**Compliance Guide for New Regulations for Small Businesses**

* What does this regulation do?

The purpose of the proposed action is to increase the professional dispensing fees paid to Maryland Medicaid community participating pharmacy providers for covered services. This includes covered services rendered to participants in nursing facilities and covered services rendered to individuals who do not reside in nursing facilities, in order to comply with federal mandates established by CMS' Covered Outpatient Drug Final Rule (CMS-2345-FC).

* Who is Subject to the new regulation?

Maryland pharmacies

* Why were the new regulations adopted?

The new regulations are being adopted in order to comply with federal mandates established by Covered Outpatient Drugs Final Rule (CMS-2345-FC) and the results of the Survey of the Average Cost of Dispensing a Prescription to FFS Maryland Medicaid Participants, published January 21, 2020.

* When are the regulations effective?

The proposed actions will take effect July 1, 2020.

* Is funding available to implement new requirements established by the regulation?

N/A – the proposed action increases a fee paid to providers.

* Are there other resources available for implementing the requirements of the regulation?

N/A

* Is there assistance available to help understand the requirements of the regulation?

Yes. The Office of Pharmacy Services is available to explain rate changes made in this regulatory amendment. Questions about specific provisions of the regulation should be directed to Chukwuemeka Okoronkwo at (410)767-1460, or chukwuemeka.okoronkwo@maryland.gov.

Key Terms and Definitions

“Professional dispensing fee” means the professional fee which:

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies

“Pharmacy” means an establishment or institution licensed in good standing that is required to obtain a permit in accordance with Health Occupations Article, Title 12, Annotated Code of Maryland, or a similar entity legally authorized to dispense legend drugs to the public in the state in which the establishment or institution is located.

“Drugs” means legend drugs (those requiring a prescription under federal or State law) or over-the-counter (OTC) drugs (those not requiring a prescription under federal or State law).

“Participant” means a person who is certified as eligible for and is receiving Medical Assistance benefits.

“Nursing facility” means an institution is primarily engaged in providing to residents:

Skilled nursing care and related services for residents who require medical or nursing care;

Rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or

On a regular basis, health-related care and services to individuals who, because of their mental or physical condition, require care and services (above the level of room and board) which can be made available to them only through institutional facilities.

"Nursing facility" means an institution which is licensed by the Department under COMAR 10.07.02.

"Nursing facility" does not include an institution which is primarily for the care and treatment of mental diseases, an intellectual disability, or a developmental disability.