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110TH CONGRESS
1ST SESSION

H. R. 3061

To amend title XVIII of the Social Security Act to require that Medicare prescription drug plans using formularies cover all drugs included in 6 specified therapeutic categories, to establish protective requirements for coverage determinations, reconsiderations, and appeals related to such drugs, and to require annual reports on such determinations, reconsiderations, and appeals.

IN THE HOUSE OF REPRESENTATIVES

JULY 17, 2007

Mr. DOGGETT (for himself, Mr. ABERCROMBIE, Mr. ALLEN, Mr. DAVIS of Illinois, Mr. EMANUEL, Mr. ENGEL, Mr. AL GREEN of Texas, Mr. HINCHEY, Ms. KAPTUR, Mr. LARSON of Connecticut, Ms. MCCOLLUM of Minnesota, Mr. MCDERMOTT, and Mr. STARK) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to require that Medicare prescription drug plans using formularies cover all drugs included in 6 specified therapeutic categories, to establish protective requirements for coverage determinations, reconsiderations, and appeals related to such drugs, and to require annual reports on such determinations, reconsiderations, and appeals.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare Part D Drug Class Protection Act of 2007''.

SEC. 2. SPECIAL TREATMENT UNDER MEDICARE PART D FOR DRUGS IN 6 SPECIFIED THERAPEUTIC CATEGORIES.

(a) MEDICARE PART D FORMULARIES REQUIRED TO COVER ALL DRUGS IN 6 SPECIFIED THERAPEUTIC CATEGORIES.—

(1) IN GENERAL.—Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)) is amended—

(A) in subparagraph (C)(i), by inserting '', except as provided in subparagraph (G),'' after ''although''; and

(B) by inserting after subparagraph (F) the following new subparagraph:

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

''(i) REQUIREMENT.—The formulary must include, subject to clause (iii), all or substantially all drugs in each of the fol-

lowing therapeutic categories of covered part D drugs:

"(I) Immunosuppresessants.

"(II) Antidepressants.

"(III) Antipsychotics.

"(IV) Anticonvulsants.

"(V) Antiretrovials.

"(VI) Antineoplastics.

"(ii) COVERAGE OF ALL UNIQUE DOSAGE FORMS.—To meet the requirement under clause (i), the formulary must include all covered part D drugs and unique dosages and forms of such drugs in the categories specified in such clause, except for—

"(I) multi-source brands of the identical molecular structure;

"(II) extended release products in the case that the immediate release product involved is included on the formulary;

"(III) products that have the same active ingredient; and

"(IV) dosage forms that do not provide a unique route of administration, such as tablets and capsules.

"(iii) APPLICATION TO NEW FDA-APPROVED DRUGS.—In the case of a drug that becomes a covered part D drug and that is included in a category specified in clause (i), clause (i) shall apply to such drug 30 days after the drug has been placed on the market. Nothing in the previous sentence shall be construed as preventing a pharmacy and therapeutic committee from advising a PDP sponsor of a prescription drug plan on the clinical appropriateness of formulary management practices and policies related to new drugs in such categories.

"(iv) UTILIZATION MANAGEMENT TOOLS NOT PERMITTED.—A PDP sponsor of a prescription drug plan may not apply a utilization management tool, such as prior authorization or step therapy, to a drug required under clause (i) to be included on the formulary.

"(v) RULES OF CONSTRUCTION.—

"(I) ISSUANCE OF GUIDANCE OR REGULATIONS TO ESTABLISH FORMULARY OR UTILIZATION MANAGEMENT REQUIREMENTS PERMITTED.—Nothing in this subparagraph shall be construed as prohibiting the Secretary from issuing guidance or regulations to establish formulary or utilization management requirements under this section for any category or class of covered part D drugs if such guidance or regulations are consistent with the requirements of this subparagraph.

"(II) ADDITIONAL THERAPEUTIC CATEGORIES PERMITTED.—Nothing in this subparagraph shall be construed as prohibiting the Secretary from including any additional therapeutic category or class of covered part D drugs under clause (i) for purposes of this subparagraph.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to plan years beginning on or after January 1, 2008.

(b) SPECIAL REQUIREMENTS FOR COVERAGE DETERMINATIONS, RECONSIDERATIONS, AND APPEALS FOR DRUGS INCLUDED IN SPECIFIED THERAPEUTIC CATEGORIES.—

(1) IN GENERAL.—Section 1860D–4(g) of the Social Security Act (42 U.S.C. 1395w–104(g)) is amended by adding at the end the following new paragraph:

"(3) RECONSIDERATION OF DETERMINATIONS RELATED TO DRUGS INCLUDED IN SPECIFIED THERAPEUTIC CATEGORIES CONDUCTED BY INDEPENDENT REVIEW ENTITY.—With respect to a part D eligible individual enrolled in a prescription drug plan, in the case of a determination under this subsection that denies such individual coverage (in whole or in part) of a drug in a category specified in subsection (b)(3)(G)(i), the individual may request that the reconsideration of such determination authorized under section 1852(g)(2) (as applied by paragraph (1)) be conducted by the independent, outside entity described in paragraph (4) of section 1852(g) in accordance with the procedures for an expedited reconsideration under paragraph (3) of such section.

''(4) REQUIRED COVERAGE OF DRUGS INCLUDED IN SPECIFIED THERAPEUTIC CATEGORIES DURING DETERMINATIONS, RECONSIDERATIONS, AND APPEALS.—If a part D eligible individual enrolled in a prescription drug plan offered by a PDP sponsor requests a redetermination or reconsideration under this subsection (or an appeal under subsection (h)) with respect to an utilization management requirement or denial of coverage (in whole or in part) of a drug in a category specified in subsection (b)(3)(G)(i), such sponsor shall provide such individual with coverage of such drug as prescribed during the pendency of such redetermination, reconsideration, or appeal until 60 days after the date of receipt of a written notification of—

''(A) in the case that the individual does not request a reconsideration or appeal, the determination on such redetermination;

''(B) in the case that the individual requests a reconsideration but not an appeal, the determination on such reconsideration; or

''(C) in the case that the individual requests an appeal, the determination on such appeal or the dismissal of the appeal;

except that in no case shall such coverage end before the end of the period in which an individual may file an appeal with respect to the determination involved.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to requests for redeterminations, reconsiderations, and appeal hearings made on or after the effective date described in subsection (a)(2).

(c) REPORTING REQUIREMENTS FOR DRUGS INCLUDED IN SPECIFIED THERAPEUTIC CATEGORIES.—

(1) IN GENERAL.—Section 1860D–4(b) of the Social Security Act (42 U.S.C. 1395w–104(b)) is amended by adding at the end the following new paragraph:

''(4) REPORTING REQUIREMENTS FOR DRUGS INCLUDED IN SPECIFIED THERAPEUTIC CATEGORIES.—

''(A) REPORTS BY PDP SPONSORS.—A PDP sponsor offering a prescription drug plan shall submit to the Secretary (in a form and manner specified by the Secretary), with respect to drugs in a category of covered part D drugs specified in subsection (b)(3)(G)(i), information on the number of favorable and unfavorable de-

cisions under the plan relating to coverage determinations, redeterminations, reconsiderations, appeals, and enrollee requests for exceptions to formulary policies for such drugs.

''(B) REPORT TO CONGRESS.—The Secretary shall submit an annual report to Congress summarizing the information submitted under subparagraph (A) and shall publish each report in the Federal Register.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to prescription drug plans and MA plans for plan years beginning on or after the effective date described in subsection (a)(2).

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