I. PURPOSE

Aurora Health Care seeks to ensure that all caregivers conduct business in an honest, ethical and fair manner and in accordance with all applicable laws and regulations. This policy is intended to prevent inappropriate influence by pharmaceutical manufacturers and impermissible inducement of patients. The provisions set forth in this policy provide requirements for co-pay assistance programs and drug replacement programs that offer financial and in kind assistance to cover the cost of medications.

II. SCOPE

This policy applies to all Aurora caregivers including all students, trainees, residents, employees, officers, directors and agents of the owned and/or controlled entities of Aurora Health Care.

III. DEFINITIONS

A. “Aurora” means Aurora Health Care, Inc., and any of its affiliated entities.

B. “Drug Assistance Program” means a program to provide medication under a Drug Replacement Program or monetary assistance in the form of co-pay or premium payment assistance through a Co-Pay Assistance Program.

C. “Drug Replacement Program” means a program to provide medication free or at reduced cost to patients who meet financial criteria, legal residency status, and who are under the care of a healthcare provider licensed and authorized to prescribe, dispense, and administer medications. A Drug Replacement Program may offer assistance directly to patients or it may replenish drugs furnished by Aurora to eligible patients whose drugs are not covered by an insurance program.

D. “Co-pay Assistance Program” means a program to provide monetary co-pay assistance or premium payment assistance grants to patients who meet financial criteria, legal residency status, and who are under the care of a healthcare provider licensed and authorized to prescribe, dispense, and administer medications.

E. “Compliance Department” means the Aurora system Compliance Department.

IV. POLICY

A. Drug Assistance Programs Generally

1. Aurora will participate in and refer patients to only those Drug Assistance Programs that comply with applicable guidelines established by the US Department of Health and Human Services Office of Inspector General (“OIG”).

2. The Compliance Department will work collaboratively with care management and social workers to prospectively identify those Drug Assistance Programs that meet applicable OIG guidelines. A listing of approved programs will be maintained by the Compliance Department and provided to clinical caregivers.
3. Once a Drug Assistance Program has been approved, patients may be referred to such program for the purpose of obtaining assistance with their medication without further review or approval by the Compliance Department.

4. Applicability of a generic substitution or therapeutic alternative to name brand pharmaceuticals should be considered and documented in the patient’s medical record as either not available or not the most clinically appropriate therapy in the medical judgment of the ordering physician.

5. At the request of an Aurora patient advocate or caregiver, the Compliance Department will review on a case by case an individual patient status and/or a program that does not otherwise fall within the general terms of this policy.

B. Drug Replacement Programs

1. To qualify, patients must:
   • meet financial criteria set by the program,
   • meet legal residency status, and;
   • be under the care of a health care provider licensed and authorized to prescribe, dispense, and administer medications.

2. The medications that are the subject of the Drug Replacement Program must not be prescribed for off label use unless that use is recognized as standard of care by a recognized professional source such as Micromedex or NCCN guidelines.

3. A Drug Replacement Program operated by a bona fide charitable organization or a pharmaceutical manufacturer may provide free medications for uninsured patients or for commercially insured patients who do not have coverage for the medication. For Medicare and Medicaid beneficiaries, free medications can be provided for a medication not covered under Medicaid or the Medicare Part D benefit.

4. Bulk drug replacement (non-patient specific) Drug Replacement Programs will be reviewed and approved by the Compliance Department on a case by case basis.

C. Co-pay Assistance Programs

1. To qualify for a Co-pay Assistance Program, patients must:
   • meet the financial criteria set by the program;
   • meet legal residency status; and
   • be under the care of a health care provider licensed and authorized to prescribe, dispense, and administer medications.

2. The medications which are the subject of Co-pay Assistance Program must not be prescribed for off label use unless that use is recognized as standard of care by a recognized professional source such as Micromedex or NCCN guidelines.

3. Co-pay assistance or premium payment assistance from a bona fide charitable organization can be made to financially qualified Medicare beneficiaries for Part D covered medications, or Medicaid beneficiaries for covered medications.

4. Co-pay assistance or premium payment assistance from a non-charitable organization, such as pharmaceutical manufacturer Drug Assistance Program can be provided to a patient if the medication is either not covered as a patient benefit by Medicare or Medicaid or the patient is not insured by Medicare or Medicaid.
Cross References: None

References: OIG Advisory Opinion No. 09-08, July 28, 2009

Patient Assistance Programs for Medicare Part D Enrollees—OIG Special Advisory Opinion 70 FR, No. 224, November 22, 2005, p. 70623

OIG Advisory Opinion No. 07-18, December 19, 2007

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