Exhibit 1
Medicare Coverage Gap Discount Program 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 X 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 , Pub. L. 111-148, and the Health Care and Education Reconciliation Act of 2010, Pub. L. 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, as determined at the time of dispensing or thereafter, of 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 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 (e) of this agreement) and that remains after the negotiated price is reduced by any Part D Supplemental benefits that are available.

(c) "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 treated as if on formulary for the applicable beneficiary, for example when provided through an exception or appeal.

(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) "Coverage Gap" means the 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.

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

(g) "Date of Dispensing" means the date of service.

(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.

(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. For purposes of the Discount Program, such term does not include a wholesale distributor of drugs or a retail

pharmacy licensed under State law, but includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

(k) "Medicare Part D Discount Information" means information set forth in Exhibit A that will be sent from CMS or the Third Party Administrator (TPA), to the Manufacturer along with each quarterly invoice for the applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler code(s) received by applicable beneficiaries during a previous 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 listed with the Food and Drug Administration (FDA). For the purposes of this Agreement, unless otherwise specified, the NDC refers to the 11-digit (inclusive of 5 digit labeler code, 4 digit product code, and 2 digit package size code) NDC.

(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. In connection with applicable drugs dispensed by an out-of-network provider in accordance with the applicable beneficiary's Part D plan out-of-network policies, the negotiated price shall mean the plan allowance as set forth in 42 CFR 423.124, less any dispensing fee.

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

(o) "Part D plan" has the meaning given such term in section 42 CFR 423.4.

(p) "Part D Sponsor" has the meaning given such term in section 42 CFR 423.4.

(q) "Part D Supplemental benefits" means enhanced alternative coverage that exceeds the value of the basic benefit and meets the requirements in 42 CFR 423.104(f)(1)(ii)(B).

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

(s) "Qualified Retiree Prescription Drug Plan" has the meaning given such term in section 1860D-22(a)(2) of the Act.

(t) "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.

(u) "Third Party Administrator (TPA)" means the CMS contractor responsible for administering the requirements established by the Secretary to carry out section 1860D-14A of the Act.

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 all applicable discounts provided by Part D sponsors on behalf of the Manufacturer for all applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler code(s) invoiced to the Manufacturer within a maximum of three (3) years of the date of dispensing based upon PDE information reported to CMS by Part D sponsors and utilized by CMS (or the TPA) to calculate the invoice.

(b) To pay each Part D sponsor within 38 calendar days of receipt from the TPA of the electronic invoice and Medicare Part D Discount Information for the quarterly applicable discounts included on the invoice provided by such Part D sponsor on behalf of the Manufacturer for all of the applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler code(s). The invoice will be calculated by CMS (or the TPA) based upon PDE information reported to CMS by such Part D sponsor during the specified quarter, which may include PDEs with dates of service from prior quarters. Receipt of the invoice shall be considered to be one (1) calendar day after the TPA electronically transmits the invoice to the Manufacturer or otherwise notifies the Manufacturer that it is available (e.g., it is posted on a secure web site for download).

(c) To provide the Secretary with all labeler codes covered under this Agreement and to promptly update such list with any additional labeler codes for applicable drugs.

(d) 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 quarterly invoices and any other data the Secretary determines are necessary to carry out the Discount Program, for a period of not less than 10 years from the date of payment of the invoice to ensure that it can demonstrate to the Secretary compliance with the requirements of the Discount Program.

(e) To comply with conditions in sections 1860D-14A and 1860D-43 of the Act as interpreted and applied by this Agreement and any changes to the Medicare statute that affect the Discount Program.

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

(g) To pay all applicable discounts provided by Part D sponsors on behalf of the Manufacturer for all applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler code(s) 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.

(h) To submit to periodic audits of data and documentation referenced in sections II (d) and V (d) of this Agreement upon sixty (60) days notice to the Manufacturer. Such notice shall include a description of the scope of the audit and shall be reasonably tailored to the specific purpose of the audit. Periodic shall be no more often than annual.

(i) To comply with the audit and payment dispute resolution process in section V of this Agreement.

(j) To comply with the confidentiality requirements set forth in section VI of this Agreement.

(k) To electronically list and maintain an up-to-date electronic FDA registration and listing of all NDCs of the Manufacturer, including the timely removal of discontinued NDCs from the FDA NDC Directory, so that CMS and Part D sponsors can accurately identify applicable drugs (as defined in section I (c) of this Agreement).

(l) To enter into and have in effect, under terms and conditions specified by the Secretary, an agreement with the TPA that has a contract with the Secretary under section 1860D-14A(d)(3) of the Act.

(m) To pay quarterly invoices 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 5 business days of the transfer to provide the TPA with electronic documentation in a manner

specified by CMS that demonstrates that the Manufacturer sent the payments and includes the date and amount of the payments.

(n) The Manufacturer's full compliance with the responsibilities listed in this Section II shall constitute satisfaction of the Manufacturer's responsibilities under the Discount Program. Reliance on the information in the invoice shall satisfy any obligation of the Manufacturer to determine the amount of money to pay to any Part D sponsor under this Agreement or Section 1860D-14A or other relevant statutes.

III. SECRETARY'S RESPONSIBILITIES

(a) The Secretary shall require Part D sponsors to make applicable discounts available to applicable beneficiaries at the pharmacy, by mail order service, or at any other point of sale for applicable drugs beginning January 1, 2011. The Secretary shall also require Part D sponsors to make applicable discounts available to applicable beneficiaries after the point-of-sale if it is later determined that a drug dispensed to a beneficiary was an applicable drug dispensed to an applicable beneficiary.

(b) The Secretary is responsible for monitoring compliance by the Manufacturer with the terms of this Agreement and with monitoring compliance by Part D sponsors and the TPA with their respective obligations in connection with the Discount Program.

(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 and reimbursed by Manufacturers for applicable drugs, , and for implementing internal control measures designed to ensure the accuracy and appropriateness of discount payments provided by Part D sponsors.

(d) In accordance with section V, 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 invoices and Medicare Part D Discount Information, and any other data the Secretary determines are necessary to carry out the Discount Program.

(e) The Secretary shall directly or through a contract with one or more third parties (the TPA):

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

2. Receive, distribute, or facilitate the distribution of funds of the Manufacturer to appropriate individuals or entities;

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

4. Calculate the invoice and reconcile any discrepancies with applicable discounts reported by Part D sponsors prior to invoicing Manufacturers;

5. Notify the Manufacturer of invoice errors or retroactive adjustments and make any necessary adjustments to subsequent invoices;

6. Permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used to determine the applicable discounts for applicable drugs of the Manufacturer under the Discount Program in accordance with section V of this Agreement.

(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 Manufacturers' and their reported labeler codes that are subject to an existing Discount Program Agreement.

(i) The Secretary shall ensure that adjustments are made to invoices as a result of any information obtained relating to errors, including information obtained as a result of the Secretary's audit of a Part D sponsor or the TPA or an audit of data and information made available by the TPA as specified in section V performed by a Manufacturer. In the event a systemic error is discovered, the Secretary shall ensure that either CMS or the TPA identify all invoices affected by the error, notify the Manufacturer and determine the impact of the error on invoiced discounts, and adjust the invoices of the affected Manufacturers (or implement an alternative reimbursement process if determined necessary by the Secretary) to correct any underpayment or overpayment that was requested on prior invoices.

IV. PENALTY PROVISIONS

(a) The Secretary may impose a civil monetary penalty on a Manufacturer that fails to pay applicable discounts under the Agreement. For purposes of this Agreement, the Manufacturer will have failed to pay applicable discounts if payment has not been transmitted within 38 calendar days of receipt of the applicable invoice for each identified Part D sponsor. 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 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. AUDIT AND DISPUTE RESOLUTION

(a) Both parties shall have the right to conduct periodic audits as specified in this section V, directly or through third parties. Periodic shall mean no more often than annual.

(b) The party requesting the audit shall provide the other party with sixty (60) days notice of the reasonable basis for the audit and a description of the information required for the audit. The TPA will determine an audit schedule for Manufacturers based upon available resources.

(c) The Manufacturer shall have the right to audit the data and information (specified in Exhibit B) for a statistically significant sample size of PDEs used to determine the applicable discounts for applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler code(s) under the Discount Program. The Manufacturer is limited to auditing the data and information made available by the TPA and is not permitted to audit CMS records or the records of a Part D sponsors. The TPA will make such data and information available on-site and, with the exception of work papers, such information cannot be removed from the audit site. The auditor is further limited to releasing only an opinion of the results of the audit and cannot release any

other information obtained from the audit, including its work papers, to its client, employer or any other party.

(d) The Secretary shall have the right to audit 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 quarterly invoices and, any other data the Secretary determines are necessary to carry out the Discount Program.

(e) In the event that a Manufacturer disputes a quarterly invoice, the Medicare Part D Discount Information provided by the TPA with the quarterly invoice, or raises other issues arising under the Agreement, the Manufacturer shall provide written notice of the issue or dispute to the TPA within 60 days of receipt of the information that is the subject of the dispute. Such notice shall be accompanied by supporting evidence that is material, specific, and related to the dispute or issue.

(f) The Manufacturer shall not withhold any invoiced discount payments pending dispute resolution with the sole exception of invoiced amounts for applicable drugs having NDCs not specified as being subject to the Agreement. If payment is withheld to dispute that an NDC is subject to the Agreement, the Manufacturer shall notify the TPA and applicable Part D sponsors that payment is being withheld for this reason within 38 calendar days of receipt of the applicable invoice.

(g) The Manufacturer and TPA will use their best efforts to resolve the dispute within 60 calendar days of receipt of such notification. If the Manufacturer receives an unfavorable determination from the TPA or the dispute is not resolved within 60 calendar days, CMS will provide for an independent review and determination by an entity specified by CMS within 90 calendar days of receipt of a request by the Manufacturer for such a review. A request for

review must be made within 30 calendar days of the Manufacturer's receipt of an unfavorable determination from the TPA, or 60 calendar days after CMS's receipt of notice of the dispute if the Manufacturer and TPA cannot resolve the dispute within 60 calendar days, whichever is earlier. If the Manufacturer receives an unfavorable determination from independent review entity, the Manufacturer may request review by the CMS Administrator within 30 calendar days of receipt of notification of such determination. The decision by the CMS Administrator is final and binding.

(h) CMS will adjust future invoices (or implement an alternative reimbursement process if determined necessary by the Secretary) 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 or as necessary pending the outcome of any disputes.

VI. CONFIDENTIALITY PROVISIONS

(a) Any confidential information disclosed by the Manufacturer in connection with this Agreement will not be disclosed by the Secretary in a form that identifies the Manufacturer, except as necessary to carry out provisions of section 1860D-14A of the Act or otherwise required by law. This restriction does not limit the Office of Inspector General's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

(b) Information disclosed to the Manufacturer pursuant to this Agreement shall only be used for purposes of paying the discount under the Discount Program in accordance with the provisions set forth in section VII of this Agreement. CMS or the TPA will disclose to the Manufacturer

only the minimum data necessary for the Manufacturer to fulfill its 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. DATA USE PROVISIONS

The Data Use provisions set forth in Exhibit C of this Agreement govern the use of data CMS provides to the Manufacturer either directly or through the TPA for purposes of the administration of the Discount Program pursuant to sections 1860D-14A and 1860D-43 of the Act.

VIII. 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 VIII.(b) or (d) 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 in relation to the Manufacturer's participation in the Discount Program. The termination shall not be effective earlier than 30

calendar days after the date of notice to the Manufacturer of such termination. The Secretary shall provide the Manufacturer with an opportunity to cure any ground for termination for cause or to show the Manufacturer is in compliance with Section II within thirty (30) calendar days of the Manufacturer's receipt of the written termination notice. If the Manufacturer cures the violation, or establishes that it was in compliance within the cure period, the Secretary shall repeal the termination notice by written notice.

(c) The Secretary shall provide, upon request, a Manufacturer a hearing with a hearing officer concerning such termination if requested in writing within 15 calendar 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 calendar year if the termination occurs before January 30 of a calendar year or as of the day after the end of the succeeding calendar year if the termination occurs on or after January 30 of a calendar year.

(e) Any termination shall not affect the Manufacturer's responsibility to reimburse Part D sponsors for applicable discounts for applicable drugs having NDCs with the Manufacturer's FDA-assigned labeler codes that were incurred under the Agreement before the effective date of its termination.

(f) Upon the effective date of the termination of this Agreement, CMS will cease releasing data to the Manufacturer under this Agreement, except as necessary to ensure that the Manufacturer

reimburses applicable discounts for previous time periods in which the Agreement was in effect, and will notify the Manufacturer to destroy the data file(s) described in section VII of this Agreement. The provisions of sections IV, VI and VII shall survive termination of this Agreement.

(g) 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 reinstatement will be consistent with the requirements for entering into an Agreement under section 1860D-14A(b)(1)(C) of the Act.

IX. 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, 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. Any litigation arising from or relating to this Agreement shall be resolved in Federal court.

(f) The terms "Medicare" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the Agreement unless specifically provided for in this Agreement.

(g) Except for the conditions specified in paragraph (a) of this section, this Agreement once finalized, will not be altered by the parties. However, the Secretary retains the authority to amend the model Agreement after consulting with manufacturers and allowing for comment on such amendments.

(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.

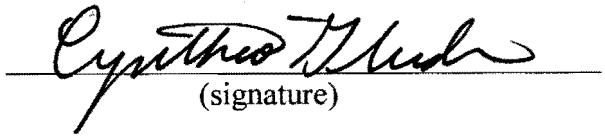
(i) Neither party shall be liable for failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such party's reasonable control, including,

but not limited to, lockouts, riots, wars, fires, floods or storms (a "Force Majeure Event"). A party claiming a right to excused performance under this section shall promptly notify the other party in writing to the extent of its inability to perform, which notice shall specify the Force Majeure Event that prevents such performance and include a timeline for remediation. The party failing to perform shall use reasonable efforts to avoid or remove the cause of the Force Majeure Event and shall resume performance under the Agreement promptly upon the cessation of the Force Majeure Event.

(j) This Agreement and the exhibits attached hereto contain the entire agreement of the parties with respect to the subject matter of this Agreement, and supersede all prior negotiations, agreements, and understandings with respect thereto.

X. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: Cynthia G. Tudor, Ph.D. 
(please print name) (signature)

Title: Director, Medicare Drug Benefit and C & D Data Group

Date: September 30, 2010

FOR THE MANUFACTURER

A. By signing this Agreement, the Manufacturer agrees to abide by all provisions set out in this Agreement and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

B. On behalf of the Manufacturer the undersigned individual hereby attests that he or she is authorized to legally bind the Manufacturer to the terms of this Agreement and agrees to all the terms specified herein.

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

By: Robert Moccia
(please print name)

Robert Moccia
(signature)

Title: President & Chief Operating Officer

P# 1129

Name of Manufacturer: Gracenay Pharmaceuticals, LLC

Manufacturer's Mailing Address: 222 Valley Creek Blvd. Ste 300
Exton, PA 19341

Date: 08-13-10

Exhibit A

MEDICARE PART D DISCOUNT INFORMATION DATA ELEMENTS

1. Date of Service
2. Service Provider Identifier Qualifier
3. Service Provider Identifier
4. Prescription/Service Reference Number
5. Product/Service Identifier
6. Quantity Dispensed
7. Days Supply
8. Fill Number
9. Reported Gap Discount

Exhibit B

PDE DATA ELEMENTS AVAILABLE UPON AUDIT ONLY

1. Contract Number
2. Plan Benefit Package Identifier
3. Ingredient Cost Paid
4. Dispensing Fee Paid
5. Total Amount Attributed to Sales Tax
6. Low-Income Cost Sharing Amount
7. Non-covered Plan Paid Amount
8. Vaccine Administration Fee
9. Total Gross Covered Drug Cost Accumulator (New Field for 2011; Data validation protocol under development)
10. True Out-of-Pocket Accumulator (New Field for 2011; Data validation protocol under development)

Exhibit C

DATA USE PROVISIONS

(a) PURPOSE

CMS agrees to provide the Manufacturer with certain data that reside in the Drug Data Processing System (DDPS), an established CMS Privacy Act System of Records. In exchange, the Manufacturer agrees 1) to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and applicable law, including the Privacy Act and the Health Insurance Portability Accountability Act; and 2) to use the prescription or claim-level data only for purposes of evaluating the accuracy of claimed discounts and resolving disputes concerning the Manufacturer's payment obligations under the Discount Program as described in the applicable statutes, regulations, and this Agreement.

The following provisions address the conditions under which CMS will disclose and the Manufacturer will obtain and use the CMS data file(s) specified in subsection (b)(1) of this section and/or any derivative file(s) that can be used in concert with other information to identify individuals. These provisions supplement any and all agreements between the parties with respect to the use of data from the files specified in subsection (b)(1).

(b) MANUFACTURER'S RESPONSIBILITIES CONCERNING AND LIMITATIONS ON USE OF DISCOUNT INFORMATION

1. The CMS data file(s) covered under this Agreement shall be referred to as "Medicare Part D Discount Information" as defined in section I (k) of this Agreement and shall also include any data provided by CMS or the TPA to the Manufacturer in support of the resolution of payment disputes and audits pursuant to section V of this Agreement (hereinafter referred to as "Discount Information").

2. The Manufacturer agrees to limit the use of the Discount Information to those uses necessary to evaluate the accuracy of claimed discounts and resolve disputes concerning the Manufacturer's payment obligations under the Discount Program. The Manufacturer may not use the Discount Information to perform any functions not governed by this Agreement, including but not limited to non-Coverage Gap Discount payments to Part D sponsors and their subcontractors, payments to other providers of health and drug benefits under any Federal health care program and marketing activities. These restrictions do not apply to the use of aggregated, summary-level data (i.e. not prescription or claim-level data) for financial statement forecasting and accounting purposes.

3. The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the Manufacturer does not obtain any right, title, or interest in any of the data furnished by CMS.

4. The Manufacturer agrees not to disclose, use or reuse the data covered by this Agreement, including data derived from data covered by this Agreement, except as specified in this Agreement or except as CMS shall authorize in guidance it issues in writing related to the administration of the Discount Program or as otherwise required by law. The Manufacturer further agrees not to, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement, with the exception that the Manufacturer may grant access to such data to contracted

third parties for purposes of assisting the Manufacturer in evaluating the accuracy of claimed discounts, resolving disputes, and otherwise exercising its rights and responsibilities under the Agreement so long as such contracted third parties are subject to the same confidentiality requirements set forth in this Agreement and that the Manufacturer maintains responsibility for ensuring compliance by these third parties with the confidentiality requirements of this Agreement.

5. The Manufacturer agrees that, within the Manufacturer's organization and the organizations of its agents, access to the data covered by the Agreement shall be limited to the minimum amount of data necessary and minimum number of individuals who need access to the data for permitted activities such as those described under paragraphs 2 and 4 above. (i.e., individual's access to the data will be on a need-to-know basis).

6. The parties mutually agree that the aforesaid files(s) (and/or any derivative file(s)), including those files that directly identify proprietary or confidential information of a Part D sponsor or its subcontractors or affiliates and those files that can be used in concert with other information to identify individuals), may be retained by the Manufacturer for a period of ten (10) years from the date of payment of the invoice, hereinafter known as the "Retention Period." The Manufacturer agrees to maintain, and provide upon request to CMS, written documentation of the regular destruction of the files within the required timeframe. The Manufacturer may retain the data beyond the ten year timeframe if the data is the subject of an unresolved audit, government investigation, or litigation, or if required by another applicable law and the Manufacturer notifies the Secretary of such matter and promptly destroys the data once the pending matter is resolved.

7. The Manufacturer agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to

it. Further, the Manufacturer (or a contracted third party) agrees that the data must not be physically moved, transmitted or disclosed in any way from or by any site(s) owned, operated, or otherwise controlled by the Manufacturer (or the contracted third party) to any sites outside of the control of the Manufacturer (or the contracted third party) without written approval from CMS unless such movement, transmission or disclosure is required by a law.

8. The Manufacturer agrees to grant access at its facilities to the data to authorized representatives of CMS or DHHS Office of the Inspector General for the purpose of inspecting to confirm compliance with the terms of this Agreement upon reasonable notice and during normal business hours.

9. The Manufacturer agrees that it shall not attempt to link records included in the file(s) specified in subsection (b) 1 to any individually identifiable source of information. This includes attempts to link the data to other CMS data file(s) except that Manufacturers may link to Discount Program data from prior quarters in order to validate that a claim has not been duplicated or that retroactive adjustments have been made. CMS may establish through guidance issued separately to the Manufacturer exceptions to this prohibition that may be necessary for purposes of the administration of the Discount Program.

10. In the event that a Manufacturer inadvertently receives individually identifiable information, the Manufacturer will report the incident to the CMS Action Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the Manufacturer's discovery of the incident. The Manufacturer agrees not to disclose, use or reuse such data or information and acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the file(s) specified in subsection (b)(1) is prohibited.

11. The Manufacturer agrees that in the event CMS determines or has a reasonable belief that the Manufacturer has made or may have made a use, reuse or disclosure of the aforesaid file(s) that is not authorized by this Agreement, CMS, at its sole discretion, may require the Manufacturer to: (a) promptly investigate and report to CMS the Manufacturer's determinations regarding any alleged or actual unauthorized use, reuse or disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized use, reuse or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and (e) if requested by CMS, return data files to CMS or destroy the data files it received from CMS under this agreement. The Manufacturer understands that as a result of CMS's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to release further CMS data to the Manufacturer for a period of time to be determined by CMS.

12. The Manufacturer agrees to report any breach of any information from the CMS data file(s), loss of these data or disclosure to any unauthorized persons to the CMS Action Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour of the Manufacturer's discovery of the incident and to cooperate fully in the federal security incident process. While CMS retains all ownership rights to the data file(s), as outlined above, the Manufacturer shall bear the cost and liability for any breaches of the data file(s) while they are entrusted to the Manufacturer.

13. The Manufacturer hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding $10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by § 1106

and that are not authorized by regulation or by Federal law. The Manufacturer further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i)(3)) may apply if it is determined that the any individual employed or affiliated with the Manufacturer knowingly and willfully obtained the file(s) under false pretenses. Any person found to have violated sec. (i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than $5,000. Finally, the Manufacturer acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the Manufacturer, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of $1,000, they shall be fined under Title 18 or imprisoned not more than 1 year, or both.