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TO: EMS Service Directors
EMS Service Medical Directors
EMS Training Centers
EMS Personnel

FROM: Brian Litza, Chief
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SUBJECT: Medication Shortages

As many may already know there is a nation wide shortage on several medications but especially epinephrine, D50, and calcium chloride that affect EMS. Our EMS state medical director, Dr. Cady, received a memo from Aurora Medical Center Kenosha of which he has received permission to distribute. We believe this to be the most comprehensive information that we have seen locally and thought it would be good information to disseminate to all providers.

See attached.

<p>Very limited supply available</p>	<p>demand for the product.</p> <p>Estimated Resupply Dates</p> <p>Hospira has available dextrose injection 50% in Ansyrl II 50 mL luer-lock syringes (NDC 00409-7517-16) and 50 mL vials (NDC 00409-6648-02). The 50 mL Lifeshield syringes are on back order with an estimated release date of late-March, 2010.</p>
<p>Epinephrine 1:10,000 (1mg/10ml) syringe</p> <p>Very limited supply available</p>	<p>Reason for the Shortage</p> <ul style="list-style-type: none"> Hospira has epinephrine 0.1 mg/mL emergency syringes on back order due to increased demand. Amphastar discontinued their unapproved emergency drug syringes, including epinephrine 0.1 mg/mL, in December, 2009. <p>Estimated Resupply Dates</p> <p>Hospira has available epinephrine 0.1 mg/mL Abboject emergency syringes with attached 3.5 inch, 18-gauge needle (NDC 00409-4901-18). LifeShield Abboject emergency syringes are on back order with an estimated release date of late-June, 2010.</p>
<p>Ephinephrine 1:1,000 (1mg/1ml) ampules</p> <p>Very limited supply available</p>	<p>Increase demand due to the Ephinephrine syringe shortage</p>
<p>Furosemide injection all sizes (20mg/2ml, 40mg/4ml and 100mg/10ml vials)</p> <p>Very limited supply available</p>	<p>Reason for the Shortage</p> <ul style="list-style-type: none"> APP, American Regent, and Hospira could not provide a reason for the shortage. Wockhardt has discontinued all of their furosemide injection presentations. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> APP has available furosemide 10 mg/mL injection in 2 mL (NDC 63323-0280-02) and 4 mL (NDC 63323-0280-04) vials with an expiration date of January, 2011. The 10 mL vials are on back order and the company cannot estimate a release date. American Regent has all furosemide 10 mg/mL injection presentations on back order and the company estimates a release date of late-June, 2010. <p>Hospira has all furosemide 10 mg/mL injection presentations on allocation.</p>
<p>Heparin - all products affected</p>	<p>Reason for the Shortage</p> <ul style="list-style-type: none"> Baxter has recalled all single-dose and multiple-dose vials of heparin sodium 1,000 unit/mL, 5,000 unit/mL and 10,000 unit/mL concentrations, as well as all heparin lock flush products (i.e., 10 unit/mL and 100 unit/mL). In early 2008, Baxter recalled nine lots of the 1,000 unit/mL concentration and temporarily stopped manufacturing all multiple-dose vials of its 1,000 unit/mL, 5,000 unit/mL, and 10,000 unit/mL heparin sodium injection, due to recent reports of severe allergic reactions in patients receiving bolus doses of these products. However, the warning was broadened to include all heparin vial products in all concentrations, as these are obtained from the same

Very limited supply

source manufacturer. Baxter has stopped manufacturing and shipping these products in order to investigate the cause of these adverse events. In late November, 2009 Baxter announced that all large volume heparin sodium in Dextrose 5% premix solutions will become unavailable for an extended time period. The company is working to implement new manufacturing procedures associated with the new USP reference standard for heparin products.10 Large volume heparin sodium in 0.9% sodium chloride is available.

- APP was allocating supplies of its heparin sodium in response to the Baxter action.
- Hospira states the shortage of heparin vials is due to supply and demand issues. In January, 2010 Hospira announced that all large volume heparin sodium in Dextrose 5% premix solutions and one presentation of heparin sodium in 0.45% sodium chloride (NDC 00409-7650-62) will be unavailable through the end of March, 2010. The company is working to implement new manufacturing procedures associated with the new USP reference standard for heparin products. The company states the large volume solutions formulated in either Dextrose 5% or 0.45% Sodium Chloride are specifically affected because of the impact pH differences have on the new testing.
- Braun recalled 23 lots of their heparin sodium large volume infusion solutions as a precautionary measure after their supplier found a heparin-like contaminant in one lot of raw material. Product subject to the recall was distributed in both the US and Canada, including.
 - Heparin sodium 1,000 unit/500 mL in 0.9% Sodium Chloride injection (NDC 00264-9872-10): Lot numbers J7C477, J7C557, J7C611, J7C705, J7D485, J7E415, J7E416, J7E589, J7N519, and J7N676.
 - Heparin sodium 20,000 unit/500 mL in Dextrose 5% injection (no NDC number, not distributed in US): Lot number J7D580
 - Heparin sodium 25,000 unit/250 mL in Dextrose 5% injection (NDC 00264-9587-20): Lot numbers J7C470, J7D490, J7E420 (not distributed in US), J7E494, J7N556, and J7P476.
 - Heparin sodium 25,000 unit/500 mL in Dextrose 5% injection (NDC 00264-9577-10): Lot numbers J7C684, J7D496, J7E500, J7E577 (not distributed in US), J7N604, and J7P404.
- Covidien recalled 32 lots of prefilled heparin lock syringes after their supplier found a heparin-like contaminant in two lots of raw material. The affected lots include:
 - Heparin sodium 10 unit/mL, 2.5 mL lock flush syringe, NDC 17474-0123-02 (Lot 7051444)
 - Heparin sodium 10 unit/mL, 3 mL lock flush syringe, NDC 17474-0123-03 (Lots 7051524, 7113214)
 - Heparin sodium 10 unit/mL, 5 mL lock flush syringe, NDC 17474-0123-05 (Lots 7051524, 7082274, 7113164, 7113174)
 - Heparin sodium 10 unit/mL, 5 mL lock flush syringe with Bluntip cannula, NDC 08881-1571-25 (Lot 7082274)
 - Heparin sodium 10 unit/mL, 10 mL lock

flush syringe, NDC 17474-0123-01 (Lot 7082274, 7113214)

- Heparin sodium 100 unit/mL 3 mL lock flush syringe, NDC 17474-0125-03 (Lots 7041194, 7072154, 7113034, 8010194)
- Heparin sodium 100 unit/mL 5 mL lock flush syringe, NDC 17474-0125-05 (Lots 7041194, 7041204, 7051534, 7051544, 7051554, 7071924, 7072034, 7072044, 7072054, 7072064, 7072154, 7082284, 7102804, 7113034, 7113044, 7113054, 7113104, 7113114, 7113154, 8010064, 8010114, 8010134, 8010174)
- Heparin sodium 100 unit/mL 5 mL lock flush syringe with Bluntip cannula, NDC 08881-5911-25 (Lot 7082284)
- Heparin sodium 100 unit/mL 10 mL lock flush syringe, NDC 17474-0125-01 (Lot 7113064)

Estimated Resupply Dates

Heparin Sodium for Injection

- Baxter is not currently shipping any heparin in vials.
- APP has supplies of heparin sodium in most presentations available. The company is allocating the 10,000 unit/mL **1 mL vials**
- Hospira has their 10,000 unit/mL iSecure syringes available when ordered directly through the manufacturer. The 10,000 unit/mL 0.5 mL Carpuject Luer Lock Slim-Pak syringes in packages of 10 are not available and the company cannot estimate a release date. All other presentations of heparin sodium injection are available. *Heparin Sodium Large Volume Infusion Solutions*
- Baxter has available heparin 1,000 units/500 mL in 0.9% Sodium Chloride (NDC 00338-0431-03) and heparin 2,000 units/1,000 mL in 0.9% Sodium Chloride (NDC 00338-0433-04). All other heparin large volume infusion solutions are unavailable and the company cannot estimate a release date.
- Hospira is allocating all large volume heparin infusion solutions.
- B.Braun's has heparin 1,000 units/500 mL in 0.9% Sodium Chloride, 25,000 units/250 mL in Dextrose 5% injection, and 25,000 units/500 mL in Dextrose 5% injection on back order and the company estimates a release date of mid-**June**, 2010.

Heparin Sodium Flush Solution

- Baxter is not currently shipping any heparin in vials.
- Heparin sodium flush solutions are made by several manufacturers. The FDA does not anticipate a shortage of these products.
- APP has their 10 units/mL 10 mL vials on back order and the company cannot estimate a release date. Heparin sodium flush 100 units/mL 1mL on back order with an estimated release date of mid-**June**, 2010. All other presentations of heparin sodium flush solution are available.
- Hospira's heparin sodium 10 unit/mL flush solution is

	<p>available.</p> <ul style="list-style-type: none"> • Covidien has their 100 units/mL 10 mL Monojet Prefill product on back order and the company cannot estimate a release date. All other presentations of heparin sodium flush solution are available.
<p>Hydromorphone injection</p> <p><i>Sporadic supply</i> - currently have good supply of Hydromorphone 2mg/1ml syringes (which is non-formulary). As the supply of 1mg/1ml syringes are depleted in the Pyxis machines, pharmacy will load the 2mg/1ml syringes with stickers alerting the change in dose</p>	<p>Reason for the Shortage</p> <ul style="list-style-type: none"> • Hospira's Carpuject syringes have been in short supply due to increased demand for product. • Purdue Pharma, Teva, and Baxter could not provide a reason for the shortage. <p>Estimated Resupply Dates</p> <ul style="list-style-type: none"> • Purdue Pharma has Dilaudid 1 mg/mL 1 mL ampules on back order and the company cannot estimate a release date. Dilaudid HP powder for injection is also on back order with an estimated release date of late-June, 2010. Purdue has all other presentations of Dilaudid and Dilaudid HP available. • Hospira has available several presentations of hydromorphone injection in Carpuject syringes, vials, and ampules. Hydromorphone 2 mg/mL Carpuject syringes (NDC 00409-1312-30) and 4 mg/mL Carpuject syringes (NDC 00409-1304-31) are readily available. The 1 mg/mL (NDC 00409-1283-31) Carpuject syringes are available through direct orders only. The 1 mg/mL 1 mL ampule is also available through direct orders only. The 2 mg/mL 1 mL ampule and vial, and 10 mg/mL 5 mL vials are on back order with an estimated release date of mid- to late-June, 2010. The 10 mg/mL 50 mL vials are on back order with an estimated release date of July, 2010. The 10 mg/mL 1 mL vials (NDC 00409-2634-01) and 4 mg/mL 1 mL ampules (NDC 00409-2540-01) are readily available. • Baxter has available hydromorphone 2-mg/mL in 20 mL (NDC 00641-2341-41) vials. The 1 mL vials are on back order and the company cannot estimate a release date. • Teva (formerly Barr) has all hydromorphone presentations on back order with an estimated release date of August, 2010.
<p>Naloxone 0.4mg/1ml ampules</p>	<p>Reason for the Shortage</p> <ul style="list-style-type: none"> • Endo discontinued its Narcan 0.02 mg/mL 2 mL ampules, 1 mg/mL 10-mL multidose vial, and 2-mL ampule presentations in 2005. The company discontinued their 0.4 mg/mL presentations September, 2006. Endo would not provide a reason for the discontinuations. • Abbott discontinued naloxone 0.02 mg/mL 2 mL ampules and vials in 2001. The company would not provide a reason for the discontinuation.

