

**Congress of the United States**  
**House of Representatives**

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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<http://oversight.house.gov>

July 7, 2015

The Honorable Larry Hogan  
Governor  
State of Maryland  
100 State Circle  
Annapolis, MD 21401

The Honorable Boyd Rutherford  
Lieutenant Governor  
State of Maryland  
100 State Circle  
Annapolis, MD 21401

The Honorable Brian E. Frosh  
Attorney General  
State of Maryland  
St. Paul Plaza, 200 St. Paul Place  
Baltimore, MD 21202

Dear Governor Hogan, Lieutenant Governor Rutherford, and Attorney General Frosh:

I believe the State of Maryland is being overcharged for a critical drug called naloxone that is used by first responders and medical personnel to reverse the life-threatening effects of heroin and other opioid overdoses, and I urge you to make sure that the company charging these prices is not allowed to continue taking advantage of the citizens of Maryland. Governors and Attorneys General in other states, including New York, have taken aggressive action to reduce the amounts paid to this company, Amphastar Pharmaceuticals, and I encourage you to do the same.

I have been investigating the increasingly high prices that Amphastar has been charging for naloxone since last fall. As you may know, naloxone has become a staple for first responders and other medical personnel responding to overdoses of heroin and other opioids. Over the past year, however, police departments, law enforcement agencies, and public health officials across the country have expressed concern over the rising prices being charged for this drug.

According to a report in the *New York Times*, "police and public health officials from New York to San Francisco are facing sticker shock: Prices for a popular form of the

medication, naloxone, are spiking, in some cases by 50 percent or more.”<sup>1</sup> Some have suggested that these price spikes coincide with an increasing number of large city police departments deciding to supply their officers with the drug. Chuck Wexler, the Executive Director of the Police Executive Research Forum, stated: “It’s not an incremental increase. ... There’s clearly something going on.”<sup>2</sup>

In January, after months of negotiation, the Attorney General of New York 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.<sup>3</sup> The agreement also requires Amphastar to increase these rebates to match—dollar-for-dollar—any future price increases.<sup>4</sup> In March, the Attorney General of Ohio announced a similar agreement with Amphastar.<sup>5</sup> I am enclosing these agreements for your review.

Maryland has not been immune to these price increases. According to press reports, the price of naloxone in Maryland has increased by a staggering 111% from June 2014 to January 2015, rising from \$19 per dose to \$41 per dose.<sup>6</sup> In addition, Maryland’s Department of Health and Mental Hygiene recently surveyed the 37 entities participating in the State’s naloxone training and distribution program, and 19—more than 75% of those participating in the survey—reported price increases.<sup>7</sup> In addition, 17 of these entities reported that these price increases negatively affect their ability to train and certify individuals and undertake outreach and promotion efforts. Several entities warned that they may not be able to afford to distribute naloxone going forward.<sup>8</sup>

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<sup>1</sup> *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](http://www.nytimes.com/2014/12/01/nyregion/prices-increase-for-antidote-to-heroin-overdoses-used-by-police.html)).

<sup>2</sup> *Id.*

<sup>3</sup> Attorney General Eric T. Schneiderman, *Press Release: A.G. Schneiderman Announces Agreement to Cut and Cap the Price of Heroin Overdose Antidote for All Agencies in New York State* (Feb. 5, 2015) (online at [www.ag.ny.gov/press-release/ag-schneiderman-announces-agreement-cut-and-cap-price-heroin-overdose-antidote-all](http://www.ag.ny.gov/press-release/ag-schneiderman-announces-agreement-cut-and-cap-price-heroin-overdose-antidote-all)).

<sup>4</sup> *Id.*

<sup>5</sup> Attorney General Mike DeWine, *Press Release: Ohio Attorney General DeWine Announces Agreement with Naloxone Manufacturer* (Mar. 4, 2015) (online at [www.ohioattorneygeneral.gov/Media/News-Releases/March-2015/Ohio-Attorney-General-DeWine-Announces-Agreement-w](http://www.ohioattorneygeneral.gov/Media/News-Releases/March-2015/Ohio-Attorney-General-DeWine-Announces-Agreement-w)).

<sup>6</sup> *Rising Prices Threaten Baltimore’s Heroin Overdose Plan*, Baltimore Business Journal (Jan. 30, 2015) (online at [www.bizjournals.com/baltimore/print-edition/2015/01/30/rising-prices-threaten-baltimores-heroin-overdose.html](http://www.bizjournals.com/baltimore/print-edition/2015/01/30/rising-prices-threaten-baltimores-heroin-overdose.html)).

<sup>7</sup> Maryland Department of Health and Mental Hygiene Behavioral Health Administration, *Overdose Response Program Entity Survey Results* (Apr. 2015).

<sup>8</sup> *Id.*

Deaths from heroin and other opioids have been increasing at an alarming rate in Maryland. Between 2010 and 2013, the fatal heroin overdose rate in Maryland increased by 95%, and the number of heroin-related emergency room visits has more than tripled since 2010.<sup>9</sup> In 2014 alone, 578 people died of heroin overdoses in Maryland, 192 of which occurred in Baltimore City.<sup>10</sup> Prescription drug abuse is also a serious problem: in 2014 alone, 329 people died from prescription opioid overdoses in Maryland.<sup>11</sup>

Governor Hogan and Lieutenant Governor Rutherford have both described opioid abuse in Maryland as a public health “emergency.”<sup>12</sup> I share their deep concern, and I am encouraged that Maryland has taken a number of steps to combat this epidemic, including creating the Heroin and Opioid Emergency Task Force and the Inter-Agency Coordinating Council, setting aside federal funding to expand correctional reentry programs that address addiction, and providing naloxone training, certification, and distribution services to members of the public through the Department of Health and Mental Hygiene.

Maryland should not let Amphastar jeopardize the positive steps the State has already taken by overcharging for this critical drug. I encourage you to take the same aggressive action as other states to negotiate an agreement with this company and then use these savings to make naloxone more widely available. I understand that my staff has already been in contact with your offices and provided you with preliminary information, and we stand ready to help in any way we can.

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<sup>9</sup> Heroin and Opioid Emergency Task Force, *Heroin Facts* (online at <http://governor.maryland.gov/ltgovernor/home/heroin-and-opioid-emergency-task-force/heroin-facts/>).

<sup>10</sup> Maryland Department of Health and Mental Hygiene, *Drug- and Alcohol-Related Intoxication Deaths in Maryland, 2014* (May 2015) (online at [http://bha.dhmh.maryland.gov/OVERDOSE\\_PREVENTION/Documents/2015.05.19%20-%20Annual%20OD%20Report%202014\\_merged%20file%20final.pdf](http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION/Documents/2015.05.19%20-%20Annual%20OD%20Report%202014_merged%20file%20final.pdf)).

<sup>11</sup> *Id.*

<sup>12</sup> Office of Governor Larry Hogan, *Press Release: Governor Hogan, Lt. Governor Rutherford Establish Maryland Heroin And Opioid Task Force and Coordinating Council* (Feb. 25, 2015) (online at <http://governor.maryland.gov/2015/02/24/governor-hogan-lt-governor-rutherford-establish-maryland-heroin-and-opioid-task-force-and-coordinating-council/>). *See also Governor Calls Maryland's Heroin Crisis an Emergency*, WBAL-TV Baltimore (Feb. 24, 2015) (online at [www.wbaltv.com/politics/governor-calls-marylands-heroin-crisis-an-emergency/31452212](http://www.wbaltv.com/politics/governor-calls-marylands-heroin-crisis-an-emergency/31452212)).

The Honorable Larry Hogan, Governor  
The Honorable Boyd Rutherford, Lieutenant Governor  
The Honorable Brian E. Frosh, Attorney General  
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Thank you for your consideration of this request.

Sincerely,

A handwritten signature in blue ink, appearing to read "Elijah E. Cummings". The signature is stylized with large, flowing loops and a prominent flourish at the end.

Elijah E. Cummings  
Ranking Member

Enclosures

## 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: \_\_\_\_\_

Title: \_\_\_\_\_

Jason Shandell

President

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

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Simon G. Brandler

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 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 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: Jason Shandell  
Title: President

Mike DeWine

Attorney General of the State of Ohio

By:   
Name: MIKE DEWINE  
Title: ATT. GEN. (OHIO)