May 23, 2022

DAL: DHDTC 22-04
Subject: Ongoing Medical Device Shortages

Dear Chief Executive Officer:

The New York State Department of Health (Department) has recently become aware of supply issues on the Federal Drug Administration’s (FDA) lists of medical device and drug shortages. These shortages include:

X-Ray contrast media, including iodixanol (Visipaque) and iohexol (Omnipaque) injection

General Electric, a major supplier of iodinated contrast media, was required to shut down a product facility in China due to COVID-19 lockdowns. While the facility has since been reopened, the shortage is expected to continue for at least the next 6-8 weeks, with a possible resolution by late June 2022 for Omnipaque and July 2022 for Visipaque.

It is recommended that facilities implement conservation strategies, including:

- Limiting the number of contrast media per study and by study type;
- Consideration of alternatives to contrast use;
- Seeking approvals for certain types of studies that would not require contrast media; and
- Reviewing the American College of Radiology statement on the shortage of contrast media¹, which contains additional conservation strategies.

Blood Collection Tubes (vacutainers)

This shortage has been expanded to include all types of blood collection tubes including product codes GIM and JKA. The FDA estimates these shortages to continue through at least the end of 2022.

It is recommended that facilities implement conservation strategies, including:

- Performing only those tests that are medically necessary, and avoiding or extending intervals between tests when necessary;
- Reducing testing at routine wellness and allergy visits to situations where test results may change patient treatment;

¹ American College of Radiology, "ACR Statement on Drug Shortages for Radiology: Conservation Strategies".
• Consulting additional suppliers to identify alternatives to current supplies;
• Considering add on or sharing samples between laboratory departments if possible; and
• Considering point of care testing that does not require blood specimen collection tubes.

The Department strongly encourages facilities and healthcare systems to continue to check the FDA list of medical device shortages¹ and drug shortages² for updates to remain informed about increases in stock levels or new device additions.

In addition, the Department strongly recommends a few proactive measures to prevent supply shortages due to supply chain issues. First, hospitals should clearly assess their supply needs and proactively acquire supply levels that will help them withstand a six-week shortage of necessary supplies whenever possible. Second, hospitals should establish standards and/or protocols to help extend supplies. Third, communication between facilities on the local and regional level to understand supply levels should take place. The Department encourages voluntary interfacility reallocation when surpluses exist, to ensure all facilities can continue to provide high levels of care to all New Yorkers.

Sincerely,

Stephanie Shulman, DrPH, MS
Director
Division of Hospitals and Diagnostic Treatment Centers

²Current and Resolved Drug Shortages and Discontinuations Reported to FDA https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm