Written comments should be received within 60 days of this notice.

Dated: May 17, 2010.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. 2010–12644 Filed 5–25–10; 8:45 am]

BILLING CODE 4126–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4151–NC]

RIN 0938–AQ04

Medicare Program; Medicare Coverage Gap Discount Program Model Manufacturer Agreement and Announcement of the June 1, 2010 Public Meeting

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice with comment period contains a draft model agreement for use by the Secretary and manufacturers under the Medicare Coverage Gap Discount Program established by section 3301 of the Patient Protection and Affordable Care Act, as amended by section 1101 of the Health Care and Education Reconciliation Act of 2010. Under the agreement, manufacturers of applicable covered Part D drugs must provide applicable discounts to applicable Medicare beneficiaries for applicable covered Part D drugs while in the coverage gap beginning in 2011. It also announces the June 1, 2010 public meeting regarding the draft model agreement.

DATES: *Meeting Date:* Tuesday, June 1, 2010, 9 a.m. to 5:30 p.m., eastern daylight time (e.d.t.).

Meeting Registration and Request for Special Accommodations Deadline: Register between May 21, 2010 and June 1, 2010.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. e.d.t on June 21, 2010.

ADDRESSES: *Meeting Location:* The meeting will be held in the Sheraton Baltimore City Center Hotel, 101 West Fayette Street, Baltimore, MD 21201.

Registration and Special Accommodations: Register and request special accommodations at *http://cmsconference.hcmsllc.com.*

Submitting Comments: In commenting, please refer to file code CMS–4151–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this notice to *http://www.regulations.gov.* Follow the instructions "For submitting a comment."

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4151–NC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–4151–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Craig Miner, for questions regarding the model agreement, (410) 786–7937. Sonia Eaddy, for questions regarding the meeting registration, 410–786–5459.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) which was enacted on December 8, 2003 established the Voluntary Prescription Drug Benefit Program (hereinafter referred to as "Part D"). The Part D program is available for individuals who are entitled to Medicare Part A or enrolled in Medicare Part B. The Centers for Medicare & Medicaid Services (CMS) contracts with private companies, referred to as Part D sponsors, to administer the Part D program via stand alone prescription drug plans (PDPs) and prescription drug plans offered by Medicare Advantage Organizations (MA–PDs). The Part D program became effective January 1, 2006.

Standard Part D prescription drug coverage consists of coverage subject to an annual deductible, 25 percent coinsurance (or an actuarially equivalent cost-sharing design) up to the initial coverage limit (ICL), and catastrophic coverage for individuals that exceed the annual maximum true out-of-pocket (TrOOP) threshold with cost-sharing equal to the greater of a $2/$5 copayment or coinsurance of 5

percent. Under the standard coverage, individuals that do not receive additional cost-sharing subsidies from CMS or additional coverage by other secondary payers (for example, State Pharmaceutical Assistance Programs) are responsible for paying 100 percent of the Part D negotiated price for covered Part D claims above the ICL until their TrOOP costs exceed the annual threshold amount.

Section 3301 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 1101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (these public laws are collectively known as the Affordable Care Act), establishes the Medicare Coverage Gap Discount Program (Discount Program) by adding sections 1860D–43 and 1860D–14A of the Social Security Act (Act). Effective January 1, 2011, the Discount Program will make manufacturer discounts available to applicable Medicare beneficiaries receiving applicable covered Part D drugs while in the coverage gap. In general, the discount on each applicable covered Part D drug is 50 percent of an amount equal to the negotiated price (as defined in section 1860D–14A(g)(6) of the Act).

Beginning January 1, 2011, an applicable Part D drug will only be covered under Part D if the manufacturer has a signed agreement with the Secretary to participate in the Discount Program, provides applicable discounts on coverage gap claims for all of its applicable drugs, and remains in compliance with the terms of that agreement. The requirement to sign an agreement applies to manufacturers of applicable Part D drugs. However, the Secretary reserves the right to require all manufacturers to sign the agreement in the future if we discover that access to applicable Part D drugs is restricted. We also encourage manufacturers of non-applicable drugs to enter into an agreement if they intend to manufacture applicable Part D drugs in the future.

While section 1860D–43(c) of the Act permits us to allow coverage of drugs not covered under an agreement if we determine that availability of the drug is essential to the health of beneficiaries or, for 2011 only, that there are extenuating circumstances, we do not intend to apply this authority as we fully expect all manufacturers of applicable drugs to sign the agreement so that there will be no changes in the availability of coverage for Part D drugs. We will notify the public as early as possible if certain manufacturers have failed to sign an agreement.

II. Provisions of the Notice

A. Draft of the Model Manufacturer Agreement

Pursuant to section 1860D–14A(d)(5) of the Act, the Secretary is authorized to implement the Discount Program "by program instruction or otherwise." Accordingly, in the Addendum to this notice with comment period, we provide a draft of the model manufacturer agreement for use in the program that a manufacturer must enter into with the Secretary agreeing to provide the applicable discount on coverage gap claims by applicable beneficiaries for all of its applicable drugs if it wants its drugs to be covered under Part D. We intend to use the model manufacturer agreement as a standard agreement that will not be subject to further revision based on negotiations with individual manufacturers. The model manufacturer agreement will be finalized and posted on the CMS Web site after we have considered the public comments and consulted with manufacturers as required by section 1860D–14A(a) of the Act.

B. Meeting Regarding Draft Model Manufacturer Agreement

The following is the tentative agenda for the June 1, 2010 meeting:

9–9:30 Opening Remarks
9:30–10:30 CMS Overview of Administration of Discount Program—15 minutes
CMS Overview of PDE Records–45 minutes
10:30–11 Q&A Session
11–11:15 Break
11:15–11:45 CMS Review of Draft Manufacturer Agreement
11:45–12:15 Q&A Session
12:15–1:30 Lunch
1:30–2:30 Beneficiary Advocate Panel
2:30–3:30 Part D Plan Sponsor/PBM Panel
3:30–3:45 Break
3:45–5:15 Pharmaceutical Manufacturer Panel
5:15–5:30 Closing remarks.

III. Collection of Information Requirements

In accordance with section 1860D–14A(d)(6) of the Affordable Care Act, Chapter 35 of title 44, United States Code shall not apply to the program under this section. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

ADDENDUM—Draft Model Agreement

Medicare Coverage Gap Discount Program Agreement Between the Secretary of Health and Human Services (Hereinafter Referred to as "the Secretary") and the Manufacturer Identified in Section IX of This Agreement (Hereinafter Referred to as "the Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer, on its own behalf, for purposes of sections 1860D–14A and 1860D–43 of the Social Security Act (the Act), as set forth in the Patient Protection and Affordable Care Act of 2010, Public Law 111–148, and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, collectively known as the Affordable Care Act, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this Agreement, have the meanings specified in sections 1860D–1 through 1860D–43 of the Act as interpreted and applied herein:

(a) "*Applicable Beneficiary*" means an individual who, on the date of dispensing a covered Part D drug:

1. Is enrolled in a prescription drug plan or an MA–PD plan;

2. Is NOT enrolled in a qualified retiree prescription drug plan;

3. Is NOT entitled to an income-related subsidy under 1860D–14(a) of the Act;

4. Has reached or exceeded the initial coverage limit under section 1860D–2(b)(3) of the Act during the year; and

5. 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) of the Act. This does not mean that an applicable beneficiary who has already moved through the coverage gap is not eligible for applicable discounts for applicable drugs dispensed while the applicable beneficiary was in the coverage gap.

(b) "*Applicable Drug*" means, with respect to an applicable beneficiary, a covered Part D drug—

1. Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act

(FDCA) or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (PHSA) (other than a product licensed under subsection (k) of such section 351 of PHSA); and

2.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.

(c) "*Applicable Discount*" means 50 percent of the portion of the negotiated price (as defined in section I.(m) of this agreement), of the applicable drug of a Manufacturer that falls within the coverage gap (as defined in section I.(f) of this agreement).

(d) "*Centers for Medicare & Medicaid Services (CMS)*" means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicare program.

(e) "*Contractor*" means the CMS contractor responsible for administering the requirements established by the Secretary to carry out section 1860D–14A of the Act.

(f) "*Coverage Gap*" means the gap phase in prescription drug coverage that occurs between the initial coverage limit (as defined in 1860D–2(b)(3) of the Act) and the out-of-pocket threshold (as defined in section 1860D–2(b)(4)(B) of the Act). For purposes of applying the initial coverage limit, Part D sponsors shall apply their plan-specific initial coverage limit under basic alternative actuarially equivalent or enhanced alternative Part D benefit designs.

(g) "*Covered Part D drug*" has the meaning as set forth in 42 CFR 423.100.

(h) "*Discount Program*" means the Medicare Coverage Gap Discount Program established under section 1860D–14A of the Act.

(i) "*Labeler Code*" means the first 5 digits in the 11-digit national drug code (NDC) format that is assigned by the FDA and identifies the Manufacturer.

(j) "*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.

(k) "*Medicare Part D Discount Information*" means information sent from CMS, or its contractor, to the Manufacturer for the Manufacturer's applicable drugs received by applicable beneficiaries for Medicare Part D consisting of summary-level information showing the total units dispensed and total applicable discounts paid by Part D sponsors for each Manufacturer's NDC number during the applicable calendar quarter. This information will be derived from applicable data elements available on the prescription drug events (PDEs) as determined by CMS.

(l) "*National Drug Code (NDC)*" means the identifying prescription drug product number that is registered and listed with the Food and Drug Administration (FDA). For the purposes of this Agreement, the NDC refers to either the 9-digit (inclusive of 5 digit labeler code and 4 digit product code) or 11-digit (inclusive of 5 digit labeler code, 4 digit product code, and 2 digit package size code) NDC, as designated by the Secretary.

(m) "*Negotiated Price*" has the meaning given such term in 42 CFR 423.100 (as in effect on the date of enactment of section 1860D–14A of the Act), except that such negotiated price shall not include any dispensing fee for the applicable drug.

(n) "*Part D drug*" has the meaning given such term in 42 CFR 423.100.

(o) "*Part D Sponsor*" The term Part D sponsor has the meaning given such term in section 42 CFR 423.4.

(p) "*Prescription Drug Event (PDE)*" refers to a summary record that documents the final adjudication of a Part D dispensing event.

(q) "*Qualified Retiree Prescription Drug Plan*" The term qualified retiree prescription drug plan has the meaning given such term in section 1860D–22(a)(2) of the Act.

(r) "*Secretary*" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this Agreement has been delegated.

II. Manufacturer's Responsibilities

In order for Part D coverage to be available for covered Part D drugs of a Manufacturer, the Manufacturer agrees to the following:

(a) To reimburse the applicable discount for all applicable discounts provided by Part D sponsors on behalf of the Manufacturer for all of the Manufacturer's applicable drugs based upon PDE information reported to CMS by Part D sponsors.

(b) To pay to each Part D sponsor within 14 days of being invoiced by the contractor the total quarterly applicable discounts provided by each Part D sponsor on behalf of the Manufacturer for all of the Manufacturer's applicable drugs provided during a previous specified quarter based upon PDE information utilized by CMS (or the contractor) to calculate the applicable discounts.

(c) To collect and have available appropriate data, including data related to Manufacturer's labeler codes, expiration date of NDCs, utilization and pricing information relied on by the Manufacturer to dispute the CMS contractor's discount calculations, and any other data the Secretary determines is necessary to carry out the discount program, for a period of not less than 10 years to ensure that it can demonstrate to the Secretary compliance with the requirements of the Discount Program.

(d) To comply with conditions in sections 1860D–14A and 1860D–43 of the Act, and any changes to the Medicare statute that affect the Discount Program.

(e) To comply with the requirements imposed by the Secretary for purposes of administering the Discount Program.

(f) To pay all applicable discounts provided by Part D sponsors on behalf of the Manufacturer for all of the Manufacturer's applicable drugs for applicable dates of service except for those dates of service after the marketing end date, which is the last lot expiration date, specified in a product's structured product labeling electronically submitted to the FDA if such marketing end date was submitted to the FDA prior to such date.

(g) To submit to periodic audits of data and documentation referenced in section II.(c) of this agreement.

(h) To comply with the payment amount dispute resolution process in section V. of this agreement.

(i) To comply with all applicable confidentiality requirements of the Health Insurance Portability and Accountability Act and 45 CFR parts 160, 162, and 164.

(j) To electronically list and maintain an up-to-date electronic FDA registration and listing of all NDCs so that CMS and Part D sponsors can accurately identify applicable drugs (as defined in section I.(b) of this agreement).

(k) To enter 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 a contract with under section 1860D–14A(d)(3) of the Act.

(l) To provide to CMS or its contractor, electronic connectivity to receive "Medicare Part D Discount Information" reports.

(m) To make quarterly payments directly to accounts established by Part D sponsors via electronic funds transfer within the time period specified in subsection (b) of this section and within 1 business day of the transfer to provide CMS with electronic documentation in a manner specified by CMS that details the successful transmission of such payments.

III. Secretary's Responsibilities

(a) The Secretary shall require Part D sponsors to make applicable discounts available at the pharmacy, by mail order service, or at any other point of sale for applicable drugs beginning January 1, 2011.

(b) The Secretary is responsible for monitoring compliance by the Manufacturer with the terms of this Agreement.

(c) The Secretary is responsible for collecting PDE information from Part D sponsors for monitoring and tracking the applicable discounts provided by Part D sponsors on behalf of Manufacturers for applicable drugs and implementing internal control measures designed to ensure the accuracy and appropriateness of discount payments provided by Part D sponsors.

(d) The Secretary may audit the Manufacturer periodically with respect to the Manufacturer's labeler codes, expiration date of NDCs, and utilization and pricing information relied on by the Manufacturer to dispute the CMS contractor's discount calculations, and any other data the Secretary determines is necessary to carry out the Discount program.

(e) The Secretary shall contract with one or more third parties (the contractor) to:

1. Receive and transmit information, including Medicare Part D Discount Information (as defined in section I.(k) of this Agreement), between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

2. Receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under this agreement;

3. Provide adequate and timely information to manufacturers as necessary for the manufacturer to fulfill its obligations under this Agreement;

4. Permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the contractor to determine discounts for applicable drugs of the manufacturer under the Discount Program.

(f) The Secretary shall not disclose any identifying beneficiary information in these reports or otherwise under this Discount Program except as may be required by a court with competent jurisdiction.

(g) The Secretary shall be the sole source of information regarding beneficiary eligibility to receive the applicable discount and the Secretary's determination regarding beneficiary eligibility is not subject to audit or dispute by Manufacturer.

(h) The Secretary shall make public a list of Manufacturer's labeler codes that are subject to an existing Discount Program Agreement.

IV. Penalty Provisions

(a) The Secretary may impose a civil monetary penalty on a Manufacturer that fails to pay applicable discounts under the Program. The amount for each such failure is the amount the Secretary determines is commensurate with the sum of the amount that the Manufacturer would have paid with respect to such discounts under the Agreement, which will then be used to pay the applicable discounts which the Manufacturer had failed to provide, plus an additional 25 percent of the amount the Manufacturer would have paid with respect to such discounts under the agreement.

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

V. Payment Amount Dispute Resolution

(a) In the event that a Manufacturer disputes the Medicare Part D Discount Information provided by CMS on the periodic summary, the Manufacturer shall provide written notice of the disputed information, by NDC number, to CMS and its contractor within 60 days of receipt of the information. The disputed information must be material, specific and related to the dispute at issue, and supported by evidence provided to the Secretary that establishes the basis of such dispute.

(b) The Manufacturer shall not withhold any invoiced discount payments pending dispute resolution.

(c) The Manufacturer and contractor will use their best efforts to resolve the dispute within 60 days of receipt of such notification. If the dispute is not resolved within 60 days, CMS will provide for an independent review and determination by an entity specified by CMS within 120 days of receipt of notification. If the Manufacturer disagrees with the determination, the Manufacturer may request review by the CMS Administrator. The decision by the CMS Administrator is final and binding.

(d) Adjustments to future applicable discount payments shall be made if new information demonstrates that either there have been material changes in Medicare Part D Discount Information or the negotiated prices originally used to compute previous applicable discount payments.

VI. Confidentiality Provisions

(a) Information disclosed by the manufacturer and deemed by the manufacturer and the Secretary to be confidential in connection with this Agreement is confidential and will not be disclosed by the Secretary in a form which reveals the manufacturer, except as necessary to carry out provisions of section 1860D–14A of the Act and for purposes authorized in section 1860D–15(f)(2) of the Act.

(b) Information disclosed to Manufacturers pursuant to this agreement shall only be used for purposes of paying the discount under the Discount Program. CMS or the contractor will only disclose to manufacturers the minimum data necessary for manufacturers to fulfill their obligations under this Agreement.

(c) Except where otherwise specified in the Act or Agreement, the Manufacturer will observe applicable State confidentiality statutes, regulations and other applicable confidentiality requirements.

(d) Notwithstanding the nonrenewal or termination of this Agreement for any reason, the confidentiality provisions of this Agreement will remain in full force and effect with respect to information disclosed under this Agreement prior to such nonrenewal or termination.

VII. Nonrenewal and Termination

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of not less than 24 months beginning on January 1, 2011 and shall be automatically renewed for a period of 1 year unless terminated under section VII.(b) or (c) of this Agreement.

(b) The Secretary may terminate this Agreement for a knowing and willful

violation of the requirements of the Agreement or other good cause shown. The termination shall not be effective earlier than 30 days after the date of notice to the Manufacturer of such termination.

(c) The Secretary shall provide, upon request, a Manufacturer a hearing with a hearing officer concerning such termination if requested in writing within 15 days of receiving notice of the 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. If the Manufacturer receives an unfavorable decision from the hearing officer, the Manufacturer may request review by the CMS Administrator. The decision of the CMS Administrator is final and binding.

(d) The Manufacturer may terminate this Agreement for any reason. Any such termination shall be effective as of the day after the end of the plan year if the termination occurs before January 30 of a plan year or as of the day after the end of the succeeding plan year if the termination occurs on or after January 30 of a plan year.

(e) Any termination shall not affect applicable discounts for applicable drugs of the Manufacturer that were incurred under the Agreement before the effective date of its termination.

(f) Manufacturer reinstatement will be available only upon payment of any and all outstanding applicable discounts incurred during any previous period of the Agreement. The timing of any such reinstatements will be consistent with the requirements for entering into an Agreement under section 1860D–14A(b)(1)(C) of the Act.

VIII. General Provisions

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

1. Notice to the Secretary will be sent to: Center for Medicare, Division of Pharmaceutical Manufacturer Management, Mailstop C1–26–16, 7500 Security Boulevard, Baltimore, MD 21244–1850.

2. The CMS address may be updated upon written notice to the Manufacturer.

3. Notices to the Manufacturer will be sent to the address as provided with this Agreement and updated upon Manufacturer notification to CMS at the address in this Agreement.

(b) In the event of a transfer in ownership of the Manufacturer or product, this Agreement is automatically assigned to the new owner, and all terms and conditions of this Agreement remain in effect.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law with competent jurisdiction, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other Federal laws, or State laws.

(e) This Agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "Medicare" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the Agreement unless specifically provided for in this Agreement or specifically agreed to by an appropriate CMS official in accordance with paragraph (g) of this section.

(g) Except for the conditions specified in section VIII.(a) of this Agreement, this Agreement once finalized, will not be altered by the parties.

(h) Nothing in this Agreement shall be construed as requiring coverage under Part D of a Manufacturer's product if that product does not otherwise meet the definition of a covered Part D drug under 42 CFR 423.100.

IX. Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____

(please print name)

_____

(signature)

Title: _____

Date: _____

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this Coverage Gap Discount Program Agreement.

By: _____

(please print name)

_____

(signature)

Title: _____

Name of Manufacturer: _____

Manufacturer's Mailing Address: _____

Manufacturer's E-mail Address: _____

Manufacturer labeler Code(s): _____

Date: _____

Authority: Section 3301 of the Patient Protection Affordable Care Act and section 1101 of the Health Care and Education Reconciliation Act of 2010 (Sections 1860D–43 and 1860D–14A of the Social Security Act) Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: May 13, 2010.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: May 20, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–12559 Filed 5–21–10; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

The 13th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference in Irvine, California: "Regulatory Affairs: The Business of Regulatory Affairs"

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

The Food and Drug Administration (FDA) is announcing the following conference: 13th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the drug, device, biologics and dietary supplement industries with an opportunity to interact with FDA reviewers and compliance officers from the centers and District Offices, as well as other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the four medical product areas. Industry speakers, interactive Q & A, and workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 16 and 17, 2010, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at the Irvine Marriott, 18000 Von Karman Ave., Irvine, CA 92612.

Contact: Linda Hartley, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, Voice: 949–608–4413, FAX: 949–608–4417; or Orange County Regulatory Affairs Discussion Group