MARYLAND MEDICAID PHARMACY PROGRAM

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ADVISORY

In an effort to give timely notice to the pharmacy community concerning important pharmacy topics, the Department of Health and Mental Hygiene's (DHMH) ***Maryland Medicaid Pharmacy Program*** *(MMPP) has developed the* ***Maryland Medicaid Pharmacy Program Advisory****. To expedite information timely to the pharmacy and prescriber communities, an email network has been established which incorporates the email lists of the Maryland Pharmacists Association, EPIC, CARE, Long Term Care Consultants, headquarters of all chain drugstores and prescriber associations and organizations. It is our hope that the information is disseminated to all interested parties. If you have not received this email through any of the previously noted parties or via DHMH, please contact the MMPP representative at 410-767-1455.*

Updates to Clozapine REMS Program

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THIS COMMUNICATION DOES NOT AFFECT THE PROCESSING OF MD MEDICAID CLAIMS – IT DOES AFFECT THE PHARMACY'S ABILITY TO ORDER AND DISPENSE CLOZAPINE

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Clozapine, a medication used in the treatment of refractory schizophrenia, has an updated safety program. The Food and Drug Administration released a new Risk Evaluation and Mitigation Strategy (REMS) program to simplify reporting standards for prescribers, pharmacies and patients.

Important: *Prescribers and pharmacies* will need to be ***certified to participate*** **in the new Clozapine REMS program, which is scheduled for implementation starting October 12, 2015. Instructions for certification appear at the bottom of this article. Beginning in December, you may not order or dispense clozapine unless your pharmacy is certified and the prescriber is certified, even if the patient is already receiving the medication.**

The new program will replace existing programs maintained by individual drug manufacturers. Clozapine is known to cause neutropenia, a serious adverse event. The new program will be a centralized database for monitoring patients receiving therapy. The goal is to reduce the burden of reporting requirements, while maintaining the safe use of the medication. All current patients receiving clozapine should be transitioned into the new program automatically. Pharmacies and prescribers should make sure their patients' information transferred correctly after October 12, 2015. The reporting requirements will be simplified to use the Absolute Neutrophil

Count (ANC) as a marker of neutropenia, instead of a full Complete Blood Count (CBC) panel to monitor white blood cell count (WBC). In addition, to simplifying reporting requirements, the new program will change the threshold for holding therapy to allow patients to continue on the medication if a clear benefit is seen. Also, patients who previously were ineligible for therapy due to benign ethnic neutropenia (BEN) will now be able to receive treatment.

To certify, prescribers and pharmacists must review the prescribing information for clozapine and the *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers.* They must also successfully pass the Knowledge Assessment for Healthcare Providers and complete and submit the Clozapine REMS Enrollment Form. These materials are available at http://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=351.

Additionally, beginning in December 2015, outpatient pharmacies will be required to obtain a pre-dispense authorization code to process clozapine prescriptions. More information can be found at http://www.fda.gov/Drugs/DrugSafety/ucm461853.htm