

## Medicare Coverage Gap Discount Program (Filling the Donut Hole)

**Summary:** Requires drug manufacturers to provide a 50 percent discount to Part D beneficiaries for brand-name drugs and biologics purchased during the coverage gap beginning January 1, 2011.

### Status Updates:

- On August 4, 2011, the Centers for Medicare and Medicaid Services (CMS) posted data that shows 898,938 Medicare beneficiaries have benefitted this program. These beneficiaries saved a total of \$461,582,797.10, or an average savings of \$517.26 per beneficiary.
- On September 8, 2011, CMS posted data showing that nearly 1.3 million people have benefitted from this program, saving a total of \$660 million so far this year.

### Next steps:

- April 30, 2010 – Centers for Medicare and Medicaid Services (CMS) issued draft guidance regarding implementation of the Medicare coverage gap discount program.
- May 14, 2010 – Comments due on draft guidance.
- May 21, 2010 – CMS issued updated guidance regarding implementation of the program.
- May 21, 2010 – CMS issues draft model agreement for the program and announces meeting on June 1.
- May 25, 2010 – CMS issues additional guidance regarding implementation of the program.
- June 1, 2010 – CMS meeting on this program.
- June 21, 2010 – Comments due on draft model agreement for the program.
- August 2, 2010 – CMS issues final drug manufacturers agreements.
- September 1, 2010 – Manufacturers must sign agreement to be able to continue to offer drugs under Part D.
- September 23, 2010 -- Department of Health and Human Services (HHS) announced that all the nation's pharmaceutical manufacturers will provide 50 percent discounts on the cost of covered brand-name prescription drugs for beneficiaries in the Medicare Part D coverage gap, or donut hole, starting in 2011.
- By January 1, 2011 – Secretary establishes Medicare coverage gap discount program.
- January 21, 2011 – Secretary announced that three million Medicare beneficiaries nationwide have received prescription drug cost relief through the Affordable Care Act.
- March 22, 2011 – Secretary announced that four million Medicare beneficiaries nationwide had received the rebate check during all of 2010.
- June 28, 2011 – CMS posted data that shows 478,272 Medicare beneficiaries have benefitted this program in the first five months of 2011.
- August 4, 2011 – CMS posted data that shows 898,938 Medicare beneficiaries have benefitted this program.

- September 8, 2011, CMS posted data showing that nearly 1.3 million people have benefitted from this program, saving a total of \$660 million so far this year.
- January 30, 2012 – Agreements for the Medicare coverage discount program for 2012 must be in order.

### **Additional information:**

- HHS September 8, 2011 information -- <http://www.hhs.gov/news/press/2011pres/09/20110908a.html>
- HHS August 4, 2011 information -- [http://www.cms.gov/NewMedia/03\\_partd.asp#TopOfPage](http://www.cms.gov/NewMedia/03_partd.asp#TopOfPage)
- HHS June 28, 2011 press release -- [http://www.cms.gov/apps/media/press\\_releases.asp](http://www.cms.gov/apps/media/press_releases.asp)
- HHS March 21, 2011 press release -- <http://www.hhs.gov/news/press/2011pres/03/20110322a.html>
- HHS March 21, 2011 full report -- <http://www.healthcare.gov/center/reports/donuthole03222011a.html>
- HHS January 21, 2011 press release -- <http://www.hhs.gov/news/press/2011pres/01/20110121a.html>
- HHS September 23, 2010 press release -- <http://www.hhs.gov/news/press/2010pres/09/20100923a.html>
- CMS background on the program -- [http://www.cms.gov/PrescriptionDrugCovGenIn/05\\_Pharma.asp](http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp) and [http://www.cms.gov/PrescriptionDrugCovGenIn/05\\_Pharma.asp#TopOfPage](http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp#TopOfPage)
- Manufacturer agreement -- <http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/ManuAgreement.pdf>
- Third party administrator's agreement -- <http://www.cms.gov/PrescriptionDrugCovGenIn/Downloads/TPAAgreement.pdf>
- CMS draft guidance regarding implementation of the program (April 30)-- [http://www.fdanews.com/ext/files/2011CoverageGapDiscount\\_043010v2.pdf](http://www.fdanews.com/ext/files/2011CoverageGapDiscount_043010v2.pdf)
- CMS revised guidance regarding implementation (May 21) -- <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/2011CoverageGapDiscountRevised%20Guidance%20052110.pdf>
- CMS additional guidance regarding coverage of generic drugs (May 25) [http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Memo7percentGenericCoverage\\_05.25.10\\_corrected.pdf](http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Memo7percentGenericCoverage_05.25.10_corrected.pdf)
- CMS draft model agreement -- <http://edocket.access.gpo.gov/2010/pdf/2010-12559.pdf>
- PhRMA statement on the program -- [http://www.phrma.org/news/news/phrma\\_statement\\_coverage\\_gap\\_discount\\_program](http://www.phrma.org/news/news/phrma_statement_coverage_gap_discount_program)
- Kaiser Family Foundation summary of Part D changes due to health care reform -- <http://www.kff.org/healthreform/upload/8059.pdf> and <http://www.kff.org/medicare/upload/7044-11.pdf>

### **Long summary:**

#### **Sec. 3301. Medicare coverage gap discount program (as modified by sec. 1101 of HCERA).**

**Medicare coverage gap discount program.** Secretary must establish a Medicare coverage gap discount program by January 1, 2011. In doing so, the Secretary must enter into agreements meeting specific requirements with drug manufacturers and provide for the performance of specified duties. To facilitate this, the Secretary must establish a model agreement for use by the program no later than September 19, 2010, in consultation with manufacturers, and allow for

comment on such model agreement. Manufacturers must enter into these agreements by 30 days after the establishment of the model agreement for 2011. Initial agreements are for 18 months; subsequent renewals would be for not less than one year (unless terminated).

**Termination.** The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Manufacturers may terminate an agreement for any reason but the termination would not be effective until the end of the benefit year or the second benefit year if terminated after January 30 of a year.

**Condition for coverage of Part D drugs.** A manufacturer must participate in the coverage gap program by entering into and having in effect an agreement meeting specified conditions for its drugs to be covered under Part D.

**Required discount.** Requires manufacturer to give Part D enrollees access to discounted prices (defined as 50% off the negotiated price for sole-source and multiple source brand-name drugs) on brand-name drugs and biologics that are covered under Part D and are on prescription drug plan (PDP) formularies or are treated as being on PDP formularies through exceptions and appeals processes. Defines the negotiated price to be the price that plans pay to pharmacies minus the amount of price concessions (i.e., rebates and discounts) that plans pass on to beneficiaries, while excluding dispensing fees from the negotiated price and from the discount (thus, beneficiaries who receive the discount continue to pay pharmacy dispensing fees as under current law). The discounts are available during the entire coverage gap, and end when the beneficiary exceeds the catastrophic limit.

**Eligible beneficiaries.** Applies the discount program to Medicare beneficiaries who enroll in Part D, do not qualify for the low-income subsidy, and are not enrolled in an employee-sponsored retiree drug plan.

**Counting discount toward TrOOP.** Provides that 100% of the negotiated price of discounted drugs (excluding dispensing fees) count toward the annual out-of-pocket threshold (TrOOP).

**Changes coinsurance rates.** Beginning in 2011, phases-in a reduction in coinsurance in the coverage gap for eligible beneficiaries such that in 2020 the coinsurance rates for both brand name and generic drugs is 25%.

**Annual out of pocket threshold.** Reduces the rate by which the upper limit of the coverage gap (i.e., annual out-of-pocket threshold) increases each year.

**Administration of the discount and manufacturer compliance.** Manufacturers must discount drug prices at the pharmacy or through a mail order service. The Secretary may provide for the discount after the point-of-sale for a temporary period until the necessary data systems are in place to implement the discount at the point-of-sale. Manufacturers must collect and have available appropriate data as determined by the Secretary to ensure compliance. Secretary may contract with a third party to administer the drug discount. Secretary may assess fines (or program exclusion for repeated violations).

**Safe harbor.** Provides a safe harbor from anti-kickback penalties for discounts provided under the program.

**Medicaid best price.** Includes the discounts in the definition of best price for the Medicaid program.

### Legislative text:

#### **SEC. 3301. MEDICARE COVERAGE GAP DISCOUNT PROGRAM.**

(a) CONDITION FOR COVERAGE OF DRUGS UNDER PART D.—Part D of Title XVIII of the Social Security Act (42 U.S.C. 1395w- 101 et seq.), is amended by adding at the end the following new section:

“CONDITION FOR COVERAGE OF DRUGS UNDER THIS PART

“SEC. 1860D-43. (a) IN GENERAL.—In order for coverage to be available under this part for covered part D drugs (as defined in section 1860D-2(e)) of a manufacturer, the manufacturer must—

“(1) participate in the Medicare coverage gap discount program under section 1860D-14A;

“(2) have entered into and have in effect an agreement described in subsection (b) of such section with the Secretary; and

“(3) have entered into and have in effect, under terms and conditions specified by the Secretary, a contract with a third party that the Secretary has entered into under subsection (d)(3) of such section.

“(b) EFFECTIVE DATE.—Subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011.

“(c) AUTHORIZING COVERAGE FOR DRUGS NOT COVERED UNDER AGREEMENTS.—Subsection (a) shall not apply to the dispensing of a covered part D drug if—

“(1) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

“(2) the Secretary determines that in the period beginning on January 1, 2011, and December 31, 2011, there were extenuating circumstances.

“(d) DEFINITION OF MANUFACTURER.—In this section, the term ‘manufacturer’ has the meaning given such term in section 1860D-14A(g)(5).”.

(b) MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—Part D of title XVIII of the Social Security Act (42 U.S.C. 1395w-101) is amended by inserting after section 1860D-14 the following new section:

“MEDICARE COVERAGE GAP DISCOUNT PROGRAM

“SEC. 1860D-14A. (a) ESTABLISHMENT.—The Secretary shall establish a Medicare coverage gap discount program (in this section referred to as the ‘program’) by not later than January 1, 2011. Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c)(1). The Secretary shall establish a model agreement for use under the program by not later than 180 days after the date of the enactment of this section, in consultation with manufacturers, and allow for comment on such model agreement.

“(b) TERMS OF AGREEMENT.—

“(1) IN GENERAL.—

“(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer.

“(B) PROVISION OF DISCOUNTED PRICES AT THE POINT-OF-SALE.—Except as provided in subsection (c)(1)(A)(iii), such discounted prices shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an applicable drug.

“(C) TIMING OF AGREEMENT.—

“(i) SPECIAL RULE FOR 2011.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2011, and ending on December 31, 2011, the manufacturer shall enter into such agreement not later than not later than 30 days after the date of the establishment of a model agreement under subsection (a).

“(ii) 2012 AND SUBSEQUENT YEARS.—In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2012 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

“(2) PROVISION OF APPROPRIATE DATA.—Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

“(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under clause (i) of subsection (c)(1)(A) or procedures established under such subsection (c)(1)(A).

“(4) LENGTH OF AGREEMENT.—

“(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 18 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

“(B) TERMINATION.—

“(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

“(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

“(I) if the termination occurs before January 30 of a 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 a plan year, as of the day after the end of the succeeding plan year.

“(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

“(iv) NOTICE TO THIRD PARTY.—The Secretary shall provide notice of such termination to a third party with a contract under

subsection (d)(3) within not less than 30 days before the effective date of such termination.

“(c) DUTIES DESCRIBED AND SPECIAL RULE FOR SUPPLEMENTAL BENEFITS.—

“(1) DUTIES DESCRIBED.—The duties described in this subsection are the following:

“(A) ADMINISTRATION OF PROGRAM.—Administering the program, including—

“(i) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

“(ii) except as provided in clause (iii), the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale of an applicable drug;

“(iii) in the case where, during the period beginning on January 1, 2011, and ending on December 31, 2011, it is not practicable to provide such discounted prices at the point-of-sale (as described in clause (ii)), the establishment of procedures to provide such discounted prices as soon as practicable after the point-of-sale;

“(iv) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

“(I) the negotiated price of the applicable drug; and

“(II) the discounted price of the applicable drug;

“(v) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify;

“(vi) the establishment of procedures to implement the special rule for supplemental benefits under paragraph (2); and

“(vii) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (d)(3).

“(B) MONITORING COMPLIANCE.—

“(i) IN GENERAL.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

“(ii) NOTIFICATION.—If a third party with a contract under subsection (d)(3) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

“(C) COLLECTION OF DATA FROM PRESCRIPTION DRUG PLANS AND MA-PD PLANS.—The Secretary may collect appropriate data from prescription drug plans and MA-PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

“(2) SPECIAL RULE FOR SUPPLEMENTAL BENEFITS.—For plan year 2011 and each subsequent plan year, in the case where an applicable beneficiary has supplemental benefits with respect to applicable drugs under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in, the applicable beneficiary shall not be provided a discounted price for an applicable drug under this section until after such supplemental benefits have been applied with respect to the applicable drug.

“(d) ADMINISTRATION.—

“(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall provide for the implementation of this section, including the performance of the duties described in subsection (c)(1).

“(2) LIMITATION.—

“(A) IN GENERAL.—Subject to subparagraph (B), in providing for such implementation, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

“(B) EXCEPTION.—The limitation under subparagraph (A) shall not apply to the Secretary with respect to drugs dispensed during the period beginning on January 1, 2011, and ending on December 31, 2011, but only if the Secretary determines that the exception to such limitation under this subparagraph is necessary in order for the Secretary to begin implementation of this section and provide applicable beneficiaries timely access to discounted prices during such period.

“(3) CONTRACT WITH THIRD PARTIES.—The Secretary shall enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this section. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

“(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

“(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;

“(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and

“(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

“(4) PERFORMANCE REQUIREMENTS.—The Secretary shall establish performance requirements for a third party with a contract under paragraph (3) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this section.

“(5) IMPLEMENTATION.—The Secretary may implement the program under this section by program instruction or otherwise.

“(6) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the program under this section.

“(e) ENFORCEMENT.—

“(1) AUDITS.—Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

“(2) CIVIL MONEY PENALTY.—

“(A) IN GENERAL.—The Secretary shall impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—

“(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

“(ii) 25 percent of such amount.

“(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“(f) CLARIFICATION REGARDING AVAILABILITY OF OTHER COVERED PART D DRUGS.—Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA– PD plan that the applicable beneficiary is enrolled in).

“(g) DEFINITIONS.—In this section:

“(1) APPLICABLEBENEFICIARY.—The term ‘applicable beneficiary’ means an individual who, on the date of dispensing a covered part D drug—

“(A) is enrolled in a prescription drug plan or an MA– PD plan;

“(B) is not enrolled in a qualified retiree prescription drug plan;

“(C) is not entitled to an income-related subsidy under section 1860D–14(a);

“(D) who—

“(i) has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) during the year; and

“(ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).

“(2) APPLICABLEDRUG.—The term ‘applicable drug’ means, with respect to an applicable beneficiary, a covered part D drug—

“(A) approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and

“(B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

“(ii) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

“(iii) is provided through an exception or appeal.

“(3) APPLICABLE NUMBER OF CALENDAR DAYS.—The term ‘applicable number of calendar days’ means—

“(A) with respect to claims for reimbursement sub- mitted electronically, 14 days; and

“(B) with respect to claims for reimbursement submitted otherwise, 30 days.

“(4) DISCOUNTED PRICE.—

“(A) INGENERAL.—The term ‘discounted price’ means 50 percent of the negotiated price of the applicable drug of a manufacturer.

“(B) CLARIFICATION.—Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

“(C) SPECIAL CASE FOR CERTAIN CLAIMS.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall at or above the initial coverage limit under section 1860D–2(b)(3) and below the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such initial coverage limit and below such annual out-of-pocket threshold.

“(5) MANUFACTURER.—The term ‘manufacturer’ means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

“(6) NEGOTIATEDPRICE.—The term ‘negotiated price’ has the meaning given such term in section 423.100 of title 42, Code of Federal Regulations (as in effect on the date of enactment of this section), except that such negotiated price shall not include any dispensing fee for the applicable drug.

“(7) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term ‘qualified retiree prescription drug plan’ has the meaning given such term in section 1860D–22(a)(2).”.

(c) INCLUSION IN INCURRED COSTS.—

(1) IN GENERAL.—Section 1860D–2(b)(4) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)) is amended—

(A) in subparagraph (C), in the matter preceding clause

(i), by striking “In applying” and inserting “Except as provided in subparagraph (E), in applying”; and

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

“(E) INCLUSION OF COSTS OF APPLICABLE DRUGS UNDER MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—In applying subparagraph (A), incurred costs shall include the negotiated price (as defined in paragraph (6) of section 1860D– 14A(g)) of an applicable drug (as defined in paragraph (2) of such section) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1860D–14A, regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D).

(2) EFFECTIVEDATE.—The amendments made by this subsection shall apply to costs incurred on or after July 1, 2010.

*Note: Section 1101(b)(3) of HCERA amended section 1860D–2(b)(2) of the SSA to add subparagraphs (C) and (D) that provide coverage for generic drugs and applicable drugs in the coverage gap; and section 1101(b)(4) of HCERA amends section 1860D–22(a)(2)(A) in relation to not taking into account value of discounts or coverage in gap; Section 1101(d) of HCERA amended section 1860D–2(b)(4)(B)(i) and (7) of SSA to reduce growth rate of out-of-pocket cost threshold;*

(d) CONFORMING AMENDMENT PERMITTING PRESCRIPTION DRUG DISCOUNTS.—

(1) INGENERAL.—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

(A) by striking “and” at the end of subparagraph (G);

(B) in the subparagraph (H) added by section 237(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2213)—

(i) by moving such subparagraph 2 ems to the left; and

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

(C) in the subparagraph (H) added by section 431(a) of such Act (117 Stat. 2287)—

(i) by redesignating such subparagraph as subparagraph (I);

(ii) by moving such subparagraph 2 ems to the left; and

(iii) by striking the period at the end and inserting “; and”; and

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

“(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1860D-14A(g)) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1860D-14A.”.

(2) CONFORMING AMENDMENT TO DEFINITION OF BEST PRICE UNDER MEDICAID.—Section 1927(c)(1)(C)(i)(VI) of the Social Security Act (42 U.S.C. 1396r-8(c)(1)(C)(i)(VI)) is amended by inserting “, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A” before the period at the end.

(3) EFFECTIVE DATE.—The amendments made by this sub-section shall apply to drugs dispensed on or after July 1, 2010.

