

**PUERTO RICO HEALTH INSURANCE ADMINISTRATION**

**REBATE AGREEMENT**  
**PHYSICAL AND MENTAL HEALTH**

This **Rebate Agreement** (hereinafter the "Agreement"), effective January 1, 2015 at San Juan, Puerto Rico ("Effective Date"), by and between the **PUERTO RICO HEALTH INSURANCE ADMINISTRATION**, a public instrumentality of the Commonwealth of Puerto Rico, organized under Law No. 72 approved on September 7, 1993, as amended, hereinafter referred to as the "ADMINISTRATION", represented by its Executive Director, **Mr. Ricardo Rivera Cardona, and Sunovion Pharmaceuticals, Inc.**, a corporation duly organized under the laws of **Delaware**, and doing business under the laws of the Commonwealth of Puerto Rico, with employer social security number **22-2536587** hereinafter referred to as the "SUPPLIER".

**WITNESSETH**

**FIRST:** Under Law No. 72 of September 7, 1993 and corresponding regulations (hereinafter Law No. 72, Law 72 or Act No. 72), the legislature empowered the ADMINISTRATION to seek, negotiate and contract health insurance programs, allowing its Beneficiaries, in particular the medically indigent and the public employees and pensioners of the central Government, access to overall comprehensive quality health services, including pharmaceuticals.

**SECOND:** Pursuant to Article IV of Law No. 72, the ADMINISTRATION is authorized to establish financial structures and agreements that will allow for the management of funds and revenue streams, including the administration of cash and disbursements. Thus, the ADMINISTRATION may contract directly with private manufacturers of pharmaceutical Products that have been deemed safe and clinically effective for the treatment of Beneficiaries of the Puerto Rico Government Health Insurance Plan, also known as MI Salud.

**THIRD:** The ADMINISTRATION, has executed an agreement with a pharmacy benefit management corporation, to contract a pharmacy network to provide prescription drugs to Beneficiaries, and to process the claims from those pharmacies for the prescription drugs dispensed by them to Beneficiaries.

**FOURTH:** THE ADMINISTRATION has executed an agreement with abarca health LLC to provide services as a Pharmacy Program Administrator ("PPA"), to manage the Rebate Program as a means of containing the cost of pharmacy benefit and formulary programs for the Beneficiaries.

**FIFTH:** Pursuant to the Agreement, the PPA was authorized by the ADMINISTRATION to issue an RFP dated April 10<sup>th</sup>, 2014 soliciting rebates and administrative fees for pharmaceutical products under both the Physical and Mental Health related therapeutic classes for inclusion in the respective Preferred Drug Lists

  
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(PDLs) as of January 1, 2015, and to negotiate such rebates and discounts on the ADMINISTRATION'S behalf.

**SIXTH:** The SUPPLIER desires to assure Beneficiaries access to its pharmaceutical Product(s) by inclusion in the PDL(s), subject to the terms and conditions of this Agreement.

**SEVENTH:** The ADMINISTRATION has accepted the proposal submitted by SUPPLIER to provide rebates and administrative fees in connection with the Products pursuant to the terms and conditions contained in this Agreement. Each Product will be treated as a separate contractual relationship subject to the terms and conditions contained in this Agreement as if multiple agreements with exactly the same terms and conditions had been executed.

**NOW THEREFORE,** the Parties agree to enter into, and duly perform their mutual obligations under this Agreement, subject to the following:

## TERMS AND CONDITIONS

### ARTICLE I DEFINITIONS

abarca health LLC: a Puerto Rico limited liability company engaged in the business of providing services as a private full service Pharmaceutical Benefits Manager, headquartered in San Juan, Puerto Rico, and which has contracted with the ADMINISTRATION to conduct services as a Pharmacy Program Administrator (PPA), responsible to negotiate rebate contracts on behalf of ASES, to support the Pharmacy Benefit Financial Committee (PBFC) in updating the Preferred Drug List (PDLs), for both, physical and mental health services and other required services necessary to support ASES rebates' program.

ACCESS: Adequate availability of all necessary physical and mental health care and substance abuse services to fulfill the needs of the Beneficiaries of the GHIP.

ADMINISTRATION: Shall mean the Puerto Rico Health Insurance Administration created by Act No. 72 of September 7, 1993, as amended, also known as ASES (Administración de Seguros de Salud).

ADMINISTRATIVE FEE: Shall mean a fee paid by SUPPLIER to the ADMINISTRATION for the provision of administrative services provided by ADMINISTRATION to SUPPLIER pursuant to this Rebate Agreement. The amount of the Administrative Fee is separate from the applicable Rebate amount.

AFFILIATE: Shall mean with respect to either party, all corporations or other business entities, which, directly or indirectly, are controlled by, or are under the common control with that party. For this purpose, the meaning of the word "control"

shall include, but not be limited to direct or indirect ownership of more than five percent (5%) of the voting shares or interest of such corporation or other business entity.

BENEFICIARY: Any person that under Act 72 of September 7, 1993, as amended, is certified as eligible by the Medicaid Office to receive healthcare services under the Government Health Insurance Plan (GHIP) or a person eligible by virtue of other eligibility categories or criteria (now or hereinafter established) by the GHIP (as permitted by applicable law), and that is enrolled by a TPP or other similar entity contracted by ASES, as a Beneficiary of the GHIP and who is reported as such to the PBM by any such entity contracted by ASES.

BEST PRICE: shall mean Best Price as defined in 42 U.S.C. Section 1396r-8 and 42 C.F.R. Section 447.505 and 447.508.

CLAIM: Any transmission or request for payment submitted by a Participating Pharmacy, TPP, Participating Provider, or other contracted entity of GHIP, for medications dispensed or administered to a Beneficiary under coverage offered by the GHIP, including claims for medications administered by a Participating Provider which are invoiced through Form 1500 or electronically, using J Codes with a corresponding NDC.

CMS: Acronym for the Centers for Medicare and Medicaid Services.

COVERED SERVICES: Shall mean the prescription drug benefits to which a Beneficiary is entitled under the GHIP as permitted by Law 72 or any other applicable law.

DATA: Shall mean the complete set of claims-level and Product information and utilization data to be provided by the PPA on behalf of the ADMINISTRATION to SUPPLIER pursuant to this Rebate Agreement.

DEPARTMENT OF HEALTH: State Agency created by Law No. 81 on March 14<sup>th</sup>, 1912, as amended, that is responsible for developing the health policies and services of Puerto Rico and for developing the process of ruling and oversight of all the health services provided by public and private institutions on the island.

ELIGIBLE UTILIZATION: Shall mean a Product dispensed or administered by a Participating Pharmacy or Participating Provider to a Beneficiary which results in a Claim.

FORMULARY: Refers to Master Formulary of Medications of the GHIP, which includes all medications approved by the P&T Committee, and from which the Preferred Drug Lists, Physical and Mental, are developed.

GHIP: Acronym for the Government Health Insurance Plan. Shall mean the health care insurance program sponsored by the Government of Puerto Rico and administered by ASES, also known as MI Salud, to provide healthcare services to

certain sectors of the population in Puerto Rico; as established by Law 72 of September 7, 1993, as amended, as well as any other derivation thereof or new program developed by ASES now or in the future to provide certain healthcare services to certain sectors of the Puerto Rico population. Services under the GHIP are provided through TPPs under contract with ASES.

MBHO: An organization that provides behavioral health services, by implementing managed care techniques, related to the Mental Health Benefits Coverage, in an integrated manner with the services within the Physical Health Benefits Coverage.

MCO: Shall mean an insurance organization dedicated to the business of offering insurance services to the public, that is in compliance with the laws of Puerto Rico and is authorized by the Puerto Rico Insurance Commissioner to offer insurance in the health services area, and that integrates the financing and delivery of appropriate health care services to patients by means of arrangements with selected providers to furnish a comprehensive set of healthcare services to members; explicit criteria for the selection of health care providers; formal programs for ongoing quality assurance and utilization review.

NOTICE OF DEFAULT: Written communication by certified mail notifying the failure to perform or comply according to the terms of this Agreement.

PARTICIPATING PHARMACIES: Those pharmacies which have agreed, pursuant to a contract with PBM, to provide Covered Services for prescription drugs to Beneficiaries for their own use.

PARTICIPATING PROVIDER: An individual or entity that is authorized under the laws and regulations of the Commonwealth of Puerto Rico to provide physical and / or mental health care and provides such services to Beneficiaries pursuant to a contract with a TPP contracted by the ADMINISTRATION for this purpose.

PBFC: A committee composed by an uneven number of internal and external representatives (other Government entities) appointed by ASES' Executive Director which periodically evaluates those drugs included in the Master Formulary and those recommended by the P&T Committee for inclusion and/or exclusion in the PDLs, and utilized in the rendering of physical and mental healthcare and substance abuse services to Beneficiaries, for overall cost-effectiveness. The PBFC is administered PPA, on behalf of ASES pursuant to a services agreement with ASES.

PHARMACY BENEFIT MANAGER (PBM): An entity that provides services such as: claims processing and adjudication, contracting and administration of the pharmacy network, formulary administration and clinical programs, among others, to employers, government entities, managed health care organizations, health maintenance organizations and/or health plans.

PPA: Pharmacy Program Administrator, responsible to negotiate rebate contracts on behalf of ASES, to support the PBFC in updating the Preferred Drug List (PDLs), for

both, physical and mental health services, and other required services necessary to support ASES rebates' program.

PRIOR-AUTHORIZATION: A written or electronic approval granted by the PBM, TPP, or other entity contracted by the ADMINISTRATION, to the Participating Pharmacy or Participating Provider to dispense or administer a Product to a Beneficiary.

P&T COMMITTEE (PHARMACY AND THERAPEUTICS COMMITTEE): A multidisciplinary, multi-specialty group of independent healthcare professionals in charge of providing advice regarding both, the efficacy and safety of medications. The P&T Committee is responsible for developing and maintaining the Master Formulary and, for periodically evaluating it, for inclusions and / or exclusions.

PREFERRED DRUG LISTS (PDLs): published subset of Products in each therapeutic class, for the treatment of physical, mental and substance abuse conditions, selected from the Master Formulary by the PBFC on the basis of cost-effectiveness after clinical and financial review.

PRODUCTS: A brand name drug marketed under a proprietary, trademark-protected name by SUPPLIER listed in Addendum A, as revised from time to time under the terms of this Agreement and which is included by the ADMINISTRATION in the PDL.

REBATES: Shall mean, for any period herein, retrospective discounts paid by the SUPPLIER with respect to Products based on Eligible Utilization.

THIRD PARTY ADMINISTRATOR (TPA): Entity contracted for the provision of administrative, infrastructure support services related to utilization management, claims processing and provider's network.

THIRD PARTY PROVIDER (TPP): shall include any TPA, MBHO, MCO or similar service provider offering health services and products to Beneficiaries on behalf of the ADMINISTRATION. For purposes of this definition, PPA and PBM are excluded.

UNIT: A prescription drug in its lowest identifiable form (e.g., tablet or capsule for solid dosages, milliliter for liquids, etc.)

WAC PRICE: Shall mean the wholesale net unit price published by MediSpan for the last day of the calendar quarter for which a Rebate calculation is being made.

## **ARTICLE II** **ADMINISTRATION AND PAYMENT PROVISIONS**

1. PAYMENT OF REBATES AND ADMINISTRATIVE FEES. Rebates and Administrative Fees shall be paid by SUPPLIER to ADMINISTRATION for Eligible Utilization within thirty-five (35) calendar days of SUPPLIER's receipt from PPA of a Statement and Invoice. Such Statement and Invoice shall be prepared by the PPA

and delivered to SUPPLIER within twenty (20) calendar days after the delivery by ADMINISTRATION to the PPA of the DATA at the end of each quarter period during the Term of the Agreement. The delivery of the Statement and Invoice by the PPA at a date later than the prescribed twenty (20) calendar days shall not constitute a reason to alter or delaying the SUPPLIER's obligation to pay within thirty-five (35) calendar days of receipt of the Statement and Invoice. Pharmaceutical Companies need to notify PPA immediately of such payment in writing for each payment period.

2. REBATE CALCULATIONS: The amount of Rebates payable to the ADMINISTRATION shall be calculated pursuant to the methodology set forth in Addendum A.

3. DISCREPANCIES: Any objection by SUPPLIER as to the accuracy of any Statement and Invoice shall be notified in writing by SUPPLIER to the PPA within thirty-five (35) calendar days of the receipt by SUPPLIER of the Rebate Statement and Invoice. Failure by SUPPLIER to object within such timeframe shall be construed as an acknowledgement by SUPPLIER of the accuracy and correctness of the Rebate Statement and Invoice. In the event of a timely objection by SUPPLIER, both SUPPLIER and PPA agree to endeavor to reach an understanding in good faith within thirty (30) calendar days from the date of the notice issued by SUPPLIER to PPA. If the Parties hereto fail to reach an understanding within such time period, the dispute arising out of SUPPLIER's objection shall be presented for resolution to the EXECUTIVE DIRECTOR of the ADMINISTRATION. The EXECUTIVE DIRECTOR's decision shall be subject to review according to the Uniform Administrative Procedure Act of Puerto Rico, Law 170 of August 12, 1988. SUPPLIER shall not be required to make any payment related to the objected items of a Rebate Statement and Invoice until final resolution. SUPPLIER shall be obligated to pay timely all items of a Rebate Statement and Invoice not objected to.

4. ADMINISTRATIVE FEE CALCULATIONS: SUPPLIER agrees to pay to the ADMINISTRATION, on a quarterly basis, for the implementation and administration of the Rebate Program, an Administrative Fee calculated pursuant to the methodology set forth in Addendum A. Such payments shall be made pursuant to the information contained in the Rebate Statement and Invoice referred to in paragraph 1 above.

5. INTEREST: Past due payments will be subject to a finance charge, at an annual rate of 9.0%, to be billed by PPA, and payable with the next quarter period Statement and Invoice, within thirty-five (35) calendar days of its receipt.

6. PAYMENT OF REBATES, ADMINISTRATIVE FEES AND INTEREST - The amount of the Rebates, Administrative Fees, and Interest, if any, shall be payable to the ADMINISTRATION, together with a copy of the Invoice in reference to the payment submitted, according to one of the following alternatives:

- a. **Electronic Payment** - The PPA, on behalf of the ADMINISTRATION will timely notify SUPPLIER of the bank account in which the Rebate

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Payments, Administrative Fees and Interest payments are to be deposited;  
or,

- b. **Check Payment** - Checks shall be remitted to **Administración de Seguros de Salud de P.R.** and delivered to the attention of the **Finance Director** to the following address:

Mailing address: PO Box 195661  
San Juan, PR 00919-5661

Physical address: 1571 Calle Alda  
Urbanización Caribe  
San Juan, PR 00926-2712

7. UTILIZATION REPORTS. PPA will provide to SUPPLIER on a quarterly basis a report (on electronic or machine-readable media format) of Eligible Utilization of Products for such applicable quarter by Units, based on the DATA as set forth in Addendum A.

8. NEW PRODUCTS. Inclusion of any new pharmaceutical Product in Addendum A shall require the prior written consent of the ADMINISTRATION. Inclusion of any new pharmaceutical Product in the Formulary and the PDL shall be in accordance with applicable policies and procedures of the P&T, PBFC, and the ADMINISTRATION. Rebates for any new such Product shall be negotiated in good faith by the SUPPLIER and PPA, on behalf of the ADMINISTRATION and to the extent possible shall be consistent with the methodology employed in determining the Rebate amounts.

9. BEST DISCOUNT GUARANTEE. The SUPPLIER guarantees that the WAC Price discount for the Products (Rebate) will continue to be the greatest WAC Price discount (Rebate) in the United States and the Puerto Rico market for such Products, for the Term of this Agreement. Furthermore, the SUPPLIER agrees to extend to the ADMINISTRATION any terms it agrees for the Product(s) with any health plan, insurer, or pharmacy benefit manager which, from an economic standpoint, may be more favorable than those contained in this Agreement. SUPPLIER'S Guarantee hereunder shall not apply in case of any WAC discount (Rebate) or other payment terms that SUPPLIER is required by law to extend to any other entity administering a formulary or similar program for the same Product(s) covered by this Agreement, including without limitation the United States Department of Veterans Affairs and its affiliate organizations, or prices determined by the United States Public Health Service or related entities under Section 602 of United States law and other applicable laws (Best Price), in which case, the Parties may amend this Agreement, effective as of the effective date of such legislation, regulation or ruling or terminate this Agreement as provided herein.

  
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### **ARTICLE III ACCESS**

1. All Products subject to this Agreement will be included in the ADMINISTRATION's Physical Health and / or Mental Health "Preferred Drug Lists" ("PDLs") in the manner specified herein for the Term of this Agreement.
2. After a prescription from a Participating Provider has been issued, a Beneficiary shall have access to the Products included in the PDL, except in cases where the ADMINISTRATION has deemed the necessity of a PRIOR-AUTHORIZATION. In this event, the PBM or TPP shall determine the medical necessity and subsequent coverage of the medication subject to the terms of the agreement between the ADMINISTRATION and any of the mentioned organizations.
3. The TPPs or the ADMINISTRATION will provide to each Participating Provider a copy of the Physical Health and / or the Mental Health PDLs as applicable.

### **ARTICLE IV MARKETING PROVISIONS**

1. In the event that the SUPPLIER desires to distribute through the TPPs or other organizations contracted by the ADMINISTRATION, promotional or informational material to Participating Providers and / or Beneficiaries, SUPPLIER shall provide to the Clinical Division of the PPA with three (3) copies of such materials at least forty-five (45) calendar days prior to the initial distribution date. Upon receipt of SUPPLIER's request, PPA shall review the material and obtain from the ADMINISTRATION the approval of such material. No materials shall be distributed among Participating Providers and / or Beneficiaries unless the SUPPLIER has obtained prior to the initial distribution date a written approval from the PPA, on behalf of the ADMINISTRATION.
2. As of the Effective Date of this Agreement, SUPPLIER's representatives shall have access to promote the Product(s) among Participating Pharmacies and Participating Providers in accordance with applicable policies and procedures of the TPPs and the ADMINISTRATION. SUPPLIER's promotion of its Product(s) shall be in compliance with applicable laws and regulations. SUPPLIER's access to the aforementioned health care providers shall not be more restricted than the access to such providers by other pharmaceutical companies.

### **ARTICLE V RECORDS RETENTION AND AUDITS**

1. Maintenance of Records and Access. During the Term of this Agreement and for a period of seven (7) years after completion of the Agreement or such later date as may be required by applicable law, each Party shall maintain records and



documentation with respect to Eligible Utilization of Products and Rebates and Administrative Fees paid pursuant to this Agreement. Each Party shall have the right to review and audit solely those records necessary for verifying the validity and accuracy of the Utilization Reports, Statements and Invoices submitted by PPA or the Rebates and Administrative Fees paid or disputed by SUPPLIER. Each Party shall have the right to review such records at its own expense, provided that no more than one (1) audit may be conducted during any two (2)-year period and that such audit shall be limited to the most recent four (4) quarters. Audits may only be conducted during the Term of this Agreement and for a period of one (1) year following the Term of this Agreement. Each Party shall have such right to audit inasmuch as it provides the other Party with eighty (80) days prior written notice in advance of any such audit. The records and documentation hereunder shall be accessible to the auditing Party or third-party audit personnel employed by the auditing Party and reasonably acceptable to the audited Party as long as the auditing Party and/or the latter third-party auditor agree—in writing and in a manner acceptable to the audited Party—to maintain the confidentiality of Confidential Information and of the audited Party's data (and any other documentation maintained hereunder). In accordance with the audit terms stipulated hereunder, records and documentation referred to herein and maintained by the audited Party only during normal business hours of operation and only at the location in which such records are generally maintained or such other location as the Parties may agree.

**2. CMS Audits.** SUPPLIER shall permit the Department of Health and Human Services, the Comptroller General, or their designees direct access to and the right to audit, evaluate, or inspect any books, contracts, or other records of SUPPLIER that pertain to provision of Rebates and Administrative Fees to PPA on behalf of the ADMINISTRATION pursuant to this Agreement or to CMS's contract with the ADMINISTRATION, or as the Secretary of the Department of Health and Human Services may deem necessary to enforce CMS's contract with the ADMINISTRATION.

In the event CMS contacts SUPPLIER directly with respect to an audit, evaluation or inspection related to this Agreement, SUPPLIER shall promptly notify PPA of such audit, evaluation or inspection. The Parties acknowledge and agree that record requests from CMS or its designees relating to the ADMINISTRATION shall be answered to by the ADMINISTRATION or PPA. If such a request involves books, contracts, records, including medical records, or other documentation relating to the ADMINISTRATION that is maintained by SUPPLIER, SUPPLIER shall provide such requested documentation to PPA or the ADMINISTRATION for production to CMS or its designees.

**3.** If SUPPLIER determines as a result of an inspection or audit as provided above, that all or part of any payment previously made by SUPPLIER to the ADMINISTRATION pursuant to this Agreement was not required hereunder, then the ADMINISTRATION shall refund such overpayment to SUPPLIER within thirty (30) calendar days of being notified by SUPPLIER through PPA of such overpayment or, at SUPPLIER's option, such overpayment may be deducted from any Rebate

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subsequently due to the ADMINISTRATION. If, on the contrary, it shall be determined that any payment to ADMINISTRATION was less than the amount required under this Agreement, SUPPLIER shall then pay the ADMINISTRATION the amount underpaid within thirty (30) calendar days of receiving such determination.

## **ARTICLE VI FINANCIAL REQUIREMENTS**

The SUPPLIER will maintain adequate procedures and controls to insure that any payments required to be made pursuant to this Agreement are properly and timely made.

## **ARTICLE VII TRANSACTIONS WITH THE SUPPLIER**

1. All transactions between the ADMINISTRATION, PPA and the SUPPLIER involving the Product(s) shall be handled according to the terms and conditions set forth in this Agreement.

2. The SUPPLIER has appointed **Brian Duda** as its duly authorized representative in all transactions with the ADMINISTRATION and PPA under or arising from this Agreement. All communications should be managed through the PPA unless otherwise provided in writing by PPA or the ADMINISTRATION.

## **ARTICLE VIII MODIFICATION CLAUSE**

The Parties to this Agreement may not make any modifications except with the written consent of all the parties hereto.

## **ARTICLE IX APPLICABLE LAW**

This Agreement, including all exhibits, addenda, schedules and the Request for Proposal that originated these, together with the Proposal submitted by SUPPLIER shall be interpreted and construed in accordance with the laws of the Commonwealth of Puerto Rico. If any controversy may arise regarding the interpretation or performance of this Agreement, the parties voluntarily submit for its resolution to the jurisdiction of the Courts of the Commonwealth of Puerto Rico.

  
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**ARTICLE X  
SEVERABILITY**

In the event any term or provision of this Agreement is declared illegal or void by a court of competent jurisdiction, the validity of the remaining terms and provisions shall not be affected thereby.

**ARTICLE XI  
LIABILITIES**

Neither PPA nor any of its Affiliates shall be liable for any loss or damage (including monetary losses) that may accrue in the event SUPPLIER is unable to perform any of its obligations and responsibilities under this Agreement.

**ARTICLE XII  
EFFECTIVE DATE AND TERM**

This Agreement shall commence at 12:01 a.m., on January 1, 2015, Puerto Rico time; and shall remain in effect until 12:00 p.m. on December 31, 2016 (the "Term"); provided, however, that any Addendum to this Agreement containing any Product(s), other than the one(s) originally included in this Agreement, which may be submitted from time to time by SUPPLIER for volume discounts and duly approved by ADMINISTRATION during the Term, shall be in effect until the date specified on such Addendum (the "New Addendum Date").

**ARTICLE XIII  
NON-ASSIGNABILITY**

Neither party shall have the right to assign this Agreement to a third party, unless the third party is an affiliate of the assignor, in any case the prior written consent of the other parties is required, and shall not be unreasonably withheld.

**ARTICLE XIV  
CONFLICT OF INTEREST**

No officer, director, employee or agent of PPA, the Department of Health, or the ADMINISTRATION, the Government of the Commonwealth of Puerto Rico, its municipalities or corporations may be a party to this Agreement, nor derive any economic benefit therefrom.

  
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**ARTICLE XV  
INCOME TAXES AND  
CERTIFICATION TO DO BUSINESS**

The SUPPLIER certifies and guarantees that at the time of execution of this Agreement, it is a corporation duly authorized to conduct business in Puerto Rico and that it has filed all applicable tax returns for the previous five (5) years, and is complying with all payments required by law, except when in reasonable dispute, by the SUPPLIER and the government authorities.

**ARTICLE XVI  
OWNERSHIP AND THIRD PARTY TRANSACTIONS**

The SUPPLIER shall report ownership, control interest, and related information to the ADMINISTRATION, and upon request, to the Secretary of the Department of Health and Human Services, the Inspector General of the Department of Health and Human Services, and the Comptroller General of the United States, in accordance with Sections 1124 and 1903 (m) (4) of the Federal Social Security Act, if applicable.

**ARTICLE XVII  
MODIFICATION OF AGREEMENT**

If the ADMINISTRATION finds that, because of amendments to Law 72 of September 7, 1993, Law 408 of October 2, 2000, as amended, or by reason of any subsequent Federal or local law that affects this Agreement, or because of any reasons deemed by the ADMINISTRATION to be in the best interest of the Government of Puerto Rico in carrying out the provisions of Law 72 of September 7, 1993, as amended, or in order to perform experiments and demonstration projects pursuant to legislative enactment, modification of this Agreement is necessary, the ADMINISTRATION may modify any of the requirements, terms and conditions, functions, part thereof or any other services to be performed by the SUPPLIER. Prior to any such modification, the ADMINISTRATION shall afford the SUPPLIER an opportunity to consult and participate in planning for adjustments which might be necessary and thereafter provide the SUPPLIER written notice that the modification is to be made within ninety (90) calendar days of the date specified in the notice. Said modifications will take place after consultation, renegotiation and mutual agreement with the SUPPLIER.

**ARTICLE XVIII  
RESOLUTION OF DISPUTES**

In the event that SUPPLIER receives a Notice of Default from PPA or that PPA receives a Notice of Default from SUPPLIER, said parties will endeavor in good faith to resolve the dispute arising from such Notice of Default. If said parties fail to reach a solution within thirty (30) calendar days of the receipt of the Notice of Default, the dispute shall then be referred to the EXECUTIVE DIRECTOR of the ADMINISTRATION for resolution.

  
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## **ARTICLE XIX TERMINATION OF AGREEMENT**

1. In the event that there is non-compliance by the SUPPLIER with any specific clause of this Agreement, the ADMINISTRATION or PPA on its behalf will notify the SUPPLIER in writing, indicating the aspect(s) of non-compliance. The SUPPLIER will be granted the opportunity to present and discuss its position regarding the issue within fifteen (15) calendar days from the date of the notification. If after hearing SUPPLIER's arguments, the ADMINISTRATION determines that SUPPLIER has not complied with a specific clause of this Agreement, then the ADMINISTRATION shall have the right to terminate this Agreement upon thirty (30) calendar days prior written notice to SUPPLIER.
2. If the SUPPLIER were to be declared insolvent, files for bankruptcy or is placed under liquidation, the ADMINISTRATION shall have the option to cancel and immediately terminate this Agreement.
3. In the event the SUPPLIER raises its WAC (even with the adjustment provided in Addendum A) during the Term of this Agreement, the PBFC may re-review the cost effectiveness of the Product and if the PBFC determines the Product is no longer cost effective for the ADMINISTRATION, the ADMINISTRATION shall have the option to cancel and immediately terminate this Agreement, and, in its sole discretion, substitute the Product on the PDL.
4. The ADMINISTRATION may, when termination is due to the SUPPLIER's failure to provide payment or refusal to perform the administrative functions required under this Agreement, remove the SUPPLIER's Product from the PDL.
5. The ADMINISTRATION may terminate this Agreement if SUPPLIER fails to comply with any applicable local or federal law.
6. The Agreement may be terminated without cause by the ADMINISTRATION upon thirty (30) calendar days' prior written notice. The Agreement may be terminated without cause by the SUPPLIER upon ninety (90) calendar days' prior written notice. Upon such termination, the ADMINISTRATION shall have the right to eliminate the Products from the PDL.
7. Termination shall not affect the rights and obligations of the parties accruing prior to the effective date of termination.

## **ARTICLE XX GENERIC AVAILABILITY**

In the event a generic presentation of a Product becomes available in Puerto Rico, the ADMINISTRATION or the SUPPLIER shall have the right to delete the SUPPLIER's Product from this Agreement upon thirty (30) calendar days written

notice to SUPPLIER prior to the effective date of such deletion. After such deletion, the Runoff Period established in Article XXI will automatically take effect:

- A. After such deletion and the termination of the Runoff Period, no party hereto shall have any further right or obligation under this Agreement with respect to said Product.
- B. If the said Product was SUPPLIER's only Product subject to this Agreement, then upon such Product's deletion, this Agreement shall be deemed terminated.

### **ARTICLE XXI RUNOFF PERIOD**

1. Following termination of the Agreement for any reason (including in the case of Products that are not included under any subsequent RFP issued after the execution of this Agreement), the SUPPLIER must continue to honor and be responsible for paying the Rebates and Administrative Fees for a period of ninety (90) calendar days after termination of the Agreement.

2. This Runoff Period will also apply if in subsequent RFPs or other negotiations, there is a change in the Rebate or Administrative Fee percentages paid for a Product by the SUPPLIER that is lower than the Rebate or Administrative Fee payable under this Agreement. In such case, SUPPLIER will honor, during the Runoff Period, the higher Rebate and Administrative Fee percentages of the two agreements for any Product.

### **ARTICLE XXII CONFIDENTIALITY**

The Parties hereto shall maintain the Confidentiality of all the terms and conditions of this Agreement to the maximum extent permissible by law as well as any data or documents delivered to each other pursuant to this Agreement, during the Term of this Agreement and any renewal thereof and for five (5) additional years thereafter. Nothing herein shall preclude any of the parties hereto from disclosure to an Affiliate, its attorneys, accountants or financial advisers, provided such persons subscribe to the foregoing obligations. Failure by a Party to comply with the foregoing confidentiality obligations shall allow the other parties to immediately terminate this Agreement.

In the event that any of the parties hereto is required by law or legal process to disclose any confidential information, it shall forthwith give notice to the other Party of such request to allow them, to the extent possible, to obtain relief from such request.

  
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**ARTICLE XXIII  
NOTICE REQUIREMENT**

Any notices given by the parties under this Agreement will be communicated in writing by certified mail, receipt requested and addressed as follows:

Attn: Ricardo Rivera Cardona  
Executive Director,  
Puerto Rico Health Insurance Administration  
PO Box 195661  
San Juan, PR 00919-5661

Attn: Brian Duda  
Senior Director, Strategic Pricing and Contracting  
Sunovion Pharmaceuticals, Inc.  
84 Waterford Drive  
Malborough, MA 01752-7010

Any party may change the above address (including the designated official) by giving prior written notice to the other party of such changes.

**ARTICLE XXIV  
HOLD HARMLESS CLAUSE**

Except to the extent caused by the negligent acts, omissions, or intentional misconduct of the ADMINISTRATION, the PBM and PPA, the SUPPLIER warrants and agrees to indemnify and save harmless the ADMINISTRATION, the PBM and PPA from and against any loss or expense by reason of any liability imposed by law upon the ADMINISTRATION, the PBM and PPA, including claims against the ADMINISTRATION, the PBM or PPA for damages because of bodily injuries, including death, arising out of the use of the Product(s) provided pursuant to this Agreement, or for damages because of SUPPLIER's material breach of this Agreement or caused by SUPPLIER and related to SUPPLIER's participation and or performance under this Agreement.

**ARTICLE XXV  
REQUIREMENTS FROM THE CMS CONTRACT AND  
DEPARTMENT OF HEALTH**

The ADMINISTRATION and the SUPPLIER agree and recognize that applicable guidance and directives from the Centers of Medicare and Medicaid Services (CMS) and Department of Health are hereby incorporated into this Agreement and constitute binding obligations on the part of the SUPPLIER.

  
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## **ARTICLE XXVI FORCE MAJEURE**

Whenever a period of time is herein prescribed for action to be taken by any of the Parties herein, such party shall not be liable or responsible for, and there shall be excluded from the computation for any such period of time, any delays due to strikes, acts of God, shortages of labor or materials, war, terrorism, governmental laws, regulations or restrictions or any other causes of any kind whatsoever which are beyond the control of the Parties.

## **ARTICLE XXVII COMPLIANCE WITH LAW**

1. Any provision of this Agreement that is in conflict with any Federal laws, Federal Medicaid Statutes, Health Insurance Portability and Accountability Act, Federal Regulations, or CMS policy guidance, as applicable, is hereby amended to conform to the provisions of those laws, regulations, and Federal policy.
2. Each party to this Agreement agrees that it will comply with applicable laws of Puerto Rico and the United States to the extent such laws govern that party's obligations and duties hereunder, and the ADMINISTRATION and PPA agree that they and each TPP and other healthcare services organizations they contract with will be required to comply with applicable provisions of 42 U.S.C., 1320a-7b.
3. Each Party agrees that it will comply with all regulations promulgated there under; and comparable local laws and regulations prohibiting illegal remuneration (including any kickback, bribe or rebate) which shall include, but not limited to, properly disclosing and appropriately reflecting all Rebate and other benefits provided by SUPPLIER hereunder in the costs claimed or the charges made pursuant to applicable reimbursement programs, including without limitation the United States Medicaid and Medicare programs, the Government Health Insurance Plan, and any applicable other government or private program, as applicable.
4. In addition, ASES is prohibited by law from entering into contracts with any person or entity that has been, or whose affiliated subsidiary companies, or any of its shareholders, partners, officers, principals, managing employees, subsidiaries, parent companies, officers, directors, board members or ruling bodies have been, under investigation for, accused of, convicted of, or sentenced to imprisonment, in Puerto Rico, the United States of America, or any other jurisdiction, for any crime involving corruption, fraud, embezzlement, or unlawful appropriation of public funds, pursuant to Puerto Rico's Act 458, as amended, and Act 84 of 2002. Also, as provided in 42 CFR 455.106(c), ASES may refuse to enter into or renew an agreement with any entity if any person who has an ownership or control interest in the entity, or is an agent or managing employee of the entity, has been convicted of a criminal offense related to the person's involvement in any program established under Medicare, Medicaid, or the Title XX services programs. Before the Effective



Date of this Contract, pursuant to 42 CFR 455.106(a), the SUPPLIER shall disclose to ASES the identity of any person described herein, who has been convicted of a criminal offense related to the Medicare, Medicaid, or Title XX services programs.

**5. Change in Law:** As of the Effective Date, the Rebates provided under this Rebate Agreement are not taken into account in establishing a Medicaid best price under section 1927, 42 U.S.C. §1396r-8, of the Social Security Act ("Best Price"). All discounts [rebates] provided under this Agreement are contingent upon this statement remaining true and effective at all times during the Term of the Agreement. It is not the Parties' intent that the prices available under this Agreement be included in any Product's Medicaid Best Price. If the Final Rule or any other change in law causes prices offered under this Rebate Agreement to be includable in the Best Price for any Product, the Parties may amend this Agreement to conform it to the Final Rule or Legislation or either Party may terminate this Agreement as of the effective date of the change in law with at least thirty (30) days prior written notice. Notwithstanding the above, to the extent that any discount or rebate otherwise payable pursuant to this Rebate Agreement would, alone or together with any other price reduction, establish a new Best Price for any Product, the amount of such discount shall NOT be adjusted retroactively.

**ARTICLE XXVIII  
EXCLUSION OF RETROACTIVE LIABILITY**

The Parties agree that nothing in the Agreement shall be construed to impose any retroactive liability or substantial expenses on the Parties because of terms or conditions not expressly reflected herein without prior notice to either Party and the right to terminate this Agreement according to Article XIX.

**ARTICLE XXIX  
ENTIRE AGREEMENT**

The Parties agree that they accept, consent and promise to abide by each and every one of the clauses contained in this Agreement and that it, together with its exhibits, addenda, schedules and the Request for Proposal that originated these, together with the Proposal submitted by SUPPLIER, shall constitute the entire agreement between the Parties regarding the subject matter hereof and shall supersede any and all other prior or contemporaneous representations, statements, understandings, negotiations, or agreements either oral or written between the Parties regarding the subject matter hereof. In the event of any discrepancy between the terms contained herein and those in the Exhibits, addenda, schedules and the Request for Proposal and response thereto, the terms of this Agreement shall prevail, unless specifically otherwise provided herein.

  
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This Agreement, together with any exhibits, addendums or appendixes may be signed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Additionally, this Agreement, together with any exhibits, addendums or appendixes may be executed and delivered by facsimile or other electronic signature by any of the parties to any other party and the receiving party may rely on the receipt of such document so executed and delivered by facsimile or other electronic means as if the original had been received.

In order to acknowledge so, the Parties initialize the margin of each of the pages and affix below their respective signatures, in San Juan, Puerto Rico, as of the dates written below.

Ricardo A Rivera Cardona  
Ricardo A Rivera Cardona (Dec 19, 2014)

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**Ricardo Rivera Cardona**  
**Executive Director**  
**Puerto Rico Health Insurance**  
**Administration**

Brian Duda  
Brian Duda (Nov 21, 2014)

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**Brian Duda**  
**Vice President, Managed Markets**  
**Sunovion Pharmaceuticals, Inc.**

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10/30/2014

**ADDENDUM A  
REBATE AGREEMENT FOR PHYSICAL AND MENTAL HEALTH  
BETWEEN THE PUERTO RICO HEALTH INSURANCE ADMINISTRATION  
(ASES), AND SUNOVION PHARMACEUTICALS, INC**

**I. EFFECTIVE DATE:** From: January 1, 2015 To: December 31, 2016

**II. PRODUCT INFORMATION & DISCOUNTS**

Product Name	Dosage Form & Strength	Smallest Unit (tab., cap., ml, etc.)	Rebate	Admin Fee	% Total
Latuda Oral Tablet	20, 40, 60, 80, 120 mg	tab.	82.2%	2.0%	84.2%

**III. FORMULARY STATUS AND/OR REMARKS**

- a. Refer to Physical and / or Mental Health PDL's

**IV. METHODOLOGY FOR CALCULATION OF REBATES AND ADMINISTRATIVE FEES**

- a. Total Volume X WAC\* Price X (Rebate % + Administrative Fee %) = Total Discount of Units per Unit Amount
- b. In the event that Supplier increases a Product's WAC price during the term of this Agreement, Pharmaceutical Company agrees that the associated Rebate percentage(s) set forth above shall be automatically increased so that the effective net price of the Product (WAC minus Rebate percentage) after the WAC increase is equivalent to the effective net price of the Product as of the RFP proposal submission deadline. The additional percentage will be added for the Product during the applicable Quarter and thereafter.

**V. REBATE STATEMENT AND INVOICE**

- a. The Statement and Invoice shall contain the following information: name of SUPPLIER, period covered, National Drug Code (NDC), drug name & strength, total number of prescriptions or medical claims, total number of units dispensed or administered, WAC price, applicable percentage discount (rebate and administrative fee) for each presentation, and total rebate/administrative fee amount per presentation. The Statement shall also include an invoice for the total rebate/administrative fee amount for the covered quarter period and a summarized market share report for the Products included in the ADMINISTRATION PDL for the Beneficiaries of the GHIP under the same therapeutic class.

**VI. FORMULARY REQUIREMENTS**

Customer is eligible to receive an Access Rebate of 82.20% off WAC for Latuda's utilization provided that Latuda be placed on formulary in the lowest branded tier with no restrictions that are no more numerous or stringent than other preferred branded products. Additionally, Latuda shall be listed as a 1 of no more than 3 branded products in the lowest branded tier. In addition, Customer shall advantage Latuda relative to non-preferred branded competitive Products in terms of:

- a. Cost Indicators; and

- b. Promotional efforts including step edits, prior authorizations, NDC blocks, and quantity limits.
- c. Not disadvantage Latuda relative to branded competitive Products in terms of:
- d. Formulary Status;
- e. Copay Levels;
- f. Cost Indicators; and
- g. Promotional efforts including step edits, prior authorizations, NDC blocks, and quantity limits.

**VII. BILLING ADJUSTMENTS**

Any billing adjustments will be evaluated by both Parties, according to the following exceptions:

- a. If the product is contracted under a Federal or Municipal program.
- b. If the product has NDC's that belong to repackages.
- c. If the product has NDC's that state "**Hospital Use Only**".

Any other exception will be in accordance with Article XVIII Resolution of Disputes of this Agreement.

**IN WITNESS WHEREOF**, the Parties have executed this **ADDENDUM A** as of the date of the Agreement.

**ASES**

By: Ricardo A Rivera Cardona  
Ricardo A Rivera Cardona (Dec 19, 2014)

(Signature)

Name: Ricardo Rivera Cardona

Title: Executive Director

**SUNOVION PHARMACEUTICALS, INC**

By: Brian Duda  
Brian Duda (Nov 21, 2014)

(Signature)

Name: Brian Duda

Title: Vice President, Managed Markets

\* Nothing herein shall exempt SUPPLIER from complying with any pricing caps imposed by the Department of Consumer Affairs of Puerto Rico ("DACO" for its Spanish acronym) for those Products identified by DACO pursuant to Act No. 228 of May 12, 1942, as amended, and its corresponding regulations. If during the Term said pricing is determined to be legally applicable for Rebate pricing calculations hereunder, the methodology for calculating the Rebates for those products listed by DACO will be modified by PPA by substituting WAC Price for DACO Price. In such case, SUPPLIER shall be responsible for providing PPA with the updated DACO pricing list for said products no later than five (5) days from the end of the applicable Quarter. PPA shall then validate such pricing with DACO's list of products and bill SUPPLIER based on DACO Price for those products, as applicable.

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**APPENDIX I**  
**SUPPLIER'S REBATE FILE FORMAT**  
**for the Puerto Rico Health Insurance Administration (ASES)**

Field Name	Field Type	Description	Accepted values
Reference Number	Text	Unique Claim Identifier provided by the PBM, TPA, or MBHO	
Account	Text	Value that identifies carrier	<b>01</b> : SSS <b>83</b> : APS
Provider Number	Text	National Provider Identification (NPI) Number	
Provider Name	Text	Pharmacy or Physician's Name	
NDC	Text	Submitted NDC Number – Zero-filled, right justified.	
Drug Name	Text	Drug name from Medispan file for NDC submitted	
Drug Strength	Text	Drug strength from Medispan file for NDC submitted.	
GPI	Text	Generic Product Index (GPI) for NDC Submitted	
Date of Service	Text	Submitted Fill Date. Format is MMDDYYYY.	
Units dispensed	Number	Submitted Quantity. Zero-filled, right justified.	
DAW Code (if applies)	Text	Submitted PSC Dispensed As Written (DAW) code (if applies)	
Rx Number (if applies)	Text	Prescription number assigned by the pharmacy. (This applies only to pharmacy claims. Medical claims will only have the claim number in the Reference Number field.)	

**Length: Tab Delimited**

# Sunovion Rebate Agreement Physical Mental Health 2015-2016










EchoSign Document History

November 21, 2014



Created: November 07, 2014  
By: Adriana Ramirez (adriana.ramirez@abarcahealth.com)  
Status: SIGNED  
Transaction ID: XG6HERYB4XU476S

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-  Document created by Adriana Ramirez (adriana.ramirez@abarcahealth.com)  
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-  Document emailed to James Shepherd (james.shepherd@sunovion.com) for approval  
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-  James Shepherd (james.shepherd@sunovion.com) entered valid password.  
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# Batch - 3 Rebate Agreement Physical Mental Health 2015-2016







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December 19, 2014



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