

“SOLE SOURCE” PROCUREMENT JUSTIFICATION

Sole source purchases are goods and services available from only one vendor. There may be just one vendor because of patents or copyrights or simply because the vendor is the only one which supplies the good or service. Using Department must provide a written explanation as to why only this particular product/service is acceptable and why no other will be suitable or acceptable to meet the need. A quote must accompany this form.

Department name: Health and Human Service

1. Name of product or service: NARCAN Nasal Spray \$150,000
2. Name of product manufacturer: Adapt Pharma, Inc.
3. Name of “sole” product supplier or service provider: Adapt Pharma, Inc.
4. Describe in general terms the product/service you are requesting and the intended application.

DAC-HHS would like to purchase a nasal administration non-assembly naloxone treatment unit to dispense to none traditional first responders. Naloxone is a drug that blocks or reverses the effects of opioids overdose in emergency situations. DAC-HHS has received funding by the Substance Abuse and Mental Health Services Administration (SAMHSA) to purchase, store, and distribute naloxone throughout Doña Ana County. SAMHSA mandates the use of a naloxone device that is approved by the Food and Drug Administration (FDA).

5. Describe the unique features/capabilities/characteristics that distinguish it from other products/services.

NARCAN (nasal spray) is a needle-free device, which is ready-to use, this product requires no assembly or priming unlike other naloxone delivery methods. There are no needles, which make it easy to use by non-traditional first responders. Given the risk of blood borne pathogens, the nasal delivery method reduces the chance of these types of exposures because individuals administering the drug do not have to inject the naloxone into the user. Narcan is the only Food and Drug Administration approved device for nasal administration of naloxone.

6. How did you determine there was only one source for the product or service? Provide information on the research that was performed to locate suppliers for this product(s) or service(s). (Please furnish names, addresses and other documentation).

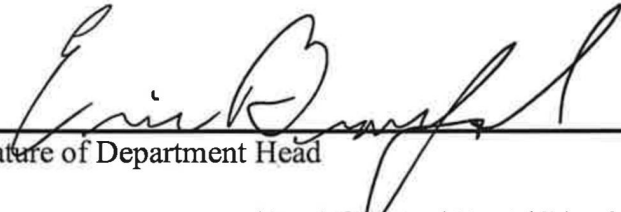
DAC-HHS researched products online and contacted the following pharmaceuticals companies; Adapt Pharma, Amphastar Pharmaceuticals, Kaléo Pharma, Mylan N.V., and Pfizer Pharmaceuticals.

Adapt Pharma (Tele: 1-844-232-7811) offers a product with no assembly, no priming, or no injection required when administering naloxone. Adapt Pharma delivers naloxone treatments in a ready to use out of the package nasal spray.

Kaléo Pharma (Tele: 1-804-545-6360), 111 Virginia St, Richmond, VA 23219, offers an auto-injector naloxone delivery system, contacted vendor on December 3, 2020 to confirm they do not offer nasal delivery naloxone applications. **Amphastar Pharmaceuticals, Inc.** (Tele: 1-800-423-4136), 11570 6th Street Rancho Cucumonga, California 91730, contacted vendor on December 3, 2020 to confirm they do not offer nasal delivery naloxone application. **Pfizer Pharmaceuticals** (tele: 1-800-533-4535), 235 East 42nd Street NY, NY 10017, contacted vendor on December 3, 2020 to confirm they do not offer a nasal delivery naloxone application. **Mylan N.V.** (tele: 1-800-533-4535), 1000 Mylan Blvd Canonsburg, PA 15317, contacted vendor on December 3, 2020 to confirm they do not offer a nasal delivery naloxone application. Mylan N.V. is now part of Viatris.

7. What product supplier or service provider has your Department used until now to satisfy similar requirements?

Our department has submitted a sole source justification for the purchase of **NARCAN** from **Emergent Bio2070Solutions** formerly known as **Adapt Pharma** for the past four fiscal years.


Signature of Department Head


Date

(Attach Quote and Use Additional Sheets As Necessary)

****This form is used by Purchasing Department to determine if a "Sole Source" procurement criterion is met. Completing this form does not guarantee approval of this type of procureme**



July 15, 2020

To Whom It May Concern:

This letter identifies Adapt Pharma as the sole manufacturer of NARCAN® (naloxone HCl) Nasal Spray. Upon approval of the product, the following Press Release was issued:

On November 19, 2015 – Adapt Pharma announced that the U.S. Food and Drug Administration (FDA) has approved NARCAN® Nasal Spray for the emergency treatment of known or suspected opioid overdose. NARCAN® Nasal Spray, a ready-to-use, needle-free device, delivers a 4 mg dose of naloxone in a single 0.1 ml nasal spray. NARCAN® Nasal Spray requires no assembly or priming prior to use.

ABOUT NARCAN® NASAL SPRAY

NARCAN® Nasal Spray is indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.

NARCAN® Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN® Nasal Spray is not a substitute for emergency medical care. Always seek emergency medical assistance in the event of a suspected, potentially life-threatening opioid emergency after administration of the first dose of NARCAN nasal spray.

If the desired response is not obtained after 2 or 3 minutes, administer an additional dose of NARCAN® Nasal Spray using a new NARCAN® Nasal Spray. If the patient responds to NARCAN® Nasal Spray and relapses back into respiratory depression before emergency assistance arrives, administer an additional dose and continue surveillance of the patient. If there is still no response and additional doses are available, administer additional doses of NARCAN® Nasal Spray every 2 to 3 minutes using a new NARCAN® Nasal Spray with each dose until emergency medical assistance arrives. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

Please see Indications and Important Safety Information below.

Please see Full Prescribing Information and Instructions for use by clicking [here](#) or by calling 844-4-NARCAN.

Indication and Important Safety Information- Professional

INDICATIONS

NARCAN® (naloxone hydrochloride) Nasal Spray is an opioid antagonist indicated for the emergency



treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. NARCAN® Nasal Spray is intended for immediate administration as emergency therapy in settings where opioids may be present.

NARCAN® Nasal Spray is not a substitute for emergency medical care.

IMPORTANT SAFETY INFORMATION

NARCAN® Nasal Spray is contraindicated in patients known to be hypersensitive to naloxone hydrochloride.

Seek emergency medical assistance immediately after initial use, keeping the patient under continued surveillance.

Risk of Recurrent Respiratory and CNS Depression: Due to the duration of action of naloxone relative to the opioid, keep the patient under continued surveillance and administer repeat doses of naloxone using a new nasal spray with each dose, as necessary, while awaiting emergency medical assistance.

Risk of Limited Efficacy with Partial Agonists or Mixed Agonists/Antagonists: Reversal of respiratory depression caused by partial agonists or mixed agonists/antagonists, such as buprenorphine and pentazocine, may be incomplete. Larger or repeat doses may be required.

Precipitation of Severe Opioid Withdrawal: Use in patients who are opioid dependent may precipitate opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated and may be characterized by convulsions, excessive crying, and hyperactive reflexes. Monitor for the development of opioid withdrawal.

Risk of Cardiovascular (CV) Effects: Abrupt postoperative reversal of opioid depression may result in adverse CV effects. These events have primarily occurred in patients who had pre-existing CV disorders or received other drugs that may have similar adverse CV effects. Monitor these patients closely in an appropriate healthcare setting after use of naloxone hydrochloride.

The following adverse reactions were observed in a NARCAN Nasal Spray clinical study: increased blood pressure, musculoskeletal pain, headache, nasal dryness, nasal edema, nasal congestion, and nasal inflammation.

See Instructions for Use and full prescribing information in the use of this product.

To report SUSPECTED ADVERSE REACTIONS, contact Adapt Pharma, Inc. at 1-844-4NARCAN (1-844-462-7226) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Jason K Jones

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Executive Director of Trade and Distribution