UNITED STATES BANKRUPTCY COURT FOR THE DISTRICT OF DELAWARE	PROOF OF CLAIM
1. Ne of Debtor (YOU MUST SELECT ONE AND MAY ONLY SELECT ONE DEBTOR):	
☐ [] Chester Valley Pharmaceuticals, LLC (11-13034)  [] Graceway Pharma Holding Corp. (11-13037)  [] Graceway Holdings, LLC (11-13038)  [] Chester Valley Holdings, LLC (11-13039)	
This form should not be used to assert a claim for an administrative expense arising after the commencement of the case, which should be filed pursuant to 11 U.S.C. § 503. Additionally, this form should not be used to assert a claim under 11 U.S.C. § 503(b)(9), which should be filed pursuant to the 503(b)(9) Administration Order, entered on October 17, 2011 [Docket No. 122].	
2. Name of Creditor (the person or other entity to whom the Debtor owes money or property): \[ \( \( \( \) \\ \) \\ \) \\ \ \ \ \ \ \	If an amount is identified above, you have a claim scheduled by one of the Debtors as
Name and address where payment should be sent (if different from above):  SEFE NABER  HEALTH CAGE 8 F AMILY SEAULCE  2 01 S. GRAND AVE., EAJT  CPRINGFIELD, IL 62763  [] Check this box if you are aware that anyone else has filed a proof of claim relating to your claim. Attach copy of statement giving particulars.  [] Check this box if you are aware that anyone else has filed a proof of claim relating to your claim. Attach copy of statement giving particulars.	shown. Please review the bar date notice to determine whether you must file a proof of claim to preserve your rights. The bar date notice is available online at www.bmcgroup.com/graceway or upon request at the address on the back of this form.  THIS SPACE IS FOR COURT USE ONLY
3. Amount of Claim as of Date Case Filed:    1   3   3   5 - 9   7	7. Amount of Claim Entitled to Priority under 11 U.S.C. § 507(a). If any portion of your claim falls in one of the following categories, check the box and state the amount.
4. Basis for Claim: RESECT/ CAI DAMACKS - DRVG REBASS DUF (See instruction #4 on reverse side.)	Specify the priority of the claim.  [ ] Domestic support obligations under 11 U.S.C. § 507(a)(1)(A) or (a)(1)(B).
5. Last four digits of any number by which creditor identifies Debtor: 9.3.36.  5a. Debtor may have scheduled account as:	[ ] Wages, salaries, or commissions (up to \$11,725*) earned within 180 days before filing of the bankruptcy petition or cessation of the debtor's business, whichever is earlier – 11
Check the appropriate box if your claim is secured by a lien on property or a right of setoff and provide the requested information.  Nature of property or right of setoff: [ ] Real Estate [ ] Motor Vehicle [ ] Equipment [ ] Other	U.S.C. § 507(a)(4).  [ ] Contributions to an employee benefit plan – 11 U.S.C. § 507(a)(5).
Describe:  Value of Property: \$ Annual Interest Rate%	[ ] Up to \$2,600* of deposits toward purchase, lease, or rental of property or services for personal, family, or household use – 11 U.S.C. § 507 (a)(7).
Amount of arrearage and other charges as of time case filed included in secured claim,  if any: \$ Basis for perfection:  Amount of Secured Claim: \$ Amount Unsecured: \$ BMC GROUP	[ ] Taxes or penalties owed to governmental units – 11 U.S.C. § 507 (a)(8).
8. Credits: The amount of all payments on this claim has been credited for the purpose of making this proof of claim.	Other – Specify applicable paragraph of 11 U.S.C. § 507(a)().
9. Documents: Attach redacted copies of any documents that support the claim, such as promissory notes, purchase orders, invoices, itemized statements or running accounts, contracts, judgments, mortgages, and security agreements. You may also attach a summary. Attach redacted copies of documents providing evidence of perfection of a security interest. You may also attach a summary. (See instruction 9 and definition of "redacted" on reverse side.)	Amount entitled to priority:
DO NOT SEND ORIGINAL DOCUMENTS. ATTACHED DOCUMENTS MAY BE DESTROYED AFTER SCANNING.  If the documents are not available, please explain in an attachment.	*Amounts are subject to adjustment on 4/1/13 and every 3 years thereafter with respect to cases commenced on or after the date of adjustment.
10. Signature: The person filing this claim must sign it. Sign and print name and title, if any, of the creditor or other person authorized to file this claim and state address and telephone number if different from the notice address above. Attach copy of power of attorney, if all william C- Kunglul, PS/t WILLIAM C- KUNGLAMC, PS/t	FOR COURT USE ONLY  Graceway Pharmaceuticals LL(
Date: $2-22$ Signature: Printed Name: $3/2-793-8$	616

#### INSTRUCTIONS FOR PROOF OF CLAIM FORM

The instructions and definitions below are general explanations of the law. In certain circumstances, such as bankruptcy cases not filed voluntarily by the Debtor, there may be exceptions to these general rules. The attorneys for the Debtors and their court-appointed claims agent are not authorized and are not providing you with any legal advice.

PLEASE SEND YOUR ORIGINAL, COMPLETED CLAIM FORM AS FOLLOWS: IF BY MAIL: BMC GROUP, INC., ATTN: GRACEWAY PHARMACEUTICALS CLAIMS PROCESSING, P.O. BOX 3020, CHANHASSEN, MN 55317-3020. IF BY HAND DELIVERY OR OVERNIGHT COURIER: BMC GROUP, INC., ATTN: GRACEWAY PHARMACEUTICALS CLAIMS PROCESSING, 18750 LAKE DRIVE EASTCHANHASSEN, MN 55317. ANY PROOF OF CLAIM SUBMITTED BY FACSIMILE OR E-MAIL WILL NOT BE A CCEPTED.

THE GENERAL BAR DATE FOR CLAIMS IN THESE CHAPTER 11 CASES IS DECEMBER 30, 2011 4:00 P.M. (PREVAILING EASTERN TIME). THE GOVERNMENTAL BAR DATE FOR CLAIMS OF GOVERNMENTAL ENTITIES IN THESE CHAPTER 11 CASES IS MARCH 27, 2012 AT 4:00 P.M. (PREVAILING EASTERN TIME).

#### 1. Court, Name of Debtor, and Case Number:

These Chapter 11 cases were commenced in the United States Bankruptcy Court for the District of Delaware. You must select the Debtor against which you are asserting your claim. A SEPARATE PROOF OF CLAIM FORM MUST BE FILED AGAINST EACH DEBTOR.

#### 2. Creditor's Name and Address:

Fill in the name of the person or entity asserting a claim and the name and address of the person who should receive notices issued during the bankruptcy case. Please provide us with a valid email address. A separate space is provided for the payment address if it differs from the notice address. The creditor has a continuing obligation to keep the court informed of its current address. See Federal Rule of Bankruptcy Procedure (FRBP) 2002(g).

#### 3. Amount of Claim as of Date Case Filed:

State the total amount owed to the creditor on the date of the bankruptcy filing. Follow the instructions concerning whether to complete items 6 and 7. Check the box if interest or other charges are included in the claim.

#### 4. Basis for Claim:

State the type of debt or how it was incurred. Examples include goods sold, money loaned, services performed, personal injury/wrongful death, car loan, mongage note, and credit card. If the claim is based on the delivery of health care goods or services, limit the disclosure of the goods or services so as to avoid embarrassment or the disclosure of confidential health care information. You may be required to provide additional disclosure if the trustee or another party in interest files an objection to your claim.

5. Last Four Digits of Any Number by Which Creditor Identifies Debtor: State only the last four digits of the Debtor's account or other number used by the creditor to identify the Debtor.

#### 5a. Debtor May Have Scheduled Account As:

Use this space to report a change in the creditor's name, a transferred claim, or any other information that clarifies a difference between this proof of claim and the claim as scheduled by the Debtor.

#### 6. Secured Claim:

Check the appropriate box and provide the requested information if the claim is fully or partially secured. Skip this section if the claim is entirely unsecured. (See DEFINITIONS, below.) State the type and the value of property that secures the claim, attach copies of lien documentation, and state annual interest rate and the amount past due on the claim as of the date of the bankruptcy filing.

#### 7. Amount of Claim Entitled to Priority Under 11 U.S.C. § 507(a):

If any portion of your claim falls in one or more of the listed categories, check the appropriate box(es) and state the amount entitled to priority. (See DEFINITIONS, below.) A claim may be partly priority and partly non-priority. For example, in some of the categories, the law limits the amount entitled to priority.

#### 8. Credits:

An authorized signature on this proof of claim serves as an acknowledgment that when calculating the amount of the claim, the creditor gave the Debtor credit for any payments received toward the debt.

#### 9. Documents:

Attach to this proof of claim form redacted copies documenting the existence of the debt and of any lien securing the debt. You may also attach a summary. You must also attach copies of documents that evidence perfection of any security interest. You may also attach a summary. FRBP 3001(c) and (d). If the claim is based on the delivery of health care goods or services, see instruction 4. Do not send original documents, as attachments may be destroyed after scanning.

#### 10. Date and Signature:

The person filing this proof of claim must sign and date it. FRBP 9011. Print the name and title, if any, of the creditor or other person authorized to file this claim. State the filer's address and telephone number if it differs from the address given on the top of the form for purposes of receiving notices. Attach a complete copy of any power of attorney. Criminal penalties apply for making a false statement on a proof of claim.

#### **DEFINITIONS**

#### Debtor

A Debtor is the person, corporation, or other entity that has filed a bankruptcy case.

The Debtors in these Chapter 11 cases are:

Graceway Pharmaceuticals, LLC (11-13036) Graceway Pharma Holding Corp. (11-13037) Graceway Holdings, LLC (11-13038) Chester Valley Holdings, LLC (11-13039) Chester Valley Pharmaceuticals, LLC (11-13041) Graceway Canada Holdings, Inc. (11-13042) Graceway International, Inc. (11-13043)

Certain of the Debtors were known by other names within the past six years; such former names are identified in the notice of commencement.

#### Creditor

A creditor is the person, corporation, or other entity owed a debt by the Debtor on the date of the bankruptcy filing.

#### Claim

A claim is the creditor's right to receive payment on a debt owed by the Debtor that arose on the date of the bankruptcy filing. See 11 U.S.C. § 101(5). A claim may be secured or unsecured.

#### Proof of Claim

A proof of claim is a form used by the creditor to indicate the amount of the debt owed by the Debt or on the date of the bankruptcy filing. The creditor must file the form with The Garden City Group, Inc. as described in the instructions above.

#### Secured Claim Under 11 U.S.C. § 506(a)

A secured claim is one backed by a lien on property of the Debtor. The claim is secured so long as the creditor has the right to be paid from the property prior to other creditors. The amount of the secured claim can-not exceed the value of the property. Any amount owed to the creditor in excess of the value of the property is an unsecured claim. Examples of liens on property include a mortgage on real estate or a security interest in a car. A lien may be voluntarily granted by a Debtor or may be obtained through a court proceeding. In some states, a court judgment is a lien. A claim also may be secured if the creditor owes the Debtor money (has a right to setoff).

#### Section 503(b)(9) Claim

A Section 503(b)(9) claim is a claim for the value of any goods received by the Debtor within 20 days before the date of commencement of a bankruptcy case in which the goods have been sold to the Debtor in the ordinary course of such Debtor's business.

#### **Unsecured Claim**

An unsecured claim is one that does not meet the requirements of a secured claim. A claim may be partly unsecured if the amount of the claim exceeds the value of the property on which the creditor has a lien.

# Claim Entitled to Priority Under 11 U.S.C. § 507(a)

Priority claims are certain categories of unsecured claims that are paid from the available money or property in a bankruptcy case before other unsecured claims.

#### Redacted

A document has been redacted when the person filing it has masked, edited out, or otherwise deleted, certain information. A creditor should redact and use only the last four digits of any social-security, individual's tax-identification, or financial-account number, all but the initials of a minor's name and only the year of any person's date of birth.

#### **Evidence of Perfection**

Evidence of perfection may include a mortgage, lien, certificate of title, financing statement, or other document showing that the lien has been filed or recorded.

#### **INFORMATION**

#### Acknowledgment of Filing of Claim

To receive acknowledgment of your filing, please provide a stamped self-addressed envelope and a copy of this proof of claim when you file the original claim.

#### Offers to Purchase a Claim

Certain entities are in the business of purchasing claims for an amount less than the face value of the claims. One or more of these entities may contact the creditor and offer to purchase the claim. Some of the written communications from these entities may easily be confused with official court documentation or communications from the Debtor. These entities do not represent the bankruptcy court or the Debtor. The creditor has no obligation to sell its claim. However, if the creditor decides to sell its claim, any transfer of such claim is subject to FRBP 3001(e), any applicable provisions of the Bankruptcy Code (11 U.S.C. § 101 et seq.), and any applicable orders of the bankruptcy court.

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\$6,458.05	\$6,4	Qtr. Total										. [	
\$315.24	42.000 \$3			0.000	\$315.24	7.505700	42.000	0.000	42.000	MAXAIR AUTOHALER 0.2 MG AERO	081521	4	2011
\$2,581.11	49			0.000	\$2,581.11	8.353100	309.000	0.000	309.000	ALDARA 5% CREAM	061024	4	2011
\$3,182.53	381.000 \$3,1			0.000	\$3,182.53	8.353100	381.000	0.000	381.000	ALDARA 5% CREAM	061012	4	2011
\$28.80	180.000 \$:			0.000	\$28.80	0.160000	180.000	0.000	180.000	MINITRAN 0.6 MG/HR PATCH	030402	4	2011
\$12.15				0.000	\$12.15	0.067500	180.000	0.000	180.000	MINITRAN 0.4 MG/HR PATCH	030302	4	2011
\$24.00				0.000	\$24.00	0.080000	300.000	0.000	300.000	MINITRAN 0.2 MG/HR PATCH	030202	4	2011
\$72.23				0.000	\$72.23	0.160500	450.000	0.000	450.000	MINITRAN 0.1 MG/HR PATCH	030102	4	2011
\$241.99				0.000	\$241.99	0.345700	700.000	0.000	700.000	METROGEL-VAGINAL 0.75% GEL	020025	4	2011
\$6,925,96	\$6.9	Qtr. Total								Pre-Petition Units			
\$427.68	56.000 \$4			0.000	\$427.68	7.637100	56,000	0.000	56.000	MAXAIR AUTOHALER 0.2 MG AERO	081521	3	2011
\$3,437.21	П			0.000	\$3,437.21	7.956500	432,000	0.000	432.000	ALDARA 5% CREAM	061024	3	2011
\$2,697.25				0.000	\$2,697.25	7.956500	339.000	0.000	339.000	ALDARA 5% CREAM	061012	3	2011
\$4.07				0.000	\$4.07	0.067800	60.000	0.000	60.000	MINITRAN 0.4 MG/HR PATCH	030302	3	2011
\$2.48				0.000	\$2.48	0.082500	30.000	0.000	30.000	MINITRAN 0.2 MG/HR PATCH	030202	3	2011
\$5.06				0.000	\$5.06	0.168500	30.000	0.000	30.000	MINITRAN 0.1 MG/HR PATCH	030102	з	2011
\$352.21				0.000	\$352.21	0.359400	980.000	0.000	980.000	METROGEL-VAGINAL 0.75% GEL	020025	3	2011
94	F	Cur. Iotal											
\$1,295.88	168.000 \$1,23			0.000	\$1,295.88	7.713600	168.000	0.000	168.000	MAXAIR AUTOHALER 0.2 MG AERO	081521	2	2011
\$9,244.68	十			0.000	\$9,244.68	9.019200	1,025.000	0.000	1,025.000	ALDARA 5% CREAM	061024	2	2011
\$6,015.81	$\top$			0.000	\$6,015.81	9.019200	667.000	0.000	667.000	ALDARA 5% CREAM	061012	2	2011
\$120.98				0.000	\$120.98	0.183300	660.000	0.000	660.000	MINITRAN 0.6 MG/HR PATCH	030402	2	2011
\$20.95				0.000	\$20.95	0.058200	360.000	0.000	360.000	MINITRAN 0.4 MG/HR PATCH	030302	2	2011
\$19.80				0.000	\$19.80	0.094300	210.000	0.000	210.000	MINITRAN 0.2 MG/HR PATCH	030202	2	2011
\$97.54				0.000	\$97.54	0.158600	615.000	0.000	615.000	MINITRAN 0.1 MG/HR PATCH	030102	2.	2011
\$1,323.00	\$1	3		0.000	\$1,323.00	0.350000	3,780.000	0.000	3,780.000	METROGEL-VAGINAL 0.75% GEL	020025	2	2011
(\$205.16)	(\$2)	Qtr. Total											
(\$136.77)	(24.00) (\$13	\$9,363.29	5.698900	1,643.000	\$9,226.52	5.698900	1,619.000	(24.000)	1,643.000	ALDARA 5% CREAM	061024	-	2011
(\$68.39)		\$1,846.44	5.698900	324.000	\$1,778.05	5.698900	312.000	(12.000)	324.000	ALDARA 5% CREAM	061012		2011
181.52		Qur. Total							3	Minor Balances for 2008Q2 through 2010Q1			
ars Comments	Units Dollars		Rate	Units	Billed	Rate	Oty	Q Ag	ည်း သူ	Description	#	윧	Year
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	Date	Report Date			mber	Manufacturer Number	3	_		Manufacturer Name	Man		
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					es	Department of Healthcare and Family Services	Healthcare and	epartment of	0				
						īs	State of Illinois						
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#### REBATE AGREEMENT

Between

The Secretary of Health and Human Services (hereinafter referred to as "the Secretary")

and

The Manufacturer Identified in Section XI of this pare ment 1 56 (hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, 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 section 1927 of the Act as interpreted and applied herein:

- (a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.
- (b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" means the AMP for the 7/1/90-9/30/90 quarter for purposes of computing the AMP as of 10/1/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f)"Centers for Medicare & Medicaid Services (CMS)" (formerly HCFA) means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

- (h) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.
- (i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.
- (j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

- (k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.
- (1) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.
- (m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.
- (n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC

number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

- (o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.
- (p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.
- (q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.
- (r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.
- (s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.
- (t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.
- (u) "Quarter" means calendar quarter unless otherwise specified.
- (v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).
- (w) "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.

- (x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.
- (y) "Single-Award Contract Price" means a price established under a Single-Award Contract.
- (z) "Single Source Drug" will have the meaning set forth in Section 1927 (k) (7) (A) (iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.
- (aa) "States" means the 50 states and the District of Columbia.
- (bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.
- (cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.
- (dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.
- (ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

# II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

- (b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.
- (c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.
- (d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.
- (e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.
- (f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.
- (g) To directly notify the States of a New Drug's Coverage.
- (h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.
- (i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

#### III SECRETARY'S RESPONSIBILITIES

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- (a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.
- (b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.
- (c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

#### **IV PENALTY PROVISIONS**

- (a) The Secretary may impose a civil monetary penalty under III(b), up to \$100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).
- (b) The Secretary may impose a civil monetary penalty, in an amount not to exceed \$100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).
- (c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by \$10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

# V DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

- (a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).
- (b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

- (c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).
- (d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.
- (e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.
- (f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

#### <u>VI</u> <u>DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS</u> <u>AND STATE SYSTEMS ISSUES</u>

- (a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.
- (b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

#### VII CONFIDENTIALITY PROVISIONS

- (a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.
- (b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

#### 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 one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.
- (b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).
- (c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.
- (d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.
- (e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

#### IX GENERAL PROVISIONS

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

Notice to the Secretary will be sent to:

Center for Medicaid and State Operations Family and Children's Health Programs Group Division of Benefits, Coverage and Payment Post Office Box 26686 Baltimore, MD 21207-0486 Notices to CMS concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations Finance, Systems and Quality Group Division of State Systems Post Office Box 26686 Baltimore, MD 21207-0486

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

Notice 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 subject to the conditions specified in section 1927 and this agreement.
- (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, 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) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.
- (f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.
- (g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.
- (h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X	Α	PP)	<b>END</b>	IX

Appendix A attached hereto is part of this agreement.

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES 13
By: Savarf C. Gendan
Date
Title: Director Finance, Systems and Budget Group Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services  Department of Health and Human Services
Department of Health and Human Services
ACCEPTED FOR THE MANUFACTURER
I certify that I have made no alterations, amendments or other changes to this rebate agreement.  By: Robert Moccia
(signature) (please print name)
Title: President a coo
Name of Manufacturer: Graceway Marmaceuticals & Formerly Chester Valley Pharmaceuticals
Manufacturer Address 2West Liberty Blvd. Ste 203 222 VALLEY CREEK BLVD
Malvem, PA 19355 SUITE 300
EXTON, PA 19341
Manufacturer Labeler Code(s): 13453, 29336
Date: January 9, 2007
FEDEVARY 11, 2008

#### **REBATE AGREEMENT**

Between

The Secretary of Health and Human Services (hereinafter referred to as "the Secretary")

and

The Manufacturer Identified in Section XI of this page ment 1 56 (hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, 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 section 1927 of the Act as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

- (c) "Base Date AMP" means the AMP for the 7/l/90-9/30/90 quarter for purposes of computing the AMP as of 10/l/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.
- (d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

- (e)"Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.
- (f)"Centers for Medicare & Medicaid Services (CMS)" (formerly HCFA) means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.
- (g)"Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

- (h) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.
- (i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.
- (j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508 (November 5, 1990), can be modified to give a greater rebate percentage.

- (k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.
- (1) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.
- (m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.
- (n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC

number; and 5) Total amount paid during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

- (o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.
- (p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.
- (q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.
- (r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.
- (s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any price less than 10% of the AMP in the same quarter for which the AMP is computed.
- (t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927(k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.
- (u) "Quarter" means calendar quarter unless otherwise specified.
- (v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).
- (w) "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.

- (x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.
- (y) "Single-Award Contract Price" means a price established under a Single-Award Contract.
- (z) "Single Source Drug" will have the meaning set forth in Section 1927 (k) (7) (A) (iv) of the Act. It also includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.
- (aa) "States" means the 50 states and the District of Columbia.
- (bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.
- (cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.
- (dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.
- (ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

#### II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

- (b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.
- (c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.
- (d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.
- (e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.
- (f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.
- (g) To directly notify the States of a New Drug's Coverage.
- (h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.
- (i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

#### III SECRETARY'S RESPONSIBILITIES

- (a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.
- (b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.
- (c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

#### IV PENALTY PROVISIONS

- (a) The Secretary may impose a civil monetary penalty under III(b), up to \$100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).
- (b) The Secretary may impose a civil monetary penalty, in an amount not to exceed \$100,000, for each item of false information as set forth in 1927(b)(3)(C)(ii).
- (c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by \$10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

#### V DISPUTE RESOLUTION -- MEDICAID UTILIZATION INFORMATION

- (a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).
- (b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

- (c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).
- (d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.
- (e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.
- (f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

# VI DISPUTE RESOLUTION -- PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

- (a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.
- (b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

# VII CONFIDENTIALITY PROVISIONS

- (a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.
- (b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

#### 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 one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.
- (b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).
- (c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.
- (d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.
- (e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

### IX GENERAL PROVISIONS

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

Notice to the Secretary will be sent to:

Center for Medicaid and State Operations Family and Children's Health Programs Group Division of Benefits, Coverage and Payment Post Office Box 26686 Baltimore, MD 21207-0486 Notices to CMS concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations Finance, Systems and Quality Group Division of State Systems Post Office Box 26686 Baltimore, MD 21207-0486

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

Notice 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 subject to the conditions specified in section 1927 and this agreement.
- (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, 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) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.
- (f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.
- (g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.
- (h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

# X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES
FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES 1
By: Javan ( Jundian
Date
Title: Director Finance, Systems and Budget Group Center for Medicaid and State Operations Centers for Medicare & Medicaid Services Department of Health and Human Services
ACCEPTED FOR THE MANUFACTURER
I certify that I have made no alterations, amendments or other changes to this rebate agreement.
By: Sole Muccia Robert Moccia
(signature) (please print name)
Title: <u>Vresident 4 COO</u>
Name of Manufacturer: Graceway Prarmaceuticals, Charmery Chester Valley Pharmaceuticals
Manufacturer Address 2 West Liberty Blvd. Ste 203
Malvem, PA 19355
Manufacturer Labeler Code(s): 13453
Date: January 9, 2007



Pat Quinn, Governor Julie Hamos, Director

401 S. Clinton Chicago, IL 60607-3800

**Telephone:** (312) 793-8616

**TTY**: (800) 526-5812

February 23, 2012

BMC Group, Inc. Attn: Graceway Claims Processing PO Box 3020 Chanhassen, MN 55317-3020

Re: Graceway Pharmaceuticals, LLC 11-13036

#### Dear Sir:

I am enclosing an original Proof of Claim in the above captioned case, a copy and a stamped, self-addressed return envelope. Please file the original and date stamp and return the copy in the return envelope.

Sincerely,

William C. Kurylak

Office of General Counsel

c: Jennifer Kieffer, Assistant Attorney General

willing C. Kufur



# RETURN ADDRESS

# HEALTHCARE AND FAMILY SERVICES Bureau of Administrative Hearings Medical Vendor Hearings

401 South Clinton, 6th Floor- Chicago, IL 60607

Postmaster: This parcel may be opened for inspection if necessary.

ADDRESS SERVICE REQUESTED

To

BMC Group, Inc.

Attn: Graceway Claims Processing P. O. Box 3020

Chanhassen, MN 55317 - 3020

RECEIVED

FEB 27 2012

BMC GROUP