Emergency Medical Products (EMP) takes compliance of healthcare regulations very seriously. To ensure patient safety as well as our customers’ compliance to their local regulatory standards, we would like to share new traceability requirements that might impact your pharmaceutical ordering.

**What are the new requirements?**
Effective November 27, 2019, the FDA will be implementing new pharmaceutical traceability standards under the Drug Supply Chain Security Act (DSCSA). These new regulations will prohibit all pharmaceutical distributors and wholesalers from selling pharmaceuticals below the lowest serialized unit of measure. It will be at the pharmaceutical manufacturer’s discretion to determine the lowest unit of measure they will serialize, which could be at the individual “each” quantity, or at a larger box or case quantity. While some manufacturers, such as Pfizer, elected to implement these changes earlier in the year, all pharmaceutical distributors and manufacturers must adhere to the new DSCSA regulations beginning November 27, 2019. A distributor’s failure to comply with DSCSA requirements is prohibited and may result in civil and criminal penalties, injunction of unlawful activity and seizure of goods. In addition, individual state penalties may apply.

**What does this mean for you?**
Effective November 27, 2019, many items that you have historically ordered by the “each” quantity will no longer be available at that lower unit of measure due to lack of serialization. You will still be able to order these pharmaceuticals, but they will only be available at a larger quantity, such as a box or case. If the manufacturer has elected to serialize at the “each” quantity, you will be permitted to purchase these select items at the “each” quantity.

Click [here](#) to see a full list of pharmaceuticals impacted by these changes.

**What about pharmaceuticals currently on backorder?**
If you have an existing order containing an “each” quantity pharmaceutical that does not meet the new serialization requirements, a member of our Customer Service Team will contact you to review alternative purchasing options.

For more information, please reference the resources below:
- List of Impacted Pharmaceutical Items
- DSCSA regulation information from the FDA

If you have any questions, please contact our Customer Service Team at 800.558.6270.

Thank you,

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