

Amendment to Rules Committee Print 116-41
Offered by Mr. Lipinski of Illinois

Page 3, line 6, insert “Life-sustaining Prescription and” after “Lower Prices For”.

Page 3, line 11, insert “Life-sustaining Prescription and” after “Lower Prices For”.

Page 9, after line 15, insert the following:

- “(5) LIFE-SUSTAINING PRESCRIPTION DRUG.—The term “life-sustaining prescription drug” means a drug that is—
- (A) approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262);
 - (B) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and
 - (C) life-sustaining (as such term is defined in regulation pursuant to section 506C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c)).

Page 9, after line 21, insert the following:

“(1)(A) with respect to an initial price applicability year beginning with 2023, life-sustaining prescription drugs;”

Page 9, line 22, strike “(1)(A)” and insert “(2)(A)” before “with respect”.

Page 11, line 23, insert “all life-sustaining prescription drugs, and” after “price applicability period,”.

Page 12, line 12, insert “life-sustaining prescription” after “each”.

Page 12, line 15, insert “; and each drug that is not a life-sustaining prescription drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a ‘selected drug’ with respect to such year and” after “year”.

Page 13, line 5, insert “a life-sustaining prescription drug; or” after “applicability year,”.