

Congress of the United States
Washington, DC 20515

July 29, 2015

The Honorable Stephanie Rawlings-Blake
Mayor, City of Baltimore, Maryland
President, United States Conference of Mayors
1620 I Street NW
Washington, D.C. 20006

The Honorable Sallie Clark
Commissioner, County of El Paso, Colorado
President, National Association of Counties
25 Massachusetts Avenue NW, Suite 500
Washington, D.C. 20001

Dear Mayor Rawlings-Blake and Commissioner Clark:

We believe government agencies across the country are being overcharged for a critical drug called naloxone that is used by first responders and emergency medical personnel to reverse the life-threatening effects of heroin and other opioid overdoses. The good news is that officials in several states, including New York and Ohio, have successfully negotiated agreements with Amphastar Pharmaceuticals to reduce the final cost of naloxone, and officials in other states are now doing the same.

Naloxone has become an essential tool for first responders and other medical personnel who respond to many of these opioid overdoses. However, over the past year, police departments, law enforcement agencies, and state and local public health officials across the country have expressed concern over the rising prices charged by the manufacturers of this life-saving drug.

According to the *New York Times*, “police and public health officials from New York to San Francisco are facing sticker shock” as prices for naloxone have spiked “in some cases by 50 percent or more.” Chuck Wexler, Executive Director of the Police Executive Research Forum, notes that these price spikes have coincided with an increasing number of large city police departments deciding to supply their officers with the drug: “It’s not an incremental increase. ... There’s clearly something going on.”¹

In January, after months of negotiations, New York Attorney General Eric Schneiderman announced an agreement with Amphastar to provide rebates of \$6 per dose of naloxone paid for directly, or reimbursed by, public agencies within the state. The agreement also requires Amphastar to increase these rebates to match—dollar-for-dollar—any future price increases for naloxone. In March, Ohio Attorney General Mike DeWine announced a similar agreement with Amphastar. We are enclosing both of these agreements for your review.

¹ *Naloxone, a Drug to Stop Heroin Deaths, Is More Costly, the Police Say*, New York Times (Nov. 30, 2014) (online at www.nytimes.com/2014/12/01/nyregion/prices-increase-for-antidote-to-heroin-overdoses-used-by-police.html).

As you know, deaths from heroin and other opioid overdoses have been increasing at alarming rates. Between 1999 and 2013, there was a four-fold increase in the number of fatal overdoses of both prescription opioid pain relievers and heroin.² Meanwhile, non-fatal overdoses have also soared, with more than one million drug-related emergency room visits reported each year between 2008 and 2011—and fully 14% of visits for unintentional drug poisoning involved opioid-related drugs.³

The opioid abuse epidemic is a public health emergency that must be addressed, and no company should jeopardize the progress being made in tackling this emergency by overcharging for a critically important drug like naloxone. For these reasons, earlier this month, we wrote to the National Governors Association, the National Lieutenant Governors Association, and the National Association of Attorneys General encouraging their members to negotiate similar agreements with Amphastar.

Since city and county officials are on the front lines of our country's opioid epidemic—and since they are often the primary purchasers of naloxone—we encourage your members to make this issue a priority and urge your elected officials to negotiate agreements with Amphastar to reduce the price of this lifesaving drug.

Thank you for your attention to this critically important public health issue.

Sincerely,



Representative Elijah E. Cummings
Ranking Member
Committee on Oversight and Government Reform
United States House of Representatives



Senator Bernard Sanders
Ranking Member
Subcommittee on Primary Health and
Retirement Security
Committee on Health, Education, Labor and
Pensions
United States Senate

Enclosures

² National Institute on Drug Abuse, *National Overdose Deaths from Select Prescription and Illicit Drugs* (Feb. 2015) (online at www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates).

³ National Center for Health Statistics, *Emergency Department Visits for Drug Poisoning: United States, 2008—2011* (Apr. 2015) (online at www.cdc.gov/nchs/data/databriefs/db196.pdf).

PAYMENT AGREEMENT

This payment agreement (the "Agreement") is made as of the 27th day of January, 2015 (the "Effective Date") by and between Amphastar Pharmaceuticals, Inc., a Delaware Corporation, with its principal offices and place of business at 11570 6th Street, Rancho Cucamonga, California 91730, U.S.A. ("Amphastar") on the one hand, and the Office of the Attorney General of the State of New York, with offices at 120 Broadway, New York, New York 10271, U.S.A. ("NYAG"), on the other hand, each of Amphastar and NYAG a "Party," and together, the "Parties."

RECITALS

WHEREAS, New York and other states are confronting a profound public health challenge, as the number of heroin and opioid-related deaths continues to increase;

WHEREAS, with proper, timely administration, the generic drug naloxone reverses the effects of an overdose of heroin or another opioid, acting as an antidote and saving lives;

WHEREAS, NYAG established the Community Overdose Prevention Program, which sought to prevent avoidable opioid-related deaths by covering the costs of naloxone and associated training for law enforcement agencies in New York;

WHEREAS, the State of New York, local governments in New York, and associated public entities, including but not limited to the State Department of Health ("DOH"), the City of New York ("NYC"), and the governments of individual New York counties, likewise established programs to respond to the heroin and opioid epidemic by distributing, purchasing, or funding the purchase of naloxone;

WHEREAS, Amphastar raised prices for its current naloxone products in fall 2014 ("Naloxone");

WHEREAS, NYAG transmitted a letter to Amphastar, dated December 1, 2014, expressing concern that the increase in Naloxone pricing could adversely affect access to the drug in New York State;

WHEREAS, Amphastar transmitted a response letter to NYAG's letter on or about December 3, 2014, maintaining that its pricing of Naloxone is based upon legitimate and lawful business factors;

WHEREAS, in a mutual good faith effort to amicably resolve NYAG's stated pricing concerns, the parties have engaged in discussions regarding Amphastar's Naloxone pricing; and

WHEREAS, Amphastar and NYAG each believe that the obligations imposed by this agreement are beneficial to the public and will improve access to Naloxone, and will potentially save lives.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

AGREEMENT

1. Payment Amount. Amphastar shall make a payment ("Payment") in the amount of \$6.00 (the "Payment Amount") for each Amphastar Naloxone Syringe (a "Syringe") where either (a) the purchase price of the Syringe was reimbursed by a government or public entity in New York ("NY Agency"), including but not limited to NYAG, DOH, or NYC; or (b) an NY Agency purchased the Syringe and where that NY Agency will receive no reimbursement for the costs of that Syringe from any other NY Agency. Amphastar shall pay the Payment Amount associated with a given Syringe regardless of whether the Syringe was purchased directly from Amphastar or from a third party.
2. Payment Increase. Notwithstanding paragraph 1, in the event Amphastar increases its wholesale acquisition cost ("WAC") of a Naloxone Syringe ("WAC Increase"), Amphastar shall increase the Payment Amount by the actual dollar amount of the WAC Increase to offset any increase in the Syringe price. However, in no event shall the Payment Amount be reduced.
3. Payment Procedures. An NY Agency seeking Payments under this Agreement shall submit to Amphastar a written accounting certifying the number of Naloxone Syringes purchased or reimbursed by the NY Agency during a given quarter, i.e., a three (3) month time period (a "Certified Request"), within sixty (60) business days of the conclusion of the quarter. This Certified Request shall include paid invoices or other reasonably adequate documentation of the number of Syringes purchased. Amphastar shall pay the total accrued Payment Amounts to the submitting NY Agency within ninety (90) business days of receipt of a Certified Request. Amphastar shall mail a report to NYAG each quarter listing each NY Agency that submitted a Certified Request to Amphastar and the total Payment Amounts disbursed to each such NY Agency.
4. Special Payment Procedures. Notwithstanding paragraph 3, in the event more than ten (10) separate NY Agencies submit Certified Requests to Amphastar in a given quarter, Amphastar shall collect all Certified Requests it receives and forward them in a single submission to NYAG. Within sixty (60) days of receiving these Certified Requests from Amphastar, NYAG shall consolidate them into a single Certified Request ("Consolidated Request") and submit this Consolidated Request to Amphastar on behalf of all NY Agencies seeking Payments that quarter. Within sixty (60) business days of receipt of the Consolidated Request, Amphastar shall pay the total accrued Payment Amounts reflected in the Consolidated Request to NYAG. NYAG shall thereafter disburse Payments to NY Agencies as required.
5. Term and Termination. This Agreement shall apply to Syringes purchased within one (1) year following the Effective Date of this Agreement (the "Term"). Following the payment of all Payment Amounts accrued during the Term and submitted for reimbursement pursuant to paragraph 3 or paragraph 4 above, this Agreement shall terminate ("Termination"), except for paragraphs 6 through 14, which shall survive Termination.
6. Liability Exclusion. Except as otherwise may be stated herein, Amphastar's liability under this Agreement is limited to payment of the Payment Amount for Syringes purchased during the Term, and Amphastar otherwise shall assume no further liability pursuant to this Agreement, including liability for damages of any type (including direct, indirect, and consequential damages). Except as provided in paragraph 7 below, however, nothing in this Agreement shall be construed to alter or limit Amphastar's existing legal obligations or liabilities, including but not limited to those arising from the manufacture or marketing of Naloxone.
7. Assurance of Discontinuance. NYAG finds the financial relief and other obligations set forth in this agreement to be in the public interest, accepts the terms of this Agreement in lieu of

commencing any legal proceeding, and hereby agrees not to take legal action against Amphastar or any of its Affiliates, predecessors, successors, parents, subsidiaries, assigns, agents, administrators, attorneys, directors, shareholders, officers, employees, or representatives in connection with its 2014 pricing of Naloxone. For the avoidance of doubt, nothing in this Agreement shall be construed as an admission or concession by Amphastar of any liability in connection with its pricing of Naloxone prior to the Effective Date.

8. Disclaimer. Amphastar expressly disclaims any endorsement or promotion of off-label use by NYAG and/or any NY Agency of any of Amphastar's products, including Amphastar's Naloxone.

9. Amendment. Unless otherwise provided herein, this Agreement may not be changed, waived, discharged, or terminated orally, but instead only by a written document that is signed by the duly authorized officers of both Parties.

10. Severability. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any term or provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement and this Agreement shall be interpreted and construed as if such provision had never been contained herein.

11. Governing Law. This Agreement shall be governed by and interpreted under the laws the State of New York without regard to its conflict or choice of law provisions. Amphastar agrees not to raise or interpose in any way their state of incorporation as a defense on grounds of personal jurisdiction as to any cause of action, claim, or argument arising from the enforcement of this Agreement by NYAG or any NY Agency.

12. Third Party Beneficiaries. The Parties agree that any NY Agency purchasing Naloxone during the Term constitutes an intended third-party beneficiary of this Agreement.

13. Entire Agreement. This Agreement includes all exhibits attached hereto and constitutes the entire agreement by and between the Parties as to the subject matter hereof. This Agreement supersedes and replaces in its entirety all prior agreements, understandings, letters of intent, and memoranda of understanding by and between the Parties hereto, in either written or oral form.

14. Counterparts; Electronic or Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and upon such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

Amphastar Pharmaceuticals, Inc.

By:  _____

Name: Jason Shandell

Title: President

Eric T. Schneiderman
Attorney General of the State of New York

By:  _____ 2/4/15

Name: Simon G. Brandler

Title: Senior Advisor & Special Counsel

NALOXONE PAYMENT AGREEMENT

This Naloxone Payment Agreement (the "Agreement") is made as of the 2nd day of March, 2015 (the "Effective Date") between Amphastar Pharmaceuticals, Inc., a Delaware corporation, with its principal offices and place of business at 11570 6th Street, Rancho Cucamonga, California 91730 ("Amphastar") and the Office of Ohio Attorney General Mike DeWine, 30 E. Broad St., Columbus, Ohio 43215 ("Ohio AG"). The Ohio AG and Amphastar are collectively referred to as the "Parties" and individually as a "Party".

RECITALS

- A. WHEREAS, Amphastar produces naloxone, an opioid antagonist that various organizations in Ohio use to reduce the rates of death due to overdose ("Naloxone");
- B. WHEREAS, various organizations located within the state of Ohio established programs to respond to the current opiate epidemic by purchasing, distributing, or funding the purchase of Naloxone;
- C. WHEREAS, Amphastar raised wholesale prices for Naloxone products sometime in the fall of 2014;
- D. WHEREAS, on February 13, 2015, Ohio Attorney General Mike DeWine sent a letter expressing concern that the price increase in Naloxone could adversely affect access to the drug in Ohio;
- E. WHEREAS, Amphastar maintains that its pricing of Naloxone is based upon legitimate and lawful business factors;
- F. WHEREAS, in a good faith effort to amicably resolve Ohio AG's pricing concerns, the Parties have engaged in discussions regarding Amphastar's Naloxone pricing; and
- G. WHEREAS, Amphastar and Ohio AG believe the obligations imposed by this Agreement are beneficial to the public and will improve access to Naloxone, and will potentially save lives.

Now therefore, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

TERMS OF AGREEMENT

1. Payment Amount. Amphastar shall make a payment in the amount of \$6.00 ("Payment Amount") for each Amphastar Naloxone syringe (a "Syringe") purchased by a Public Entity in Ohio. For purposes of this Agreement, a "Public Entity" is any non-federal governmental entity located within Ohio, including but not limited to state agencies (e.g., Ohio Department of Health, Ohio Department of Mental Health and Addiction Services), Project DAWN community

programs, county or other local governments, or law enforcement agencies. In the event that a Public Entity distributes or resells Syringes to other Public Entities, the Ohio AG will only permit the last purchaser to receive reimbursement for a Syringe.

Amphastar shall pay the Payment Amount associated with a given Syringe regardless of whether the Syringe was purchased directly from Amphastar or from a third party (including wholesale distributors). In no event shall the Payment Amount be reduced.

2. Payment Increase. Notwithstanding the provisions of paragraph 1, above, in the event Amphastar increases its wholesale acquisition cost of a Syringe, Amphastar shall immediately increase the Payment Amount by the actual dollar amount of the wholesale acquisition cost increase in the Syringe price for all Syringes purchased by a Public Entity following the price increase. During the Term (as defined in Section 4) of this Agreement, Amphastar shall notify the Ohio AG within 30 business days following any wholesale price increase of Naloxone to Public Entity purchasers.
3. Payment Procedures. Within 30 days following the end of a calendar quarter, a Public Entity seeking payment under this Agreement shall submit to the Ohio AG a written accounting certifying the number of Syringes purchased by the Public Entity during a given calendar quarter or part thereof ("Certified Request"). This Certified Request shall include paid invoices or other reasonably adequate documentation of the number of Syringes purchased by the Public Entity and shall not include any Syringes that have been resold to another Public Entity for which that other Public Entity is eligible to seek reimbursement.

Within 60 days following the end of a calendar quarter, the Ohio AG shall consolidate all of the Certified Requests it has received into a single summary submission (but that includes as back-up, copies of the individual Certified Requests) (collectively, the "Summary Certified Request") to Amphastar on behalf of all Public Entities who submitted Certified Requests for that particular quarter. Amphastar shall pay the entire Payment Amount to the Ohio AG within 90 business days following its receipt of the Summary Certified Request. The Ohio AG shall in turn disburse payments to each Public Entity in a timely manner.

All Certified Requests by a Public Entity for Syringes purchased during the Term of this Agreement must be submitted to Amphastar before December 31, 2016 to participate in this program.

4. Term and Termination. This Agreement shall apply to Syringes purchased within one year following the Effective Date of this Agreement (the "Term"). Following payment of all Payment Amounts accrued during the Term and submitted for reimbursement pursuant paragraph 3 above, this Agreement shall terminate, except for paragraphs 5 through 13, which shall survive termination.

5. Liability Exclusion. Except as otherwise may be stated herein, Amphastar's liability under this Agreement is limited to payment of the Payment Amount for Syringes purchased during the Term, and Amphastar otherwise shall assume no further liability pursuant to this Agreement, including liability for damages of any type (including direct, indirect and consequential damages). Except as provided in paragraph 6 below, however, nothing in this Agreement shall be construed to alter or limit Amphastar's existing legal obligations relating to product liability, including but not limited to those arising from the manufacture or marketing of Naloxone.
6. Assurance of Discontinuance. Ohio AG finds the financial relief and other obligations set forth in this Agreement to be in the public interest, accepts the terms of this Agreement in lieu of commencing any legal proceeding, and hereby agrees not to take legal action against Amphastar or any of its affiliates, predecessors, successors, parents, subsidiaries, assigns, agents, administrators, attorneys, directors, shareholders, officers, employees or representatives in connection with the pricing of Naloxone in 2014. Nothing in this Agreement shall be construed as an admission or concession by Amphastar of any liability in connection with its pricing of Naloxone prior to the effective date of this Agreement.
7. Disclaimer. Amphastar expressly disclaims any endorsement or promotion of off-label use by any Public Entity of any of Amphastar's products, including Amphastar's Naloxone.
8. Amendment. Unless otherwise provided herein, this Agreement may not be changed, waived, discharged or terminated orally, but instead only by a written document that is signed by the duly authorized officers of the Parties.
9. Severability. Whenever possible, each provision of the Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any term or provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of the Agreement and this Agreement shall be interpreted and construed as if such provision has never been contained herein.
10. Governing law. This Agreement shall be governed by and interpreted under the laws of the state of Ohio without regard to its conflict or choice of law provisions. Amphastar agrees not to raise or interpose in any way their state of incorporation as a defense on grounds of personal jurisdiction as to any cause of action, claim or argument arising from the enforcement of this Agreement by Ohio AG or any Public Entity.
11. Third party Beneficiaries. The Parties agree that any Public Entity purchasing Naloxone during the Term constitutes an intended third-party beneficiary of this Agreement.
12. Entire Agreement. This agreement constitutes the entire agreement by and between the Parties as to the subject matter hereof. This agreement supersedes and replaces in its entirety all prior

agreements, understandings, letters of intent and memoranda of understanding by and between the Parties hereto, in either written or oral form.


13. Counterparts; Electronic of Facsimile Signatures. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument. This Agreement may be executed and delivered electronically or by facsimile and up on such delivery such electronic or facsimile signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

Amphastar Pharmaceuticals, Inc.

By: _____

Name: _____

Title: _____



Jason Shandell

President

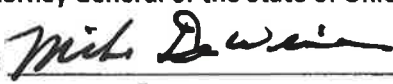
Mike DeWine

Attorney General of the State of Ohio

By: _____

Name: _____

Title: _____



MIKE DEWINE

ATT. GEN. (OHIO)