Explanation of Changes Reflected in the Chairman's
Amendment in the Nature of a Substitute to
H.R. 3, *the "Lower Drug Costs Now of 2019''*
October 22, 2019

The Chairman's amendment in the nature of a substitute includes the following changes to H.R. 3 as introduced (page and line references are to H.R. 3 as introduced):

1. Page 2, Line 2: Insert after Sec. 301. Medicare part D benefit redesign the following:

   Sec. 302. Allowing certain enrollees of prescription drugs plans and MA–PD plans under Medicare program to spread out cost-sharing under certain circumstances.
   Sec. 303. Establishment of pharmacy quality measures under Medicare part D.

   TITLE IV—PRESCRIPTION DRUG POLICIES FOR LOW-INCOME INDIVIDUALS
   Sec. 401. Adjustments to Medicare part D cost-sharing reductions for low-income individuals.
   Sec. 402. Dissemination to Medicare part D subsidy eligible individuals of information comparing premiums of certain prescription drug plans.
   Sec. 403. Providing for intelligent assignment of certain subsidy eligible individuals auto-enrolled under Medicare prescription drug plans and MA–PD plans.
   Sec. 404. Expanding eligibility for low-income subsidies under part D of the Medicare program.
   Sec. 405. Automatic eligibility of certain low-income territorial residents for premium and cost-sharing subsidies under the Medicare program; Sunset of enhanced allotment program.
   Sec. 406. Automatic qualification of certain Medicaid beneficiaries for premium and cost-sharing subsidies under part D of the Medicare program.
   Sec. 407. Eliminating the resource requirement with respect to subsidy eligible individuals under part D of the Medicare program.
   Sec. 408. Providing for certain rules regarding the treatment of eligible retirement plans in determining the eligibility of individuals for premium
   and cost-sharing subsidies under part D of the Medicare
   program.

   TITLE V—DRUG PRICE TRANSPARENCY
   Sec. 501. Drug price transparency.

2. Page 5, Line 3: Strike ", and individual who is".

3. Page 5, Line 4: Insert, "(A) in the case such drug is furnished or dispensed to the individual at a pharmacy or by a mail order service—".

4. Page 5, Line 4: Strike "(A)"; insert "(i) an individual who is"; and move the margin of each such redesignated item 2 ems to the right.

5. Page 5, Line 7: Insert “and” after “drug;”.

6. Page 5, Line 8: Strike “(B)”; insert “(ii) an individual who is”; and move the margin of each such redesignated item 2 ems to the right.

7. Page 5, Line 14: Strike “;” and insert “as so furnished or dispensed; and”.

8. Page 5, Line 15: Strike “(C)” and insert “(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier—”.

9. Page 5, Line 15: Insert “(i) an individual who is” and move the margin of each such redesignated item 2 ems to the right.

10. Page 5, Line 17: Insert after title, “if such selected drug is covered under the respective part; and”.

11. Page 5, Line 17: Insert “(ii) an individual who is enrolled under a group health plan or health insurance coverage offered in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act) with respect to which there is in effect an agreement with the Secretary under section 1197 with respect to such selected drug as so furnished or administered.”.

12. Page 6, Line 6: Strike “any dosage form and strength of”.

13. Page 6, Lines 8-9: Strike “subparagraph (C)) for” and insert “paragraph (4)) of”.

14. Page 6, Line 10: Insert after drug “(calculated across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type)”.

15. Page 7, Line 10: Strike “(C)” and insert “(4)” and move the margin of each such redesignated item 2 ems to the right.

16. Page 3, Line 21: Insert after (1) “(A) with respect to an initial price applicability year during the period beginning with 2023 and ending with 2027,”.

17. Page 7, Line 24: Insert after year “during such period”.

18. Page 8, Line 2: Strike “and”.

19. Page 8, Line 3: Insert “(B) with respect to an initial price applicability year during the period beginning with 2028 and ending with 2032, at least 30 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period, the maximum

number (if such number is less than 30) of such negotiation-eligible drugs for the year) with respect to such year; and (C) with respect to an initial price applicability year beginning after 2032, at least 35 negotiation-eligible drugs described in subparagraphs (A) and (B), but not subparagraph (C), of subsection (d)(1) (or, with respect to an initial price applicability year during such period, the maximum number (if such number is less than 35) of such negotiation-eligible drugs for the year) with respect to such year;".

20. Page 8, Line 5: Strike "." and insert "; and".

21. Page 8, Line 5: Insert "(3) all new-entrant negotiation-eligible drugs (as defined in subsection (g)(1)) with respect to such year.".

22. Page 9, Line 3: Insert after projected "across different dosage forms and strengths of the drugs and not based on the specific formulation or package size or package type of the drugs,".

23. Page 9, Lines 13-14: Strike "the drug is no longer a qualifying single source drug"; insert "two or more drug products—"; and insert "(1) are approved or licensed (as applicable)—(A) under section 505(j) of the Federal Food, Drug, and Cosmetic Act using such drug as the listed drug; or (B) under section 351(k) of the Public Health Service Act using such drug as the reference product; and (2) continue to be marketed."

24. Page 10, Line 7: Insert after the United States "(including the 50 States, the District of Columbia, and the territories of the United States)".

25. Page 10, Lines 18-19: Strike "strengths and dosage forms and routes of administration" and insert "dosage forms and strengths of the drug and not based on the specific formulation or package size or package type".

26. Page 12, Line 7: Insert after 351 ", including any insulin product that has been deemed to be licensed under section 351(a) of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and continues to be marketed pursuant to such licensure".

27. Page 12, Line 8: Strike "(B)" each time it occurs.

28. Page 12, Line 18: Strike "of" after price and insert "for"; insert "a" before drug".

29. Page 12, Line 21: Strike "drugs" and insert "drug".

30. Page 12, Line 24: Strike "drugs" and insert "a drug".

31. Page 12, Line 24: Insert after drug, "(g) New-entrant Negotiation-eligible Drugs.—"(1) IN GENERAL.—For purposes of this part, the term 'new-entrant negotiation-eligible drug' means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug—(A) that is first approved

or licensed, as described in paragraph (1), (2), or (3) of subsection (e), as applicable, during the year preceding such selected drug publication date; and (B) that the Secretary determines under paragraph (2) is likely to be included as a negotiation-eligible drug with respect to the subsequent selected drug publication date. (2) DETERMINATION.—In the case of a qualifying single source drug that meets the criteria described in subparagraph (A) of paragraph (1), with respect to an initial price applicability year, if the wholesale acquisition cost at which such drug is first marketed in the United States is equal to or greater than the median household income (as determined according to the most recent data collected by the United States Census Bureau), the Secretary shall determine before the selected drug publication date with respect to the initial price applicability year, if the drug is likely to be included as a negotiation-eligible drug with respect to the subsequent selected drug publication date, based on the projected spending under title XVIII or in the United States on such drug. For purposes of this paragraph the term 'United States' includes the 50 States, the District of Columbia, and the territories of the United States."

32. Page 13, Line 14: Strike "the" and insert "such".

33. Page 13, Line 16: Insert after individuals "who with respect to such drug are".

34. Page 13, Line 17: Strike "or (B)".

35. Page 13, Line 18: Insert after 1191(c)(1) "and are"; insert after furnished "or dispensed".

36. Page 13, Line 23: Insert "who with respect to such drug are"

37. Page 13, Line 24: Strike "(C)" and insert "(B)"; insert after section "and are furnished or".

38. Page 14, Line 6: Strike "the" and insert "such".

39. Page 14, Line 10: Strike "the" and insert "such".

40. Page 14, Line 12: Insert after individuals "who with respect to such drug are".

41. Page 14, Line 13: Strike "or (B)".

42. Page 14, Line 14: Insert after 1191(c)(1) "and are"; insert after furnished "or dispensed".

43. Page 14, Line 20: Insert "who with respect to such drug are"

44. Page 14, Line 21: Strike "(C)" and insert "(B)"; insert after section "and are furnished or".

45. Page 15, Line 2: Insert ", who with respect to such drug are"

46. Page 15, Line 3: Strike "or (B)".

47. Page 15, Line 4: Strike “the” and insert “a”.

48. Page 15, Line 7: Strike “(c)” and insert “(d)”.

49. Page 15, Line 19: Strike “the” and insert “such”.

50. Page 15, Line 20: Strike “the” and insert “such”.

51. Page 15, Line 22: Strike “of” and insert “for”.

52. Page 16, Line 22: Insert after for “a unit of”.

53. Page 16, Line 22: Insert after for “a unit of”.

54. Page 17, Lines 2-5: Strike after the amount equal to through such drug.

55. Page 17, Line 5: Insert “product of—“(A) the difference between such amount described in paragraph (2)(A) for a unit of such drug and such amount described in paragraph (2)(B) for a unit of such drug; and (B) the number of units of such drug sold in the United States, including the 50 States, the District of Columbia, and the territories of the United States, during the period described in paragraph (2)(B).”

56. Page 17, Line 12: Insert after price “(as defined in section 1927(k)(1))”.

57. Page 22, Lines 2-3: Strike “any dosage form and strength of a unit for the” and insert “a unit of such”

58. Page 22, Line 3: Insert after as computed “(across different dosage forms and strengths of the drug and not based on the specific formulation or package size or package type of the drug)”.

59. Page 22, Line 9: Strike “for” and insert “of”.

60. Page 23, Line 3: Insert after price “((as defined in section 1927(k)(1))”.

61. Page 25, Line 6: Strike “patent” and insert “patents”.

62. Page 25, Line 23: Insert after products “, taking into consideration the effects of such products on specific populations, such as individuals with disabilities, the elderly, terminally ill, children, and other patient populations. In considering information described in subparagraph (C), the Secretary shall not use evidence or findings from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill. Nothing in the previous

sentence shall affect the application or consideration of an AIM price for a selected drug".

63. Page 27, Line 10: Strike "May" and insert "April".

64. Page 27, Line 12: Insert after price "for such drug".

65. Page 29, Line 6: Insert ", who with respect to such drug are".

66. Page 29, Line 7: Strike "or (B)".

67. Page 29, Line 18: Strike "suppliers)" and insert "suppliers and agreements under section 1197 with group health plans and health insurance issuers of health insurance coverage offered in the individual or group market)".

68. Page 29 line 21: Insert after individuals "(who with respect to such drug are".

69. Page 29, Lines 22-24: Strike beginning with (C) through title and insert "(V) of section 1191(c)(1))".

70. Page 30, Line 3: Insert after (as applicable) "with respect to such individuals".

71. Page 30, Line 5: Insert after part "plan, or coverage",

72. Page 31, Line 25: Strike "that are" and insert "and".

73. Page 32, Lines 1-2: Strike "dosage or strength, packaging, or form of administration" and insert "or package size or package type of the drug."

74. Page 32, Line 8: Insert after part ", as applicable,"

75. Page 32, Line 13: Strike "and".

76. Page 32, Line 20: Insert "and" and insert "(iii) fair price eligible individuals who are entitled to benefits under part A of title XVIII or enrolled under part B of such title.".

77. Page 34, Line 12: Strike "shall" and insert "may".

78. Page 35, Lines 19-25: Strike.

79. Page 36, Line 3: Strike "In General—Under" and insert "Agreement to Participate Under Program.—(1) In General.—Subject to paragraph (2), under".

80. Page 36, Line 8: Strike "except in the case that" and insert "with respect to a price applicability period and a selected drug with respect to such period—(A) with respect to

such selected drug furnished or dispensed at a pharmacy or by mail order service if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or dispensed; and (B) with respect to such selected drug furnished or administered by a hospital, physician, or other provider of services or supplier if coverage is provided under such plan or coverage during such period for such selected drug as so furnished or administered. (2) OPTING OUT OF AGREEMENT.—The Secretary shall not be treated as having in effect an agreement under the program under this part with a group health plan or health insurance issuer offering health insurance coverage with respect to a price applicability period and a selected drug with respect to such period if."

81. Page 36, Line 9: Strike "not to participate under the program".

82. Page 36, Lines 10-11: Strike "with respect to a price applicability period and a selected drug" and insert "not to participate under the program".

83. Page 36, Lines 12-13: Strike "with respect to which coverage is provided under such plan or coverage" and insert "and drug".

84. Page 37, Line 6: Insert after individuals, "with respect to such drug is".

85. Page 37, Line 7: Strike "or (B)" and insert "or who is" after 1191(c)(1).

86. Page 37, Line 8: Insert after furnished "or dispensed".

87. Page 37, Line 11: Insert after individuals, "with respect to such drug is".

88. Page 37, Line 11: Strike "(C)" and insert "(B)".

89. Page 37, Line 12: Insert after section "and is furnished or"; and insert after drug "by such hospital, physician, or provider or supplier".

90. Page 37, Line 16: Insert after available "for such year".

91. Page 39, Line 23- Page 40, Line 1: Strike "Medicare Prescription Drug Program—(A) Except to" and insert "(A) APPLICATION TO PAYMENTS UNDER PART B.—Section 1847A(b)(1)(B) of the Social Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is amended by inserting "or in the case of such a drug or biological that is a selected drug (as defined in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), 106 percent of the maximum fair price (as defined in section 1191(c)(2) applicable for such drug and a plan year during such period". (B) EXCEPTION TO PART D".

92. Page 40, Line 7: Strike "(B)" and insert "(C)".

93. Page 40, Line 8: Strike "Price—Section" and insert "Price Under Part D.—Section".

94. Page 40, Line 22: Strike “price” and insert “prices used for payment (as”; strike “subsection” and insert “subsection)”.

95. Page 41, Line 1: Strike “(C)” and insert “(D)”.

96. Page 46, Line 21-22: Strike “to the plans offered by such plan” and insert “, as applicable—“(A) if coverage of such selected drug is provided under such plan if the drug is furnished or dispensed at a pharmacy or by a mail order service, to the”.

97. Page 46, Line 23: Strike “plans” and insert “plan”.

98. Page 47, Line 4: Insert “during such period; and” “(B) if coverage of such selected drug is provided under such plan if the drug is furnished or administered by a hospital, physician, or other provider of services or supplier, to the plan, to the individuals enrolled under such plan, and to hospitals, physicians, and other providers of services and suppliers during such period, with respect to such drug in the same manner as such provisions apply to the Secretary, to individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, and to hospitals, physicians, and other providers and suppliers participating under title XVIII during such period.”

99. Page 47, Line 7: Insert after substituting “an amount not more than”.

100. Page 47, Line 8: Insert after part “E of title XI”.

101. Page 47, Lines 9-10: Strike “contracted rate under such plan for such selected drug” and insert “drug price upon which the cost-sharing would have otherwise applied”.

102. Page 47, Line 12: Insert after part “(E)”.

103. Page 47, Line 24: Insert after made. “(ii) APPLICATION TO RETIREE AND CERTAIN SMALL GROUP HEALTH PLANS.—Section 9831(a)(2) of the Internal Revenue Code of 1986 is amended by inserting “other than with respect to section 9816,” before “any group health plan”.

104. Page 48, Line 1: Strike “(ii)” insert “(iii)”.

105. Page 50, Line 7: Strike “Percentage.—The” and insert “Percentage.—For purposes of this section, the”.

106. Page 50, Lines 21-23: Strike Definitions through 1191; insert “Selected Drug.—For purposes of this section—“(1) IN GENERAL.—The term ‘selected drug’ means any selected drug (within the meaning of section 1192”.

107. Page 50, Line 24: Strike “and the term ‘selected drug’” and insert “) which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing. (2) UNITED STATES.—The term ‘United States’”.

108. Page 50, Lines 24-25: Strike “in section 1192 of such Act” and insert “by section 4612(a)(4).”

109. Page 50, Line 1: Strike “(e)” and insert: “(3) COORDINATION WITH RULES FOR POSSESSIONS OF THE UNITED STATES.—Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section. (e) Other Definitions.—For purposes of this section, the terms ‘selected drug publication date’ and ‘maximum fair price’ have the meaning given such terms in section 1191 of the Social Security Act. (f)”.

110. Page 53, Line 2: Insert after of “units of the”; strike “units” and insert “and payment code”

111. Page 54, Line 22: Strike “as of the first quarter” and insert “for the 12 month period ending with June”.

112. Page 55, Line 5: Strike “as of the first quarter” and insert “for the 12 month period ending with June”.

113. Page 55, Line 11: Strike “(B)”.

114. Page 55, Line 16: Strike “subparagraph (B)” and insert “subparagraphs (B) and (G)”

115. Page 55, Lines 17-18: Strike “billing units, as described in section 1847A(b)(6)(B),” and insert “units of the billing and payment code”.

116. Page 56, Lines 9-10: Strike “units” and insert before billing “units of the”; insert “and payment code” after billing; insert after for “each”; strike “drugs” and insert “drug”.

117. Page 58, Line 9: Insert ““(G) COUNTING UNITS.—“(i) CUT-OFF PERIOD TO COUNT UNITS.—For purposes of subparagraph (A)(i), subject to clause (ii), to count the total number of billing units for a part B rebatable drug for a quarter, the Secretary may use a cut-off period in order to exclude from such total number of billing units for such quarter claims for services furnished during such quarter that were not processed at an appropriate time prior to the end of the cut-off period. (ii) COUNTING UNITS FOR CLAIMS PROCESSED AFTER CUT-OFF PERIOD.—If the Secretary uses a cut-off period pursuant to clause (i), in the case of units of a part B rebatable drug furnished during a quarter but pursuant to application of such cut-off period excluded for purposes of subparagraph (A)(i) from the total number of billing units for the drug for such quarter, the Secretary shall count such units of such drug so furnished in the total number of

billing units for such drug for a subsequent quarter, as the Secretary determines appropriate."

118. Page 58, Line 14: insert after approved "or licensed".

119. Page 59, Line 4: Strike "NEW" and insert "SUBSEQUENTLY APPROVED".

120. Page 59, Line 5: Insert after approved "or licensed".

121. Page 59, Line 7: Strike "clause (i) of".

122. Page 59, Line 13: Insert "amount" after rebate.

123. Page 59, Line 15: Strike "appears on the drug" and insert "is described as currently in shortage on the".

124. Page 59, Line 16: Strike "506(e)" and insert "506E".

125. Page 59, Lines 22-23: Strike ", for each applicable year beginning after the" and insert "for a"

126. Page 59, Line 24: Strike "1191(b)(2)" and insert "1191(b)(2)) and is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period".

127. Page 60, Page 13-14: Strike "for which a rebate is payable under this subsection--," and insert ", if the payment amount for a quarter exceeds the inflation adjusted payment for such quarter."

128. Page 62, Line 8: Strike "billing" and insert after of "the billing and payment code of the".

129. Page 63, Line 2: Strike "1833(a)" and insert "1833".

130. Page 63, Line 2: Insert after Social Security Act "(42 U.S.C. 1395l)".

131. Page 63, Line 3: Insert after (1) "in subsection (a)—(A)"

132. Page 63, Line 4: Strike "(A)" and insert "(i)".

133. Page 63, Line 7: Strike "(B)" and insert "(ii)".

134. Page 63, Line 9: Strike "(C)" and insert "(iii)".

135. Page 63, Lines 12-13: strike “a rebate is payable under such section” and insert “the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section for such quarter exceeds the inflation adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter”.

136. Page 63, Line 19: Strike “and”.

137. Page 63, Line 20: Strike “(2)” and insert “(B)”.

138. Page 63, Line 22: Insert after (1)(DD) “, subsections (i)(9) and (t)(3)(H),”.

139. Page 63, line 24: Strike “appropriate” and insert “appropriate, and notwithstanding any other provision of law, may do so by program instruction or otherwise. (2) in subsection (i), by adding at the end the following new paragraph: (9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of section 1833(a), and the flush left matter following paragraph (9) of section 1833(a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of sections 1834(x)(5) and 1833(a) apply under such sections; and (3) in subsection (t)(3), by adding at the end the following new subparagraph: (H) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1834(x)) furnished on or after July 1, 2021, under the system under this subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1834(x)(5), paragraph (1)(DD) of section 1833(a), and the flush left matter following paragraph (9) of section 1833(a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of sections 1834(x)(5) and 1833(a) apply under such sections.”.

140. Page 64, Line 6: Strike “Part” and insert “(a) In General.—Part”

141. Page 64, Line 12: Strike “General--Subject” and insert “General.—(1) IN GENERAL.—Subject”.

142. Page 64, Line 14: Insert after drug “(as defined in subsection (h)(1))”; insert after manufacturer, “(as defined in section 1927(k)(5))”.

143. Page 64, Line 17: Strike “For” and insert “(2) AUTHORIZING COVERAGE FOR DRUGS NOT COVERED UNDER AGREEMENTS.—Paragraph (1) shall not apply to the dispensing of a covered part D drug if—“(A) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or (B) the Secretary determines that in the period beginning on January 1, 2022, and ending on December 31, 2022, there were extenuating circumstances. (3) APPLICABLE YEAR.—For”.

144. Page 64, Line 23: Strike “applies” and insert “shall apply”.

145. Page 65, Line 3: Strike after for “the” and insert “each”.

146. Page 65, Line 4: Strike “reports” and insert “shall report”.

147. Page 65, Line 6: Insert after total “number of”.

148. Page 65, Line 7: Strike “(g)(2)) dispensed” and insert “(h)(2))”.

149. Page 66, Line 3: Strike “provides” and insert “shall provide”.

150. Page 66, Line 22: Strike “60” and insert “30”.

151. Page 67, Line 7-10: Strike after termination and insert “be effective, with respect to a plan year—(I) if the termination occurs before January 30 of the plan year, as of the day after the end of the plan year; and (II) if the termination occurs on or after January 30 of the plan year, as of the day after the end of the succeeding plan year.”

152. Page 67, Line 18: Strike after manufacturer “which” and insert “that”.

153. Page 67, Line 21: Insert after year, “the Secretary may not enter into”.

154. Page 67, Lines 20-21: Strike “may not be entered into”.

155. Pages 67-68, Lines 24-2: Strike.

156. Page 68, Line 8: Strike “(3)” and insert “(5)”.

157. Page 68, Line 10: Strike “average”.

158. Page 68, Line 11: Strike “weighted by, and dispensed for,” and insert “of”.

159. Page 68, Line 15: Strike “average” and insert “annual”.

160. Page 68, Line 16: Strike “defined in subsection (g))” and insert “determined in paragraph (2))”.

161. Page 68, Line 18: Strike “during” and insert “for”.

162. Page 68, Line 21: Strike “(2)” and insert “(3)”.

163. Page 68, Line 23-24: Strike “during the year” and insert “for the year”.

164. Page 68, Line 24: Insert “(2) DETERMINATION OF ANNUAL MANUFACTURER PRICE.—The annual manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable year, is the sum of the products of—(A) the average manufacturer price (as defined in subsection (h)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of such year; and (B) the ratio of—(i) the total number of units of such dosage form and strength dispensed during each such calendar quarter of such year; to (ii) the total number of units of such dosage form and strength dispensed during such year.”

165. Page 69, Line 1: Strike “(2)” and insert “(3)”.

166. Page 69, Line 6: Strike “(3)” and insert “(5)”.

167. Page 69, Line 7: Strike “average” and insert “benchmark year”; strike “paid” and insert “determined under paragraph (4)”.

168. Page 69, Lines 9-10: Strike “in the payment amount benchmark year (as defined in subsection (g)(3))” and insert “and an applicable year”.

169. Page 69, lines 12-13: Strike “rebate period” and insert “applicable year”; strike “(g)(5)” and insert “(h)(5)”.

170. Page 69, Line 15: Strike “(g)(4)” and insert “(h)(4)”.

171. Page 69, Line 15: Insert “(4) DETERMINATION OF BENCHMARK YEAR MANUFACTURER PRICE.—The benchmark year manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable year, is the sum of the products of—(A) the average manufacturer price (as defined in subsection (h)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each calendar quarter of the payment amount benchmark year (as defined in subsection (h)(3)); and (B) the ratio of—(i) the total number of units of such dosage form and strength dispensed during such calendar quarter of the payment amount benchmark year; to (ii) the total number of units of such dosage form and strength dispensed during the payment amount benchmark year.”

172. Page 69, Line 16: Strike “(3)” and insert “(5)”.

173. Page 69, Lines 19-20: Insert after approved “or licensed”.

174. Page 69, Line 21: Strike “subparagraph” and insert “subparagraphs”; after (A) and insert “and (B)”.

175. Page 69, Line 22: Strike “(2)” and insert “(4)”.

176. Page 69, Line 24: Strike “(g)(3)” and insert “(h)(3)”; and insert after first “calendar”.

177. Page 70, Line 1: Insert after marketed “by any manufacturer”.

178. Page 70, Line 2: Strike “(2)” and insert “(3)”.

179. Page 70, Line 4: Strike “(g)(4)” and insert “(h)(4)”.

180. Page 70, Lines 12-13: Strike “in the case of a shortage of such drug” and insert “that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act or in the case of”.

181. Page 70, Lines 19-20: Strike “single source drug or an innovator multiple source” and insert “part D rebatable”.

182. Page 71, Lines 1-2: Strike “single source drug or an innovator multiple source” and insert “part D rebatable”.

183. Page 71, Lines 16-17: Strike “, for each applicable year beginning after the” and insert “for a”.

184. Page 71, Line 18: Strike “1191(b)(2)” and insert “1191(b)(2)) and is determined (pursuant to such section 1192(c)) to no longer be a selected drug, for each applicable year beginning after the price applicability period”.

185. Page 71, Line 19: Strike “subparagraph” and insert “subparagraphs” and after (A) insert “and (B)”.

186. Page 71, Line 20: Strike “(2)” and insert “(4)”.

187. Page 71, Line 22: Strike “(g)(3)” and insert “(h)(3)”.

188. Page 71, Line 25: Strike “(2)” and insert “(3)”.

189. Page 72, Line 2: Strike “(g)(4)” and insert “(h)(4)”.

190. Page 72, Line 11: Insert “(e) Information.—For purposes of carrying out this section, the Secretary shall use information submitted by manufacturers under section 1927(b)(3).”

191. Page 72, Line 12: Strike “(e)” and insert “(f)”.

192. Page 73, Line 1: Strike “(f)” and insert “(g)”.

193. Page 73, Line 9: Strike “(f)” and insert “(g)”.

194. Page 73, Line 16: Insert after average “annual”.

195. Page 73, Lines 17-18: Strike “a prescription drug plan under this part or MA–PD plan under part C” and insert “this part”.

196. Page 73, Line 20: Strike “are” and insert “is”.

197. Page 74, Line 8: Strike “as of” and insert “for the 12-month period beginning with”.

198. Page 74, Line 15: Strike “as of” and insert “for the 12-month period beginning with”.

199. Page 74, Lines 23-25: Strike “enrolled under a prescription drug plan” and strike “or an MAPD plan under part C”.

200. Page 75, Lines 8-9: Strike “rebate period” and insert “applicable year” each time it appears.

201. Page 75, Line 16: Strike “for an applicable year”.

202. Pages 75-76, Lines 19-6: Strike after 1927.

203. Page 76, Line 6: Insert “(b) Conforming Amendment to Part B ASP calculation.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)), as amended by section 201(c), is further amended by striking “section 1927 or section 1834(x)” and inserting “section 1927, section 1834(x), or section 1860D–14B”.

204. Page 79, Lines 1-2: Strike “(ii)—(I)”

205. Page 79, Lines 3-10: Strike “and (II) by adding at the end the following new sentence: “The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2021 for purposes of section 1860D14(a)(1)(D)(iii).”;”.”

206. Page 89, Line 4: Strike “IMPLEMENTATION.—THE”; insert “IMPLEMENTATION.—Notwithstanding any other provision of law, the”.

207. Page 89, Line 21: Strike “commensurate with”; insert “equal to”.

208. Page 91, Line 9: Strike “505(b)”; insert 505(c)”.

209. Page 95, Lines 8-9: Strike “(as in effect on the date of enactment of section 1860D-14A)”; insert “(or any successor regulation)”.

210. Page 96, Line 18: Strike “an”; insert “and”.

211. Page 99, Lines 9-13: Strike “(E)—(I) by inserting “for a year preceding 2022,” after “subsection (c)”; and (II)”; insert “(E),”.

212. Page 100, Lines 17-19: Strike “Paragraph (1) of section 1860D43(a)” and “(a)) is amended to read as follows:”; insert “Section 1860D–43” and “) is amended—
(A) in subsection (a)—
(i) by striking paragraph (1) and inserting the following:”.

213. Page 101, Line 3: Strike “.”; insert “;

(ii) by striking paragraph (2) and inserting the following:

“(2) have entered into and have in effect—

“(A) for 2011 through 2021, an agreement described in subsection (b) of section 1860D–14A with the Secretary; and

“(B) for 2022 and each subsequent year, an agreement described in subsection (b) of section 1860D–14C with the Secretary; and”; and

(iii) by striking paragraph (3) and inserting the following:

“(3) have entered into and have in effect, under terms and conditions specified by the Secretary—

“(A) for 2011 through 2021, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1860D–14A; and

“(B) for 2022 and each subsequent year, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1860D–14C.”; and

(B) by striking subsection (b) and inserting the following:

“(b) Effective Date.—Paragraphs (1)(A), (2)(A), and (3)(A) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2022, and paragraphs (1)(B), (2)(B), and (3)(B) of such subsection shall apply to covered part D drugs dispensed under this part on or after January 1, 2022.”.”.

214. Page 101, Line 6: Insert “SEC. 302. ALLOWING CERTAIN ENROLLEES OF PRESCRIPTION DRUGS PLANS AND MA–PD PLANS UNDER MEDICARE PROGRAM TO SPREAD OUT COST-SHARING UNDER CERTAIN CIRCUMSTANCES.

Section 1860D–2(b)(2) of the Social Security Act (42 U.S.C. 1395w–102(b)(2)), as

amended by section 301, is further amended—

(1) in subparagraph (A), by striking "Subject to subparagraphs (C) and (D)" and inserting "Subject to subparagraphs (C), (D), and (E)"; and

(2) by adding at the end the following new subparagraph:

"(E) ENROLLEE OPTION REGARDING SPREADING COST-SHARING.—The Secretary shall establish by regulation a process under which, with respect to plan year 2022 and subsequent plan years, a prescription drug plan or an MA–PD plan shall, in the case of a part D eligible individual enrolled with such plan for such plan year who is not a subsidy eligible individual (as defined in section 1860D–14(a)(3)) and with respect to whom the plan projects that the dispensing of the first fill of a covered part D drug to such individual will result in the individual incurring costs that are equal to or above the annual out-of-pocket threshold specified in paragraph (4)(B) for such plan year, provide such individual with the option to make the coinsurance payment required under subparagraph (A) (for the portion of such costs that are not above such annual out-of-pocket threshold) in the form of periodic installments over the remainder of such plan year.".

SEC. 303. ESTABLISHMENT OF PHARMACY QUALITY MEASURES UNDER MEDICARE PART D.

Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) by redesignating the paragraph (6), as added by section 50354 of division E of the Bipartisan Budget Act of 2018 (Public Law 115–123), as paragraph (7); and

(2) by adding at the end the following new paragraph:

"(8) APPLICATION OF PHARMACY QUALITY MEASURES.—

"(A) IN GENERAL.—A PDP sponsor that implements incentive payments to a pharmacy or price concessions paid by a pharmacy based on quality measures shall use measures established or approved by the Secretary under subparagraph (B) with respect to payment for covered part D drugs dispensed by such pharmacy.

"(B) STANDARD PHARMACY QUALITY MEASURES.—The Secretary shall establish or approve standard quality measures from a consensus and evidence-based organization for payments described in subparagraph (A). Such measures shall focus on patient health outcomes and be based on proven criteria measuring pharmacy performance.

"(C) EFFECTIVE DATE.—The requirement under subparagraph (A) shall take effect for plan years beginning on or after January 1, 2021, or such earlier date specified by the Secretary if the Secretary determines there are sufficient measures established or approved under subparagraph (B) to meet the requirement under subparagraph (A).".

TITLE IV—PRESCRIPTION DRUG POLICIES FOR LOW-INCOME INDIVIDUALS

SEC. 401. ADJUSTMENTS TO MEDICARE PART D COST-SHARING REDUCTIONS FOR LOW-INCOME INDIVIDUALS.

Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by section 301(d), is further amended—

(1) in paragraph (1)—

(A) in subparagraph (D)—

(i) in clause (ii)—

(I) by striking "that does not exceed $1 for" and all that follows through the period at the end and inserting "that does not exceed—

"(I) for plan years before plan year 2021—

"(aa) for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1927(k)(7)(A)(i)), $1 or, if less, the copayment amount applicable to an individual under clause (iii); and

"(bb) for any other drug, $3 or, if less, the copayment amount applicable to an individual under clause (iii); and"; and

(II) by adding at the end the following new subclauses:

"(II) for plan year 2021—

"(aa) for a generic drug, $0; and

"(bb) for any other drug, the dollar amount applied under this clause (after application of paragraph (4)(A)) for plan year 2020 for a drug described in subclause (I)(bb); and

"(III) for a subsequent year, the dollar amount applied under this clause for the previous year for the drug, increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year."; and

(ii) in clause (iii)—

(I) by striking "does not exceed the copayment amount specified under" and inserting "does not exceed—

"(I) for plan years beginning before plan year 2021, the copayment amount specified under";

(II) by striking the period at the end and inserting "; and"; and

(III) by adding at the end the following new subclause:

"(II) for plan year 2021 and each subsequent plan year, the copayment amount applied under clause (ii) for the drug and year involved."; and

(B) by adding at the end the following new subparagraph:

"(F) ROUNDING.—Any amount established under clause (ii) of subparagraph (D), including as applied under clause (iii) of such subparagraph or paragraph (2)(D), that is based on an increase of $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.";

(2) in paragraph (2)—

(A) in subparagraph (D)—

(i) by striking "of coinsurance of" and inserting "of—

"(I) for plan years before plan year 2021, coinsurance of";

(ii) by striking the period at the end and inserting "; and"; and

(iii) by adding at the end the following new subclause:

"(II) for plan year 2021 and each subsequent plan year, a copayment amount that does not exceed the copayment amount applied under paragraph (1)(D)(ii) for the drug and year involved."; and

(B) in subparagraph (E)—

(i) by striking "subsection (c), the substitution for" and inserting "subsection (c)—

"(i) for plan years before plan year 2021, the substitution for";

(ii) by striking the period at the end and inserting "; and"; and

(iii) by adding at the end the following new clause:

"(ii) for plan year 2021, the elimination of any cost-sharing imposed under section 1860D–2(b)(4)(A).."; and

(3) in paragraph (4)(A)(ii), by inserting "(before 2021)" after "subsequent year".

SEC. 402. DISSEMINATION TO MEDICARE PART D SUBSIDY ELIGIBLE INDIVIDUALS OF INFORMATION COMPARING PREMIUMS OF CERTAIN PRESCRIPTION DRUG PLANS.

Section 1860D–1(c)(3) of the Social Security Act (42 U.S.C. 1395w–101(c)(3)) is amended by adding at the end the following new subparagraph:

"(C) INFORMATION ON PREMIUMS FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

"(i) IN GENERAL.—For plan year 2022 and each subsequent plan year, the Secretary shall disseminate to each subsidy eligible individual (as defined in section 1860D–14(a)(3)) information under this paragraph comparing premiums that would apply to such individual for prescription drug coverage under LIS benchmark plans, including, in the case of an individual enrolled in a prescription drug plan under this part, information that compares the premium that would apply if such individual were to remain enrolled in such plan to premiums that would apply if the individual were to enroll in other LIS benchmark plans.

"(ii) LIS BENCHMARK PLAN.—For purposes of clause (i), the term 'LIS benchmark plan' means, with respect to an individual, a prescription drug plan under this part that is offered in the region in which the individual resides and—

"(I) that provides for a premium that is not more than the low-income benchmark premium amount (as defined in section 1860D–14(b)(2)) for such region; or

"(II) with respect to which the premium would be waived as de minimis pursuant to section 1860D–14(a)(5) for such individual.".

SEC. 403. PROVIDING FOR INTELLIGENT ASSIGNMENT OF CERTAIN SUBSIDY ELIGIBLE INDIVIDUALS AUTO-ENROLLED UNDER MEDICARE PRESCRIPTION DRUG PLANS AND MA–PD PLANS.

(a) In General.—Section 1860D–1(b)(1) of the Social Security Act (42 U.S.C. 1395w–101(b)(1)) is amended—

(1) in subparagraph (C)—

(A) by inserting after "PDP region" the following: "or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary"; and

(B) by striking "Nothing in the previous sentence" and inserting "Nothing in this subparagraph"; and

(2) in subparagraph (D)—

(A) by inserting after "PDP region" the following: "or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary"; and

(B) by striking "Nothing in the previous sentence" and inserting "Nothing in this subparagraph".

(b) Effective Date.—The amendments made by subsection (a) shall apply with respect to plan years beginning with plan year 2022.

SEC. 404. EXPANDING ELIGIBILITY FOR LOW-INCOME SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by sections 301(d) and 401, is further amended—

(1) in the subsection heading, by striking "Individuals" and all that follows through "Line" and inserting "Certain Individuals";

(2) in paragraph (1)—

(A) by striking the paragraph heading and inserting "INDIVIDUALS WITH CERTAIN LOW INCOMES"; and

(B) in the matter preceding subparagraph (A), by inserting "(or, with respect to a plan year beginning on or after January 1, 2022, 150 percent)" after "135 percent";

(3) in paragraph (2)—

(A) by striking the paragraph heading and inserting "OTHER LOW-INCOME INDIVIDUALS"; and

(B) in subparagraph (A)—

(i) by inserting "(or, with respect to a plan year beginning on or after January 1, 2022, 150 percent)" after "135 percent"; and

(ii) by inserting "(or, with respect to a plan year beginning on or after January 1, 2022, 200 percent)" after "150 percent"; and

(4) in paragraph (3)(A)(ii), by inserting "(or, with respect to a plan year beginning on or after January 1, 2022, 200 percent)" after "150 percent".

SEC. 405. AUTOMATIC ELIGIBILITY OF CERTAIN LOW-INCOME TERRITORIAL RESIDENTS FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER THE MEDICARE PROGRAM; SUNSET OF ENHANCED ALLOTMENT PROGRAM.

(a) Automatic Eligibility of Certain Low-Income Territorial Residents for Premium and Cost-Sharing Subsidies Under the Medicare Program.—

(1) IN GENERAL.—Section 1860D–14(a)(3) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)) is amended—

(A) in subparagraph (B)(v)—

(i) in subclause (I), by striking "and" at the end;

(ii) in subclause (II), by striking the period and inserting "; and"; and

(iii) by inserting after subclause (II) the following new subclause:

"(III) with respect to plan years beginning on or after January 1, 2021, shall provide that any part D eligible individual who is enrolled

for medical assistance under the State Medicaid plan of a territory (as defined in section 1935(f)) under title XIX (or a waiver of such a plan) shall be treated as a subsidy eligible individual described in paragraph (1).”; and

(B) in subparagraph (F), by adding at the end the following new sentence: “The previous sentence shall not apply with respect to eligibility determinations for premium and cost-sharing subsidies under this section made on or after January 1, 2021.”.

(2) CONFORMING AMENDMENT.—Section 1860D–31(j)(2)(D) of the Social Security Act (42 U.S.C. 1395w–141(j)(2)(D)) is amended by adding at the end the following new sentence: “The previous sentence shall not apply with respect to amounts made available to a State under this paragraph on or after January 1, 2021.”.

(b) Sunset of Enhanced Allotment Program.—

(1) IN GENERAL.—Section 1935(e) of the Social Security Act (42 U.S.C. 1396u–5(e)) is amended—

(A) in paragraph (1)(A), by inserting after “such State” the following: “before January 1, 2021”; and

(B) in paragraph (3)—

(i) in subparagraph (A), in the matter preceding clause (i), by inserting after “a year” the following: “(before 2021)”; and

(ii) in subparagraph (B)(iii), by striking “a subsequent year” and inserting “each of fiscal years 2008 through 2020”.

(2) TERRITORY DEFINED.—Section 1935 of the Social Security Act (42 U.S.C. 1396u–5) is amended by adding at the end the following new subsection:

“(f) Territory Defined.—In this section, the term ‘territory’ means Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.”.

SEC. 406. AUTOMATIC QUALIFICATION OF CERTAIN MEDICAID BENEFICIARIES FOR PREMIUM AND COST-SHARING SUBSIDIES UNDER PART D OF THE MEDICARE PROGRAM.

Clause (v) of section 1860D–14(a)(3)(B) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(B)), as amended by section 405, is further amended—

(1) in subclause (II), by striking “and” at the end;

(2) in subclause (III), by striking the period and inserting “; and”; and

(3) by inserting after subclause (III) the following new subclause:

“(IV) with respect to plan years beginning on or after January 1, 2022, shall, notwithstanding the preceding clauses of this subparagraph, provide that any part D eligible individual not described in subclause (I), (II), or (III) who is enrolled, as of the day before the date on which such individual attains the age of 65, for

medical assistance under a State plan under title XIX (or a waiver of such plan) pursuant to clause (i)(VIII) or (ii)(XX) of section 1902(a)(10)(A), and who has income below 200 percent of the poverty line applicable to a family of the size involved, shall be treated as a subsidy eligible individual described in paragraph (1) for a limited period of time, as specified by the Secretary.".

SEC. 407. ELIMINATING THE RESOURCE REQUIREMENT WITH RESPECT TO SUBSIDY ELIGIBLE INDIVIDUALS UNDER PART D OF THE MEDICARE PROGRAM.

Section 1860D–14(a)(3)(A)(iii) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(A)(iii)) is amended by inserting "in the case of a plan year beginning before January 1, 2022," before "meets".

TITLE I—DRUG PRICE TRANSPARENCY

SEC. 501. DRUG PRICE TRANSPARENCY.

Part A of title XI of the Social Security Act is amended by adding at the end the following new sections:

"SEC. 1150C. REPORTING ON DRUG PRICES.

"(a) Definitions.—In this section:

"(1) MANUFACTURER.—The term 'manufacturer' means the person—

"(A) that holds the application for a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act; or

"(B) who is responsible for setting the wholesale acquisition cost for the drug.

"(2) QUALIFYING DRUG.—The term 'qualifying drug' means any drug that is approved under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under subsection (a) or (k) of section 351 of the Public Health Service Act—

"(A) that has a wholesale acquisition cost of $100 or more, adjusted for inflation occurring after the date of enactment of this section, for a month's supply or a typical course of treatment that lasts less than a month, and is—

"(i) subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act; and

"(ii) not a preventative vaccine; and

"(B) for which, during the previous calendar year, at least 1 dollar of the total amount of sales were for individuals enrolled under the Medicare program under title XVIII or under a State Medicaid plan under title XIX or under a waiver of such plan.

"(3) WHOLESALE ACQUISITION COST.—The term 'wholesale acquisition cost' has the meaning given that term in section 1847A(c)(6)(B).

"(b) Report.—

"(1) REPORT REQUIRED.—The manufacturer of a qualifying drug shall submit a report to the Secretary if, with respect to the qualifying drug—

"(A) there is an increase in the price of the qualifying drug that results in an increase in the wholesale acquisition cost of that drug that is equal to—

"(i) 10 percent or more within a 12-month period beginning on or after January 1, 2019; or

"(ii) 25 percent or more within a 36-month period beginning on or after January 1, 2019;

"(B) the estimated price of the qualifying drug or spending per individual or per user of such drug (as estimated by the Secretary) for the applicable year (or per course of treatment in such applicable year as determined by the Secretary) is at least $26,000 beginning on or after January 1, 2021; or

"(C) there was an increase in the price of the qualifying drug that resulted in an increase in the wholesale acquisition cost of that drug that is equal to—

"(i) 10 percent or more within a 12-month period that begins and ends during the 5-year period preceding January 1, 2021; or

"(ii) 25 percent or more within a 36-month period that begins and ends during the 5-year period preceding January 1, 2021.

"(2) REPORT DEADLINE.—Each report described in paragraph (1) shall be submitted to the Secretary—

"(A) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during the period beginning on January 1, 2019, and ending on the day that is 60 days after the date of the enactment of this section, not later than 90 days after such date of enactment;

"(B) in the case of a report with respect to an increase in the price of a qualifying drug that occurs after the period described in subparagraph (A), not later than 30 days prior to the planned effective date of such price increase for such qualifying drug;

"(C) in the case of a report with respect to a qualifying drug that meets the criteria under paragraph (1)(B), not later than 30 days after such drug meets such criteria; and

"(D) in the case of a report with respect to an increase in the price of a qualifying drug that occurs during a 12-month or 36-month period described in paragraph (1)(C), not later than April 1, 2021.

"(c) Contents.—A report under subsection (b), consistent with the standard for disclosures described in section 213.3(d) of title 12, Code of Federal Regulations (as in effect on the date of enactment of this section), shall, at a minimum, include—

"(1) with respect to the qualifying drug—

"(A) the percentage by which the manufacturer will raise the wholesale

acquisition cost of the drug within the 12-month period or 36-month period as described in subsection (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or (b)(1)(C)(ii), as applicable, and the effective date of such price increase or the cost associated with a qualifying drug if such drug meets the criteria under subsection (b)(1)(B) and the effective date at which such drug meets such criteria;

"(B) an explanation for, and description of, each price increase for such drug that will occur during the 12-month period or the 36-month period described in subsection (b)(1)(A)(i), (b)(1)(A)(ii), (b)(1)(C)(i), or (b)(1)(C)(ii), as applicable;

"(C) an explanation for, and description of, the cost associated with a qualifying drug if such drug meets the criteria under subsection (b)(1)(B), as applicable;

"(D) if known and different from the manufacturer of the qualifying drug, the identity of—

"(i) the sponsor or sponsors of any investigational new drug applications under section 505(i) of the Federal Food, Drug, and Cosmetic Act for clinical investigations with respect to such drug, for which the full reports are submitted as part of the application—

"(I) for approval of the drug under section 505 of such Act; or

"(II) for licensure of the drug under section 351 of the Pubic Health Service Act; and

"(ii) the sponsor of an application for the drug approved under such section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act;

"(E) a description of the history of the manufacturer's price increases for the drug since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351 of the Public Health Service Act, or since the manufacturer acquired such approved application or license, if applicable;

"(F) the current wholesale acquisition cost of the drug;

"(G) the total expenditures of the manufacturer on—

"(i) materials and manufacturing for such drug;

"(ii) acquiring patents and licensing for such drug; and

"(iii) purchasing or acquiring such drug from another manufacturer, if applicable;

"(H) the percentage of total expenditures of the manufacturer on research and development for such drug that was derived from Federal funds;

"(I) the total expenditures of the manufacturer on research and development for such drug that is necessary to demonstrate that it meets applicable statutory standards for approval under section 505 of the Federal Food, Drug, and

Cosmetic Act or licensure under section 351 of the Public Health Service Act, as applicable;

"(J) the total expenditures of the manufacturer on pursuing new or expanded indications or dosage changes for such drug under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act;

"(K) the total expenditures of the manufacturer on carrying out postmarket requirements related to such drug, including under section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act;

"(L) the total revenue and the net profit generated from the qualifying drug for each calendar year since the approval of the application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act or the issuance of the license for the drug under section 351 of the Public Health Service Act, or since the manufacturer acquired such approved application or license; and

"(M) the total costs associated with marketing and advertising for the qualifying drug;

"(2) with respect to the manufacturer—

"(A) the total revenue and the net profit of the manufacturer for each of the 12-month period described in subsection (b)(1)(A)(i) or (b)(1)(C)(i) or the 36-month period described in subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as applicable;

"(B) all stock-based performance metrics used by the manufacturer to determine executive compensation for each of the 12-month periods described in subsection (b)(1)(A)(i) or (b)(1)(C)(i) or the 36-month periods described in subsection (b)(1)(A)(ii) or (b)(1)(C)(ii), as applicable; and

"(C) any additional information the manufacturer chooses to provide related to drug pricing decisions, such as total expenditures on—

"(i) drug research and development; or

"(ii) clinical trials, including on drugs that failed to receive approval by the Food and Drug Administration; and

"(3) such other related information as the Secretary considers appropriate and as specified by the Secretary.

"(d) Information Provided.—The manufacturer of a qualifying drug that is required to submit a report under subsection (b), shall ensure that such report and any explanation for, and description of, each price increase described in subsection (c)(1) shall be truthful, not misleading, and accurate.

"(e) Civil Monetary Penalty.—Any manufacturer of a qualifying drug that fails to submit a report for the drug as required by this section, following notification by the Secretary to the manufacturer that the manufacturer is not in compliance with this section, shall be subject to a civil monetary penalty of $75,000 for each day on which the violation continues.

"(f) False Information.—Any manufacturer that submits a report for a drug as required by this section that knowingly provides false information in such report is subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information.

"(g) Public Posting.—

"(1) IN GENERAL.—Subject to paragraph (4), the Secretary shall post each report submitted under subsection (b) on the public website of the Department of Health and Human Services the day the price increase of a qualifying drug is scheduled to go into effect.

"(2) FORMAT.—In developing the format in which reports will be publicly posted under paragraph (1), the Secretary shall consult with stakeholders, including beneficiary groups, and shall seek feedback from consumer advocates and readability experts on the format and presentation of the content of such reports to ensure that such reports are—

"(A) user-friendly to the public; and

"(B) written in plain language that consumers can readily understand.

"(3) LIST.—In addition to the reports submitted under subsection (b), the Secretary shall also post a list of each qualifying drug with respect to which the manufacturer was required to submit such a report in the preceding year and whether such manufacturer was required to submit such report based on a qualifying price increase or whether such drug meets the criteria under subsection (b)(1)(B).

"(4) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.

"SEC. 1150D. ANNUAL REPORT TO CONGRESS.

"(a) In General.—Subject to subsection (b), the Secretary shall submit to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committees on Health, Education, Labor, and Pensions and Finance of the Senate, and post on the public website of the Department of Health and Human Services in a way that is user-friendly to the public and written in plain language that consumers can readily understand, an annual report—

"(1) summarizing the information reported pursuant to section 1150C;

"(2) including copies of the reports and supporting detailed economic analyses submitted pursuant to such section;

"(3) detailing the costs and expenditures incurred by the Department of Health and Human Services in carrying out section 1150C; and

"(4) explaining how the Department of Health and Human Services is improving consumer and provider information about drug value and drug price transparency.

"(b) Protected Information.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and

trade secrets.”.