except in the circumstances and under the conditions provided in this Section. (a) Possession and use of certain classes of property may be restricted by the facility director when necessary to protect the recipient or others from harm, provided that notice of such restriction shall be given to all recipients upon admission."

The HRA concludes that the explanation to exclude dietary/ non-formulary items - are not on the MAR, not unit dose packaging, recall information is limited and/or not available, the adulteration of the packages, and the inability to verify expiration dates - are reasons enough to prevent these items for personal use. Patients can obtain nutritional supplements with the approval of the dietary department and the physician. Thus, the allegation that patients are restricted from dietary supplements is true, but it is concluded this is not a rights violation. Patients are not being restricted from nutritional supplements; rights are not being violated.

RESPONSE

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

Illinois Department of Human Services

Bruce Rauner, *Governor*

James T. Dimas, *Secretary-designate*

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

November 2, 2015

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

Re: HRA #15-100-9011

Dear Ms. Getchell:

Thank you for your thorough review. We were pleased to learn these allegations are unsubstantiated.

The staff at Elgin Mental Health Center strives to provide the best possible care and treatment for our patients. Patients can obtain nutritional supplements with the approval of the Dietary Department and their physician.

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

Sincerely,

Meredith Kiss, MA
Acting Hospital Administrator

MK/JP/aw

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