Duke University Health System

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July 31, 2014

Via Email

Fatimah Wilson, Project Analyst
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Duke University Health System Comments Regarding Veritas Collaborative LLC CON Application for Dedicated Eating Disorder Inpatient Psychiatric Beds (J-10307-14)

Dear Ms. Wilson:

The Duke University Health System submits these comments in connection with the certificate of need application filed by Veritas Collaborative LLC to develop 25 dedicated inpatient psychiatric beds for the treatment of eating disorder patients. Such treatment requires specialized care and expertise. The Certificate of Need Section should ensure that any dedicated units be fully prepared to meet the requirements of this patient population. The recommendations below reflect the input of clinicians practicing at Duke University Hospital and the Duke Center for Eating Disorders, a comprehensive outpatient eating disorder program.

According to systematic review and clinical practice guidelines,[1234] hospitalization is recommended for patients with eating disorders who demonstrate one or more of the following medical conditions:

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[1] Eating Disorders: Core Interventions in the Treatment of and Management of Anorexia Nervosa, Bulimia Nervosa and Related Eating Disorders. National Institute for Clinical Excellence, Clinical Guideline 9. http://guidance.nice.org.uk (Accessed on December 22, 2010).

[2] Treatment of patients with eating disorders, third edition. American Psychiatric Association. Am J Psychiatry. 2006;163(7 Suppl):4.

[3] Mehler, PS, Birmingham, LC, Crow, SJ, Jahraus, JP. Medical complications of eating disorders. In: The Treatment of Eating Disorders: A Clinical Handbook, Grilo, CM, Mitchell, JE (Eds), The Guilford Press, New York 2010. p.66.

[4] Eating disorders in adolescents: position paper of the Society for Adolescent Medicine. Golden NH, Katzman DK, Kreipe RE, Stevens SL, Sawyer SM, Rees J, Nicholls D, Rome ES, Society For Adolescent Medicine, J Adolesc Health. 2003;33(6):496.

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- Unstable vital signs
- Bradycardia less than 30 beats per minute (resting, awake heart rate)
- Bradycardia less than 40 beats per minute and hypotension or symptoms of lightheadedness
- Hypothermia (core temperature <35°C or 95°F)
- Cardiac dysrhythmia other than sinus bradycardia
- Weight less than 70 percent of ideal body weight, especially if weight loss was rapid
- Marked dehydration
- Acute medical complication of malnutrition (e.g., syncope, seizures, cardiac failure, liver failure, pancreatitis, or electrolyte disturbance)
- Moderate to severe refeeding syndrome
- Marked edema
- Serum phosphorous <2 mg/dL
- Complications due to coexisting medical problems such as diabetes

Further, once nourishment of an acutely ill individual with anorexia nervosa is undertaken, there is a risk of refeeding syndrome which requires medical management.

In addition, inpatient hospitalization is appropriate for patients psychiatrically unstable as determined by:

- Rapidly worsening symptoms
- Suicidality and inability to contract for safety

Any approval of Veritas' application (or any dedicated inpatient psychiatric eating disorder facility) should be conditioned on the provision of written documentation that Veritas is prepared to meet the needs of these medically unstable or psychiatrically unstable patients as set forth below. Given the high percentage of patients projected to come from out of state, it would be an unfair burden on local emergency departments to accommodate patients from a licensed inpatient program that is unable to treat typical and expected psychiatric and medical conditions for this patient population. Particular concerns are set forth below.

Transfer of psychiatric patients

Veritas' transfer policies call into question its ability to take care of all eating disorder patients who are eligible for admission as a result of psychological instability, including those threatening self-harm. In its exhibits, Veritas has submitted its proposed "Procedures for Emergency Medical Attention – Duke University Medical Center." While Duke currently accepts transfers of Veritas' adolescent patients and would accept transfers of adult patients as appropriate consistent with its EMTALA obligations with or without a formal transfer agreement, Veritas

appears to intend not only to transfer patients with acute medical conditions (transfers that are not required when such services are provided at a facility that also offers acute care services, such as UNC Hospitals), but also to transfer certain patients for "psychiatric reasons."

On page 4 of its proposed "Procedures for Emergency Medical Attention – Duke University Medical Center," Veritas documents the following protocol: "If a Veritas Collaborative patient requires a higher level of medical attention due to acute and active psychiatric concerns (i.e., psychosis, self-harm, or aggressive/assaultive behaviors resulting in injury or potentiated injury), follow all the same steps as above (for medical transfers) with two exceptions" – including that "Veritas Collaborative members will not accompany patients to the Emergency Department."

That is, Veritas plans to deal with patients with "acute and active psychiatric concerns" including self-harm by alerting Duke to their imminent transfer, calling 911, and simply sending the patient on his or her own in an ambulance. This intent to transfer such patients for treatment at another facility is inconsistent with Veritas' own application, which recognizes that

> Patients with eating disorders have both physical and mental illness symptoms and frequently present with a multitude of comorbid diagnoses **(e.g. self-injurious behaviors, suicidality,** severe bradycardia, etc.). Due to an exceedingly high mortality risk these patients have unique needs necessitating specialized intervention at higher levels of care.

Application, p. 50 (emphasis added). Self-injurious behaviors are thus expected with this patient population and are a factor that supports inpatient hospitalization. However, Veritas appears unready to treat the full range of behaviors that would be expected in eating disorder patients. A licensed inpatient psychiatric facility, especially one accepting involuntarily committed patients, should be fully prepared to address and treat suicidal or self-harm risks as part of its patient care without transfer. Approval of any application should be conditioned on documentation of a facility's plan and commitment in this regard.

Feeding Tube Treatment

Veritas states in its application that it is seeking regulatory approval to offer nasogastric feeding tube treatment to patients under its existing license. Duke agrees that an inpatient eating disorder program cannot effectively treat its patients without the ability to provide this service effectively. Otherwise, patients needing this treatment will always have to be transferred to another facility. However, it is unclear that Veritas has taken the necessary steps to be able to provide this service safely and appropriately even if it has the right to provide the service under its license. It is the standard of care that a practitioner with specific training and privileges insert the tube upon

receipt of a physician's order. Then, after placement, it is important to request and review a chest/abdominal x-ray before administering any fluids as the ideal method to verify correct placement of the tube and avoid potentially life-threatening complications from placing the tube in an airway instead. Neither Veritas' staffing plan nor its equipment list appears to include any provision for respiratory practitioners, x-ray technicians, or x-ray equipment that would enable it to follow these protocols.

Any certificate of need for an inpatient eating disorder facility should be conditioned on the provision of a written plan for the safe provision of nasogastric feeding, including the provision of x-ray confirmation of proper placement.

Medical Management

Based on its experience treating eating disorder patients treated in its intensive outpatient treatment program as well as those transferred to Duke for acute medical care, Duke also believes that the following are necessary components of an inpatient eating disorder program. Any approval for the development or expansion of an inpatient eating disorder program should be conditioned on the provision of documentation of the following:

- 24-hour laboratory testing capabilities, including urgent or stat laboratory results
- Placement and management of nasogastric feeding tubes as set forth above
- Placement and management of intravenous access
- 24-hour medical and psychiatric MD availability
- Quarantine capabilities in the case of infectious disease incident
- Detailed protocols for management of high risk medical scenarios including established medical specialty consultative contacts and clearly delineated transfer thresholds and protocols

In addition, any inpatient eating disorder program should be required to fully document its policies and protocols for management of the following medical complications without outside transfer:

- Presyncope or Orthostasis or Mild to Moderate Hypotension: Management would include medical assessment of volume status, laboratory testing, and possibly IV fluid administration.
- Electrolyte Disturbances: Most mild to moderate electrolyte disturbances can be managed with oral medications and repeated laboratory testing and should not require emergency room transfer.

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- Mild to Moderate Manifestations of Refeeding syndrome: Assessment and management would require IV access and monitoring of electrolytes through stat laboratory testing.
- Mild to Moderate Respiratory Symptoms: Symptoms such as dyspnea and coughing may be related to aspiration, pneumothorax, diaphragmatic dysfunction or generally decreased pulmonary capacity related to malnutrition. Appropriate initial assessment and management of respiratory symptoms prior to emergency room transfer would require respiratory support staff, oxygen delivery capabilities, and chest radiograph capabilities.
- Food Refusal: Outright food refusal is a common occurrence that requires nasogastric administration of nutrition to avoid further medical compromise. Nasogastric tube placement and management is necessary to provide this critical medical intervention.
- Palpitations and Concern for Dysrhythmia: Cardiac dysrhythmias ranging from sinus bradycardia to overt ventricular dysrhythmias are potential complications of eating disorders. Prior to having severe dysrhythmias many patients have persistently abnormal cardiac rates and rhythms but do not have overt cardiovascular compromise. For instance, sinus bradycardia is very common in malnutrition and requires close monitoring. Monitoring of bradycardia requires continuous cardiac monitoring capabilities.

Duke appreciates the opportunity to submit these comments regarding the clinical needs of this patient population.

Sincerely,

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