

SEC. 3307. IMPROVING FORMULARY REQUIREMENTS FOR PRESCRIPTION DRUG PLANS AND MA-PD PLANS WITH RESPECT TO CERTAIN CATEGORIES OR CLASSES OF DRUGS.

(a) IMPROVING FORMULARY REQUIREMENTS.—Section 1860D-4(b)(3)(G) of the Social Security Act is amended to read as follows:

“(G) REQUIRED INCLUSION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

“(i) FORMULARY REQUIREMENTS.—

“(I) IN GENERAL.—Subject to subclause (II), a PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).

“(II) EXCEPTIONS.—The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).

“(ii) IDENTIFICATION OF DRUGS IN CERTAIN CATEGORIES AND CLASSES.—

“(I) IN GENERAL.—Subject to clause (iv), the Secretary shall identify, as appropriate, categories and classes of drugs for which the Secretary determines are of clinical concern.

“(II) CRITERIA.—The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).

“(iii) IMPLEMENTATION.—The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.

“(iv) REQUIREMENT FOR CERTAIN CATEGORIES AND CLASSES UNTIL CRITERIA ESTABLISHED.—Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):

“(I) Anticonvulsants.

“(II) Antidepressants.

“(III) Antineoplastics.

“(IV) Antipsychotics.

“(V) Antiretrovirals.

“(VI) Immunosuppressants for the treatment of transplant rejection.”.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to plan year 2011 and subsequent plan years.