

May 4, 2018

[Submitted electronically via [www.regulations.gov](http://www.regulations.gov)]

Drug Enforcement Administration

Attn: DEA Federal Register Representative/DRW

8701 Morrisette Drive

Springfield, VA 22152

RE: Controlled Substances Quotas [Docket No. DEA-480]

The undersigned groups thank the Drug Enforcement Administration (DEA) for the opportunity to comment on its proposed rule regarding controlled substances quotas. Although we support DEA's efforts to combat diversion, we are concerned that the proposed rule is focused on diversion to the exclusion of another critical factor – drug shortages. To ensure that legitimate medical needs are met, it is imperative that drug shortages be considered as aggregate production quotas (APQ) are set and adjusted.

As DEA is aware, hospitals and other providers are currently facing critical shortages of a number of injectable opioid medications, including morphine, hydromorphone, and fentanyl. Intravenous (IV) opioids are used in a variety of practice settings within hospitals and ambulatory surgical centers for the treatment of acute, acute on chronic, or chronic pain that cannot be managed because the patient has a contraindication for oral opioid medications. Some opioids, such as fentanyl, also are used for sedation. Injectable opioids are critical to treating the pain needs of patients undergoing interventional procedures (e.g., cardiac catheterization or colonoscopy) and surgeries. These medications are also frequently used in intensive care units for surgical, trauma, burn, or oncology patients, when it is not clinically appropriate to use oral opioids. Having diminished supply of these critical drugs, or no supply at all, can cause suboptimal pain control or sedation for patients in addition to creating burdensome workarounds for healthcare staff.

In a recent letter to DEA<sup>1</sup>, we highlighted the necessity of APQ flexibility until the IV opioid shortages resolve. In response, DEA did adjust APQ limits for certain manufacturers, which we greatly appreciate. However, the injectable opioid shortage is unlikely to resolve in the near term and additional adjustments to APQs will be needed to ensure adequate supplies are available for legitimate medical purposes. Thus, we strongly urge DEA to amend its proposed rule to ensure that shortages are explicitly factored into APQ limits and adjustments. We recommend that DEA add drug shortages as a factor for setting and adjusting APQ under Sections 1303.11 and 1303.13. Further, DEA should request relevant drug shortages data from the Food and Drug Administration's (FDA) drug shortage staff when establishing and adjusting quotas.

In the proposed rule, DEA notes that APQs are meant to provide "adequate supplies for the United States' legitimate needs." Shortages create legitimate needs. As stakeholders representing various areas of health care delivery, we recommend the DEA consider the formulation of opioid when when making quota decisions. Injectable opioids dispensed in clinical settings pose a far lower risk of

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<sup>1</sup> Please see Attachment A: Letter to DEA, dated February 27, 2018.

diversion than other dosage forms dispensed directly to patients. Proactively considering shortages when setting and adjusting APQs will safeguard patient health and safety and ensure critical needs are met.

Additionally, the more data DEA has from FDA regarding shortages, the better equipped DEA will be to calculate APQs that meet those needs. While we understand that DEA looks at the basic class of controlled substance when setting quotas, the FDA can provide shortage data broken down by dosage form, which will help contextualize the actual supply and availability of medications. This may also provide a clearer picture of diversion risk because there are distinct differences among formulations, as noted above.

Thank you for your consideration of our comments. We continue to support DEA's efforts to combat the opioid crisis, and we stand ready to assist the agency in any way possible. If you have questions, the appropriate contact person for each of the signatories can be found below.

Sincerely,

**America's Health Insurance Plans**

Contact: Daniel Nam  
Executive Director, Federal  
Programs  
dnam@ahip.org

**American Hospital Association**

Contact: Ashley Thompson  
Senior Vice President, Public Policy  
Analysis & Development  
athompson@aha.org

**American Society of Anesthesiologists**

Contact: Ashley Walton  
Pain Medicine and Federal Affairs  
Manager  
A.Walton@asahq.org

**American Society of Clinical Oncology**

Contact: Karen Hagerty  
Director, Reimbursement Policy  
Karen.Hagerty@asco.org

**American Society of Health-System  
Pharmacists**

Contact: Jillanne Schulte Wall  
Director, Federal Regulatory Affairs  
jschulte@ashp.org

**Institute for Safe Medication Practices**

Contact: Allen Vaida  
Executive Vice President  
avaida@ismp.org

Attachment A: Letter to DEA (February 27, 2018)

February 27, 2018

[Submitted via U.S. Mail]  
Robert W. Patterson  
Acting Administrator  
Drug Enforcement Administration  
700 Army Navy Drive  
Arlington, VA 22202

[Submitted electronically to [ODLP@usdoj.gov](mailto:ODLP@usdoj.gov)]  
DEA Diversion Control Division  
Attn: Liaison and Policy Section  
8701 Morrisette Drive  
Springfield, VA 22152

RE: Temporary Changes to Aggregate Production Quotas for IV Opioid Products to Address Shortages

The undersigned groups respectfully request that the Drug Enforcement Administration (DEA) adjust aggregate production quotas (APQ) for certain opioids in order to mitigate ongoing drug shortages. As DEA may be aware, hospitals and other providers are currently facing critical shortages of a number of injectable opioid medications, including morphine, hydromorphone, and fentanyl. Intravenous (IV) opioids are used in a variety of practice settings within hospitals and ambulatory surgical centers for the treatment of acute, acute on chronic, or chronic pain that cannot be managed because the patient has a contraindication for oral opioid medications. Some opioids, such as fentanyl, also are used for sedation. Injectable opioids are critical to treating the pain needs of patients undergoing interventional procedures (e.g., cardiac catheterization or colonoscopy) and surgeries. These medications are also frequently used in intensive care units for surgical, trauma, burn, or oncology patients, when it is not clinically appropriate to use oral opioids. Having diminished supply of these critical drugs, or no supply at all, can cause suboptimal pain control or sedation for patients in addition to creating burdensome workarounds for healthcare staff.

Shortages of these injectable medications are largely attributable to manufacturing delays affecting Pfizer, the primary maker of these products, following its acquisition of Hospira. In a letter to customers, Pfizer indicated that the “anticipated full recovery dates for prioritized prefilled syringes have moved to 1Q19 and deprioritized syringes have moved to 2Q19.”<sup>1</sup> On January 31, 2018, Pfizer sent customers a further update informing them that, due to a third-party supplier issue, none of these prefilled syringes of injectable opioids are currently being produced or released.<sup>2</sup>

Because these are vital medications, hospitals have been focused on locating alternative sources. We have been informed, however, that other manufacturers have been unable to step in and produce additional product because the DEA is approving only a small number of requests for the

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<sup>1</sup> See Attachment A, Pfizer Customer Letters, dated July 20, 2017, and Nov. 27, 2017.

<sup>2</sup> See Attachment B, Pfizer Customer Letter, dated Jan. 31, 2018.

requisite pharmaceutical compounds due to current APQ limits. At present, supply options are dwindling.

Severe shortages of injectable opioids may threaten patient care in hospitals and surgical centers. We understand and share the DEA's concern that these medications need to be well-managed and used judiciously to help stem the nation's opioid epidemic. We fully support and use advances in pain management, such as multimodal analgesia, that enable patients to undergo procedures with fewer opioids and less reliance on opioids after surgery. Nonetheless, injectable opioids remain a crucial component of patient management during and immediately after many operations. With no appropriate opioids available, operations would have to be postponed or cancelled. In some cases, this could prove life-threatening to the patient.

Shortages also increase the risk of medication errors. Rather than selecting a product that might be most clinically efficacious for patients, during shortages prescribers are forced to order whichever IV opioid is available. Furthermore, dosing equivalency between the IV opioids differs significantly, which can lead to dosing errors. Moreover, using a more potent opioid based on supply alone defeats the national efforts to use hydromorphone and fentanyl only when absolutely necessary.

Given the ongoing shortages for these injectable medications, we urge DEA to use its discretionary authority to temporarily reallocate or revise APQ to allow other manufacturers to supply product until the shortages resolve. Our request is specific to these injectable medications and does not extend to other dosage forms or opioid products.

We thank DEA for its ongoing efforts to combat the opioid crisis, and we stand ready to assist the agency in any way possible. If you have questions, the appropriate contact person for each of the signatories can be found below.

Sincerely,

**American Hospital Association**

Contact: Ashley Thompson  
Senior Vice President, Public Policy  
Analysis & Development  
athompson@aha.org

**American Society of Health-System  
Pharmacists**

Contact: Jillanne Schulte Wall  
Director, Federal Regulatory Affairs  
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**American Society of Anesthesiologists**

Contact: Ashley Walton  
Pain Medicine and Federal Affairs  
Manager  
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**Institute for Safe Medication Practices**

Contact: Allen Vaida  
Executive Vice President  
avaida@ismmp.org

**American Society of Clinical Oncology**

Contact: Karen Hagerty  
Director, Reimbursement Policy  
Karen.Hagerty@asco.org

Attachment A: Pfizer Customer Letters – July 20, 2017 and Nov. 27, 2017



**Pfizer Inc.**  
275 North Field Drive  
Lake Forest, IL 60045

July 20, 2017

## **Update to Pfizer Injectables Opioid and Non-Opioid Prefilled Syringe Portfolio**

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply shortages so that appropriate contingency plans can be made to facilitate patient care and safety. As such, this letter is to provide you with updated information on the supply status of opioid and non-opioid prefilled syringe (PFS) products. We anticipate that at the end of July we will not be able to meet market demand on opioid and non-opioid PFS products due to remediation efforts at our McPherson manufacturing facility. Although we will continue to manufacture and deliver select presentations throughout the remediation process, we anticipate product shortages and stock outs to begin as early as this month. We expect recovery of prioritized products by the end of Q1 2018.

Pfizer is prioritizing production to minimize patient impact and is making every effort to restock the market. We have prioritized certain CARPUJECT™ and iSecure™ prefilled syringes (see Table A), including select presentations of Diazepam, Heparin, Hydromorphone, Labetalol, Lorazepam, Morphine, and Naloxone. Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products. Pfizer remains committed to the CARPUJECT™ and iSecure™ product line. We are also increasing the production of vials and ampuls where possible to help offset the PFS shortages. However, there will be times when inventory is not available.

Table B lists the CARPUJECT™ and iSecure™ products that have been deprioritized. Once current supply of each product in Table B is exhausted, which will vary by SKU, there will be no further product deliveries until Q1 2018 due to PFS prioritization. It is recommended you check our availability report on our website at [https://www.pfizerinjectables.com/Injectables\\_Availability\\_Report](https://www.pfizerinjectables.com/Injectables_Availability_Report) to receive the most up-to-date information on product availability. You can also contact our Supply Continuity Team between 7:00am – 6:00pm CT to discuss any product availability questions at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]) or via email at [PISupplyContinuity@Pfizer.com](mailto:PISupplyContinuity@Pfizer.com).

In addition, we have worked with all trading partners and asked them to allocate opioid products to help ensure as many customers as possible have access to supply until the next anticipated shipments arrive. Please continue to work with your trading partner.

We are working closely with the FDA Drug Shortage Staff on our plans to manage this shortage. Shortage information is also being provided to the American Society of Health-System Pharmacists (ASHP), and to Group Purchasing Organizations.

We understand the challenges that this shortage poses to clinicians and patients and are fully dedicated to restoring supply, while ensuring the highest quality and safety standards. I am available to speak with you to discuss any questions you may have. You can reach out to me and the Pfizer Injectables leadership team at [PfizerInjectables@Pfizer.com](mailto:PfizerInjectables@Pfizer.com), or through your Pfizer representative, and we will respond as quickly as possible.

Kind regards,

**Shawn Olsson**  
Sr. Manager, Opioid and Syringe Technology Portfolio  
Pfizer Essential Health

**Table A: Prioritized Products with Full Recovery Expected Q1 2018\***

Description	Unit of Sale NDC	Anticipated Recovery
Diazepam Injection, USP, CIV 10 mg/2 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-1273-32	Q1 2018
Heparin Sodium Injection, USP (Preservative-Free) 5,000 USP Units/0.5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-1316-32	Q1 2018
Hydromorphone Hydrochloride Injection, USP, CII 0.5 mg/0.5 mL iSecure™ Luer Lock Glass Syringe (no needle)	00409-1283-05	Q1 2018
Hydromorphone Hydrochloride Injection, USP, CII 1 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-1283-31	Q1 2018
Hydromorphone Hydrochloride Injection, USP, CII 2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-1312-30	Q1 2018
Labetalol Hydrochloride Injection, USP 20 mg/4 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-2339-34	Q1 2018
Lorazepam Injection, USP, CIV 2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-1985-30	Q1 2018
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-1890-01	Q1 2018
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free) 4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-1891-01	Q1 2018
Naloxone Hydrochloride Injection, USP 0.4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)	00409-1782-69	Q1 2018

*\*Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products.*



**Table B: Deprioritized List of Impacted Opioid and Non-Opioid PFS Products\***

Product	Unit of Sale NDC	Description
0.9% Sodium Chloride Injection, USP	00409-1918-32	2 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-33	3 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-35	5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Buprenorphine Hydrochloride Injection, CIII	00409-2012-32	0.3 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Demerol™ (meperidine hydrochloride injection, USP) CII	00409-1176-30	25 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1178-30	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1179-30	75 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1180-69	100 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Diphenhydramine Hydrochloride Injection, USP	00409-2290-31	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Fentanyl Citrate Injection, USP, CII	00409-1276-32	100 mcg/2 mL (50 mcg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Heparin Sodium Injection, USP	00409-1402-12	5,000 USP Units/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Hydromorphone Hydrochloride Injection, USP, CII	00409-1283-10	1 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1312-10	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1304-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Ketorolac Tromethamine Injection, USP	00409-2287-31	30 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2287-23	30 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2287-61	60 mg/2 mL (30 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Lorazepam Injection, USP, CIV	00409-1539-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Metoprolol Tartrate Injection, USP	00409-1778-35	5 mg/5 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Midazolam Injection, USP CIV	00409-2306-62	2 mg/2 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2306-12	2 mg/2 mL (1 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2307-60	5 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-1890-11	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1891-11	4 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1892-01	8 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1892-11	8 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1893-01	10 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1893-11	10 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
Ondansetron Injection, USP	00409-1120-12	4 mg/2 mL (2 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)

\*Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products.

**Table C: List of Opioids that Pfizer Produces in Ampuls and Vials\*\***

<b>Product</b>	<b>Unit of Sale NDC</b>	<b>Description</b>
<b>Demerol™ (meperidine hydrochloride injection, USP) CII</b>	00049-1203-01	25 mg/0.5 mL (50 mg/mL) Glass Ampul
	00409-1253-01	50 mg/mL Glass Ampul
	00409-1254-01	75 mg/1.5 mL (50 mg/mL) Glass Ampul
	00409-1256-01	100 mg/mL Glass Ampul
	00409-1255-02	100 mg/2 mL (50 mg/mL) Glass Ampul
	00409-1181-30	1,500 mg/30 mL (50 mg/mL) Multiple Dose Glass Flip Top Vial
	00409-1201-20	2,000 mg/20 mL (100 mg/mL) Multiple Dose Glass Flip Top Vial
<b>Fentanyl Citrate Injection, USP, CII</b>	00409-9093-32	100 mcg/2 mL (50 mcg/mL) Glass Ampul
	00409-9094-22	100 mcg/2 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
	00409-9093-35	250 mcg/5 mL (50 mcg/mL) Glass Ampul
	00409-9094-25	250 mcg/5 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
	00409-9094-28	500 mcg/10 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
	00409-9094-31	1,000 mcg/20 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
	00409-9093-38	1,000 mcg/20 mL (50 mcg/mL) Glass Ampul
	00409-9094-61	2,500 mcg/50 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
<b>Hydromorphone Hydrochloride Injection, USP, CII</b>	00409-2552-01	1 mg/mL Glass Ampul
	00409-3356-01	2 mg/mL Glass Ampul
	00409-3365-01	2 mg/mL Single Dose Glass Flip Top Vial
	00409-2540-01	4 mg/mL Glass Ampul
	00409-2634-01	(High-Potency Formulation) 10 mg/mL Single Dose Glass Flip Top Vial
	00409-2634-05	(High-Potency Formulation) 50 mg/5 mL (10 mg/mL) Single Dose Glass Flip Top Vial
	00409-2634-50	(High-Potency Formulation) 500 mg/50 mL (10 mg/mL) Single Dose Glass Flip Top Vial
<b>Morphine Sulfate Injection, USP, CII (Preservative-Free and contains an antioxidant)</b>	00409-1134-03	1,000 mg/20 mL (50 mg/mL) Single Dose Glass Flip Top Vial
	00409-1134-05	2,500 mg/50 mL (50 mg/mL) Single Dose Glass Flip Top Vial
<b>Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)</b>	00409-3814-12	5 mg/10 mL (0.5 mg/mL) Single Dose Glass Flip Top Vial
	00409-3815-12	10 mg/10 mL (1 mg/mL) Single Dose Glass Flip Top Vial
	00409-1135-02	250 mg/10 mL (25 mg/mL) Single Dose Glass Flip Top Vial

\*\*Please check our availability report on our website at [https://www.pfizerinjectables.com/Injectables\\_Availability\\_Report](https://www.pfizerinjectables.com/Injectables_Availability_Report) to receive the most up-to-date information on product availability.

**Pfizer Inc.**  
275 North Field Drive  
Lake Forest, IL 60045

November 27, 2017

## **Update to Pfizer Injectables Opioid and Non-Opioid Prefilled Syringe Portfolio**

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply shortages so that appropriate contingency plans can be made to facilitate patient care. Due to longer than expected timelines for upgrade work required at our McPherson manufacturing facility, the currently anticipated full recovery dates for prioritized prefilled syringes (PFS) have moved to 1Q19 and deprioritized syringes have moved to 2Q19. We will continue to manufacture and deliver select presentations throughout the upgrade work taking place but do anticipate backorders and product shortages.

Pfizer will continue to prioritize production of certain Carpuject™ and iSecure™ prefilled syringes (see Table A). Products have been prioritized based on medical necessity and importance to patient care, as determined by customer feedback and our U.S. Medical Affairs team. It is anticipated that the Naloxone Hydrochloride Injection, USP Carpuject™ will remain in adequate supply throughout the upgrade process. Diazepam Injection, USP, CIV Carpuject™ will likely be on long-term back order. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products (see Table B) once supply recovers on the prioritized products. Pfizer remains committed to the Carpuject™ and iSecure™ product line and we are working hard to expedite full recovery.

We are also increasing the production of vials and ampuls (see Table C) where possible to help offset the PFS shortages. However, there will be times when inventory is not available and specifically, the Hydromorphone Hydrochloride Injection, USP, CII Ampul products will be on long term back order.

Please check our availability report on our website at [https://www.pfizerinjectables.com/Injectables\\_Availability\\_Report](https://www.pfizerinjectables.com/Injectables_Availability_Report) to receive the most up-to-date information on product availability. You can also contact our Supply Continuity Team between 7:00am – 6:00pm CT to discuss any product availability questions at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]) or via email at [PISupplyContinuity@Pfizer.com](mailto:PISupplyContinuity@Pfizer.com).

In addition, we have worked with all trading partners and asked them to allocate opioid products to help ensure as many customers as possible have access to supply until the next anticipated shipments arrive. Please continue to work with your trading partner.

We understand the challenges that this shortage poses to clinicians and patients and are fully dedicated to restoring supply, while helping to ensure the highest quality and safety standards. I am available to speak with you to discuss any questions you may have. You can reach out to the Pfizer Injectables leadership team and me at [PfizerInjectables@Pfizer.com](mailto:PfizerInjectables@Pfizer.com) or through your Pfizer representative, and we will respond as quickly as possible.

Kind regards,

**Shawn Olsson**  
Sr. Manager, Opioid and Syringe Technology Portfolio  
Pfizer Essential Health

**Table A: Prioritized List of Products \***

<b>Product</b>	<b>Unit of Sale NDC</b>	<b>Description</b>
<b>Diazepam Injection, USP, CIV</b>	00409-1273-32	10 mg/2 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle) <sup>†</sup>
<b>Heparin Sodium Injection, USP</b>	00409-1316-32	5,000 USP Units/0.5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Hydromorphone Hydrochloride Injection, USP, CII</b>	00409-1283-05	0.5 mg/0.5 mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1283-31	1 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1312-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Labetalol Hydrochloride Injection, USP</b>	00409-2339-34	20 mg/4 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Lorazepam Injection, USP, CIV</b>	00409-1985-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)</b>	00409-1890-01	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1891-01	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Naloxone Hydrochloride Injection, USP</b>	00409-1782-69	0.4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)

*\*Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products.*

*<sup>†</sup>Product is on long term back order*

**Table B: Deprioritized List of Impacted Opioid and Non-Opioid PFS Products\***

Product	Unit of Sale NDC	Description
0.9% Sodium Chloride Injection, USP	00409-1918-32	2 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-33	3 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-35	5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Buprenorphine Hydrochloride Injection, CIII	00409-2012-32	0.3 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Demerol™ (meperidine hydrochloride injection, USP) CII	00409-1176-30	25 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1178-30	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1179-30	75 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1180-69	100 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Diphenhydramine Hydrochloride Injection, USP	00409-2290-31	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Fentanyl Citrate Injection, USP, CII	00409-1276-32	100 mcg/2 mL (50 mcg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Heparin Sodium Injection, USP	00409-1402-12	5,000 USP Units/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Hydromorphone Hydrochloride Injection, USP, CII	00409-1283-10	1 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1312-10	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1304-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Ketorolac Tromethamine Injection, USP	00409-2287-31	30 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2287-23	30 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2287-61	60 mg/2 mL (30 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Lorazepam Injection, USP, CIV	00409-1539-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Metoprolol Tartrate Injection, USP	00409-1778-35	5 mg/5 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
Midazolam Injection, USP CIV	00409-2306-62	2 mg/2 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2306-12	2 mg/2 mL (1 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2307-60	5 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)	00409-1890-11	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1891-11	4 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1892-01	8 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1892-11	8 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1893-01	10 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1893-11	10 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
Ondansetron Injection, USP	00409-1120-12	4 mg/2 mL (2 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)

*\*Products have been prioritized based on medical necessity and importance to patient care. At this time, we are only manufacturing the prioritized products. We will resume production of the deprioritized products once supply recovers on the prioritized products.*

**Table C: List of Opioids that Pfizer Produces in Ampuls and Vials\*\***

Product	Unit of Sale NDC	Description
<b>Demerol™ (meperidine hydrochloride injection, USP) CII</b>	00049-1203-01	25 mg/0.5 mL (50 mg/mL) Glass Ampul
	00409-1253-01	50 mg/mL Glass Ampul
	00409-1254-01	75 mg/1.5 mL (50 mg/mL) Glass Ampul
	00409-1256-01	100 mg/mL Glass Ampul
	00409-1255-02	100 mg/2 mL (50 mg/mL) Glass Ampul
	00409-1181-30	1,500 mg/30 mL (50 mg/mL) Multiple Dose Glass Flip Top Vial
	00409-1201-20	2,000 mg/20 mL (100 mg/mL) Multiple Dose Glass Flip Top Vial
<b>Fentanyl Citrate Injection, USP, CII</b>	00409-9093-32	100 mcg/2 mL (50 mcg/mL) Glass Ampul
	00409-9094-22	100 mcg/2 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
	00409-9093-35	250 mcg/5 mL (50 mcg/mL) Glass Ampul
	00409-9094-25	250 mcg/5 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
	00409-9094-28	500 mcg/10 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
	00409-9094-31	1,000 mcg/20 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
	00409-9093-38	1,000 mcg/20 mL (50 mcg/mL) Glass Ampul <sup>†</sup>
	00409-9094-61	2,500 mcg/50 mL (50 mcg/mL) Single Dose Glass Flip Top Vial
<b>Hydromorphone Hydrochloride Injection, USP, CII</b>	00409-2552-01	1 mg/mL Glass Ampul <sup>†</sup>
	00409-3356-01	2 mg/mL Glass Ampul <sup>†</sup>
	00409-3365-01	2 mg/mL Single Dose Glass Flip Top Vial
	00409-2540-01	4 mg/mL Glass Ampul <sup>†</sup>
	00409-2634-01	(High-Potency Formulation) 10 mg/mL Single Dose Glass Flip Top Vial
	00409-2634-05	(High-Potency Formulation) 50 mg/5 mL (10 mg/mL) Single Dose Glass Flip Top Vial
	00409-2634-50	(High-Potency Formulation) 500 mg/50 mL (10 mg/mL) Single Dose Glass Flip Top Vial
<b>Morphine Sulfate Injection, USP, CII (Preservative-Free and contains an antioxidant)</b>	00409-1134-03	1,000 mg/20 mL (50 mg/mL) Single Dose Glass Flip Top Vial
	00409-1134-05	2,500 mg/50 mL (50 mg/mL) Single Dose Glass Flip Top Vial
<b>Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)</b>	00409-3814-12	5 mg/10 mL (0.5 mg/mL) Single Dose Glass Flip Top Vial
	00409-3815-12	10 mg/10 mL (1 mg/mL) Single Dose Glass Flip Top Vial
	00409-1135-02	250 mg/10 mL (25 mg/mL) Single Dose Glass Flip Top Vial

\*\*Please check our availability report on our website at [https://www.pfizerinjectables.com/Injectables\\_Availability\\_Report](https://www.pfizerinjectables.com/Injectables_Availability_Report) to receive the most up-to-date information on product availability.

<sup>†</sup>Product is on long term back order

Attachment B: Pfizer Customer Letter (Jan. 31, 2018)

**Pfizer Inc.**  
275 North Field Drive  
Lake Forest, IL 60045

January 31, 2018

**Notification of  
CARPUJECT™ and iSecure™ Prefilled Syringe Portfolio  
Supply Interruption**

Dear Valued Customer,

Pfizer Injectables is committed to providing information on supply shortages so that appropriate contingency plans can be made to facilitate patient care. Due to an issue with a 3<sup>rd</sup> party incoming component, all Carpuject and iSecure product releases have been placed on hold. We are currently performing a risk assessment to determine when the Carpuject and iSecure product releases can resume.

A full list of Pfizer Carpuject and iSecure products are provided in the table below.

Please check our availability report on our website at [https://www.pfizerinjectables.com/Injectables\\_Availability\\_Report](https://www.pfizerinjectables.com/Injectables_Availability_Report) to receive the most up-to-date information on product availability. You can also contact our Supply Continuity Team between 7:00am – 6:00pm CT to discuss any product availability questions at 1-844-646-4398 (select option 1 [Customer], then option 3 [Supply Continuity Team]) or via email at [PISupplyContinuity@Pfizer.com](mailto:PISupplyContinuity@Pfizer.com).

We understand the challenges that this shortage poses to clinicians and patients and are fully dedicated to restoring supply, while ensuring the highest quality and safety standards. I am available to speak with you to discuss any questions you may have. You can reach out to the Pfizer Injectables leadership team and me at [PfizerInjectables@Pfizer.com](mailto:PfizerInjectables@Pfizer.com) or through your Pfizer representative, and we will respond as quickly as possible.

Kind regards,

**Shawn Olsson**  
Sr. Manager, Opioid and Syringe Technology Portfolio  
Pfizer Essential Health



**TABLE – List of Carpuject and iSecure Products**

Product	Unit of Sale NDC	Description
<b>0.9% Sodium Chloride Injection, USP</b>	00409-1918-32	2 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-33	3 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1918-35	5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Buprenorphine Hydrochloride Injection, CIII</b>	00409-2012-32	0.3 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Demerol™ (meperidine hydrochloride injection, USP) CII</b>	00409-1176-30	25 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1178-30	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1179-30	75 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1180-69	100 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Diazepam Injection, USP, CIV</b>	00409-1273-32	10 mg/2 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Diphenhydramine Hydrochloride Injection, USP</b>	00409-2290-31	50 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Fentanyl Citrate Injection, USP, CII</b>	00409-1276-32	100 mcg/2 mL (50 mcg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Heparin Sodium Injection, USP</b>	00409-1316-32	5,000 USP Units/0.5 mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1402-12	5,000 USP Units/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Hydromorphone Hydrochloride Injection, USP, CII</b>	00409-1283-05	0.5 mg/0.5 mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1283-31	1 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1312-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1283-10	1 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1312-10	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1304-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Ketorolac Tromethamine Injection, USP</b>	00409-2287-31	30 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2287-23	30 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2287-61	60 mg/2 mL (30 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Labetalol Hydrochloride Injection, USP</b>	00409-2339-34	20 mg/4 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Lorazepam Injection, USP, CIV</b>	00409-1985-30	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1539-31	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Metoprolol Tartrate Injection, USP</b>	00409-1778-35	5 mg/5 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Midazolam Injection, USP CIV</b>	00409-2306-62	2 mg/2 mL (1 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-2306-12	2 mg/2 mL (1 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)
	00409-2307-60	5 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Morphine Sulfate Injection, USP, CII (Preservative and Antioxidant Free)</b>	00409-1890-01	2 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1891-01	4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1890-11	2 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1891-11	4 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1892-01	8 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1892-11	8 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
	00409-1893-01	10 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
	00409-1893-11	10 mg/mL iSecure™ Luer Lock Glass Syringe (no needle)
<b>Naloxone Hydrochloride Injection, USP</b>	00409-1782-69	0.4 mg/mL CARPUJECT™ Luer Lock Glass Syringe (no needle)
<b>Ondansetron Injection, USP</b>	00409-1120-12	4 mg/2 mL (2 mg/mL) iSecure™ Luer Lock Glass Syringe (no needle)