November 20, 2019

Governor Ralph Northam
P.O. Box 1475
Richmond, VA 23219

Dear Governor Northam,

The Office of the State Inspector General (OSIG) conducted a review of medication variances occurring in facilities operated by the Virginia Department of Behavioral Health and Developmental Services (DBHDS) during fiscal year (FY) 2018. OSIG reviewed incidents of medication error(s) from a variety of sources and conducted field work from December 2018 through June 2019. The goal of this review was to identify areas of improvement in reporting and monitoring medication variances in DBHDS facilities and to offer recommendations for improvement.

OSIG conducted a preliminary review which was followed by a more in-depth analysis culminating in this letter which includes observations and recommendations.

**Background**

As part of its FY 2019 work plan, OSIG identified medication variances as an area for review. OSIG sought to evaluate events to identify patterns, incidence and prevalence; generate performance improvement; and lessen the risk of future events. OSIG performed an extensive review of relevant laws, policies and procedures, regulations and guidelines concerning medication variances, healthcare risk management and event management, and relevant industry best practices.

OSIG contracted the services of a licensed pharmacist to analyze and categorize the medication variance data collected in accordance with industry standards.
Review Methodology

As part of the review, OSIG conducted interviews with the following DBHDS staff:

- DBHDS Pharmacy Services Manager,
- ESH- Nurse Executive,
- ESH- Risk Manager,
- ESH- Nurse Manager,
- ESH- Pharmacy Manager,
- ESH- Pharmacy Technician,
- SEVTC Nursing Director,
- SEVTC Risk Manager,
- SEVTC Pharmacy Liaison,
- SEVTC Pharmacy Technician, and
- SEVTC Direct Support Professional.

Additional resources requested from DBHDS facilities included, but were not limited to:

- Medication variance policies, procedures, guidance documents and forms. This includes pharmacy, medical and nursing.
- Facility Event Report (158) or other pharmacy forms completed for medication variances at the time of the event.
- Pharmacy and Therapeutics Committee protocols, policies, meeting reports and minutes.
- Facility performance improvement projects relevant to medication variances and/or medication safety.
- Virginia Board of Pharmacy inspection reports and related plans of correction for deficiencies.
- Facility quality improvement programs and associated reports.
- Interviews with staff members at DBHDS Central Office, Eastern State Hospital and Southeastern Virginia Training Center, including pharmacists, medication technicians, nursing staff and supervisors, training managers and risk managers.
- DBHDS Office of Licensing Standards, Reporting a Serious Incident as a Medication Error, October 2016.

**OBSERVATION #1: DBHDS FACILITIES LACK UNIFORM REPORTING GUIDELINES PERTAINING TO THE CLASSIFICATION OF MEDICATION VARIANCES.**

OSIG found the current DBHDS system for reporting medication variances to be in need of improvement. It should be noted that confusion related to defining variances and a lack of uniformity in reporting by facilities complicated this review. Consistent, effective reporting would allow for overall comparison and review, enabling DBHDS Central Office to better benchmark and determine areas for improvement. In reviewing DBHDS-operated facility medication variances, OSIG found differences in the way errors were being reported and categorized. In addition, pharmacy and nursing staff are using various forms and categorization types. In reviewing the forms, OSIG observed the use of many variations of the Facility
Event Report (158), each containing information deemed pertinent by staff at each facility. Many of the forms reviewed were handwritten and illegible. Staff members selected multiple variance causes for a single variance event, which created difficulty in analyzing and interpreting data. Written explanations for variances differed in quality of detail.

OSIG collected a total of 1,662 incident reports involving medication variances reported by all facilities in FY 2018 (see chart below). A lack of uniformity in reporting medication variances made it difficult to identify systemic issues. Since no centralized system or database was in use by DBHDS (see Observation #2), OSIG’s contracted pharmacist manually screened, analyzed, classified, and recorded all 1,662 incident reports, and identified discrepancies in reporting throughout DBHDS operated facilities. Performance improvement is difficult to achieve without consistency and uniformity in the reporting process.

A large discrepancy was found in the number of variances reported among facilities. Only five facilities (Piedmont Geriatric Hospital, Southern Virginia Mental Health Institute, Virginia Center for Behavioral Rehabilitation, Eastern State Hospital and Western State Hospital) provided a breakdown between pharmacy and nursing variances. The most common medication variances reported were transcription errors, omitted doses, dispensing errors, wrong dosage/strength and wrong medication.

**Observation #1 Recommendation**

DBHDS should establish a Departmental Instruction (DI) that outlines procedures for classifying and reporting medication variances and provides more frequent medication variance training.
Management Comments - Observation #1

DBHDS partially agrees with the recommendation. The facilities are committed to providing safe competent patient care, including medication safety. DBHDS facilities are compliant with guidelines as established by the Joint Commission on Accreditation of Healthcare Agencies (TJC) and the Centers for Medicare and Medicaid Services (CMS). DBHDS will convene a work group with representatives from Facility Chief Nurse Executives who will review existing practices and unique realities of each facility and ensure each facility has a policy, tailored to its needs including procedures for classifying and reporting medication variances. DBHDS will also ensure medication variance training is incorporated into applicable facility curriculums.

**OBSERVATION #2: DBHDS LACKS A CENTRALIZED SYSTEM FOR REPORTING MEDICATION VARIANCES TO ALLOW FOR THE IDENTIFICATION OF SYSTEMIC ISSUES THAT IF CORRECTED, COULD IMPROVE PATIENT SAFETY.**

DBHDS does not currently have a centralized system for reviewing and responding to facility medication variances. This responsibility is currently being managed at a facility level by risk managers. While the Pharmacy and Therapeutics Committee is reviewing errors at the facilities, there is no system for comparison among facilities. Central benchmarking processes are not in place to address systemic issues that may exist.

**Observation #2 Recommendation**

DBHDS should compile, benchmark and analyze all medication variances for all facilities at the DBHDS Central Office. This will allow for the identification of systemic issues that are affecting patient safety. Additionally, DBHDS could adopt an agency-wide training program based on information generated from a system-level reporting system at the direction of a licensed health care provider. A well-developed and managed plan for reducing medication variances and addressing problems within the system will help enhance patient safety and improve quality of care.

**Management Comments - Observation #2**

DBHDS partially agrees with the recommendation. The Department is in the process of building a system wide Incident Tracker that will require all facilities to enter data using the same requirements and definitions. DBHDS and the facilities will have the ability to pull specific reports related to the fields on the incident report (including medication variances). DBHDS is also in the process of building and deploying a system level electronic health record (EHR) - Millennium. Improved data quality is an expected outcome of the new system.
On behalf of OSIG, I would like to express our appreciation to DBHDS Chief Deputy Commissioner Mira Signer and her staff within the Central Office as well as facility directors and staff during this review.

Respectfully,

Michael C. Westfall, CPA
State Inspector General

CC: Clark Mercer, Chief of Staff to Governor Northam
Suzette P. Denslow, Deputy Chief of Staff to Governor Northam
Daniel Carey, M.D., Secretary of Health and Human Resources
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Delegate T. Scott Garrett, Vice Chair of the Joint Commission on Health Care
Alison Land, Commissioner, DBHDS
Mira Signer, Chief Deputy Commissioner, DBHDS
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