AHRMM
Advancing Health Care through
Supply Chain Excellence

American Hospital Association™
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Supply Chain Resource Council (SCRC) Report

February 12, 2024 Meeting

Executive Summary

This month the Council covered a number of new topics including the 3M spin-off of the independent health care company Solventum, Philips Consent Decree regarding their BiPAP, CPAP and select ventilators, and the CDRH release of its Critical Medical Device List - an action under Executive Order 14001 on a Sustainable Public Health Supply Chain. Recurring issues discussed include ongoing challenges associated with Fetal Scalp Electrodes, two more kit manufacturers who have issued Class I recalls associated with the Nurse Assist Sterile Water and Saline recall, and the BLM sale of the Federal Helium Reserve. Details on these topics and other updates can be found in the full report.

▲ Field Updates

- **Windstone Medical and Maquette are the latest kit manufacturers to issue Class I Recalls for Sterile Saline and Water.** Windstone Packaging DBA Aligned Medical Solutions, and Maquet Cardiovascular, LLC have issued recalls of their kits that contain the Nurse Assist Sterile Water and/or Saline products. Click here to review the list of kit manufacturer recalls. At this time it appears these recalls are not impacting patient care or hospital inventory levels.
- **Flushable Wipes** and the subsequent water damage due to clogged pipes hospital facilities are experiencing has been shared with the AHA and AHRMM. A number of council members responded, affirming the wide-ranging scope of this issue, with several hospitals engaging in awareness campaigns. *Attached is a flyer that UAB is using, and another shared a document that outlines the Traptex ® Plumbing Protection System by Stryker.*
- **Philips agrees with the terms of a consent decree with the U.S. Department of Justice.** The decree is being finalized and will be submitted to the relevant U.S. court for approval. This stems from the June 2021 recall of certain ventilators, BiPAP and CPAP machines due to the potential health risks associated with the polyester-based polyurethane (PE-PUR) foam used in these devices to reduce sound and vibration, which can break down and could be breathed in or swallowed by the person using the device. Click here to view the initial recall, or click here to view the brief comment from the CDRH regarding Philips decree announcement.

  Due to Philips market share, council members shared their challenges in identifying alternative devices and the impact to their home health programs.
- **CDRH Critical Medical Device List released.** The Critical Medical Device List Report, a consensus product resulting from an Action under Executive Order 14001 on a Sustainable Public Health Supply Chain has published on the Technical Resources, Assistance Center, and Information Exchange (TRACIE) website. Click here to access the CMDL Recommendations Report and click here to review the associated CMDL Fact sheet.
- **Bureau of Land Management has completed the sale of the Federal Helium Reserve**, with Messer confirming itself as the highest bidder for the two helium assets that were up for sale; one billion standard cubic feet of helium and real property assets. More details surrounding the sale can be found here.
- **Requirements of the California Senate Bill 253 & 261.** This lawsuit challenges two novel California laws that attempt to regulate speech related to climate change. Senate Bills 253 and 261 compel businesses to disclose their and their parent organization's carbon reduction initiatives, within and outside of California. Both laws compel speech in violation of the First Amendment, and seek to regulate an area

that is outside California's jurisdiction and subject to exclusive federal control by virtue of the Clean Air Act. Additional insights include:

- Uncertainty whether these bills will be funded
- Strong supposition that non-profits will be excluded from these requirements
- Other states are considering similar bills

▲ Supply Chain Watch List — current situations under observation

- **The 3M spin-off of the independent health care company, Sovlentum,** encompasses products such as tapes, dressing, drapes, wound vac, and hand sanitizers. Backorders have been reported for these products with expected release dates of eight (8) weeks or more for some products, and no firm release dates for others. N95 respirators will remain with 3M.
- **Fetal Scalp Electrode availability continues to plague health care organizations.** Cardinal Kendall™ Fetal Spiral Electrodes have been utilized in the absence of the Philips product, however, demand continues to outpace supply. Philips and the FDA have agreed to continued use and availability of Philip's Fetal Spiral Electrodes for medically necessary situations. Attached is the Release Form from Philips which includes a number of acknowledgements facilities must agree to if they choose to use Philips FSE's.

▲ Other Updates

- **The Global Medical Device Nomenclature (GMDN) group** is interested in discussing how Providers are incorporating the GDMN in their master data management strategies and their analytics. Based on a study from AHRMM's Learning UDI Community, the GMDN was identified as one of the best resources to use when categorizing implantable devices within the GUDID. AHRMM will work with GMDN representatives to schedule a discussion during one of our upcoming SCRC meetings.
- **AHRMM Health Care Learning Community on Sustainability.** AHRMM is pleased to bring together a community of like-minded supply chain professionals to explore how we can increase sustainability through the practices, products and services used in the delivery of care, and explore the potential impact supply chain professionals can have on advancing sustainability in health care environment. This learning community is bringing together various constituents to advance our learning, including providers, manufacturers, distributors and GPOs. *Attached is the Work Group Charter.* If you or someone from your organization would like to participate, please have them email me at mschiller@aha.org
- **The National Institute for Occupational Safety and Health (NIOSH) has honored several requests to voluntarily rescind NIOSH respirator approvals.** More information can be found below.
  - As of February 22, 2024, any **Masprot S.C., El. LTDA. respirators** marked with a NIOSH approval label and approval number listed in the table below is no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these six approval numbers:

Approval Number	Part / Model
23C-2506	Model Supreme Half Mask M-203 w/MGV-1P
84A-7785	Model M800 Half Mask w/MGV/MHE-500
84A-7786	Model M800 Half Mask w/MGA/MHE-500
84A-7787	Model M800 Half Mask w/MHE-500
23C-3217	Model M800 Half Mask w/MVO-500
23C-3218	Model M800 Half Mask w/MGV-500

- As of February 13, 2024, any **Masprot S.C., El. LTDA. respirators** marked with a NIOSH approval label and approval number listed in the table below is no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these eight approval numbers:

Approval Number	Part/Model
TC-23C-1918	M-1.2 w/MGA-1A
TC-84A-2749	M-1.2 w/MLE-1A
TC-84A-2864	M-1.2 w/MHE-1B and MGA-1A
TC-84A-2529	M-2.2 w/MLE-2 N95 FILTER
TC-23C-0872	M-2.2 w/MGA-2
TC-84A-2671	M-2.2 w/MGA/MHE-2
TC-84A-2826	M-2.2 w/MGV/MLE-2
TC-84A-4633	M-2.2 w/MGA/MHE-2S

- As of January 18, 2024, any **Honeywell International Inc. respirators** marked with a NIOSH approval label and approval number listed in the table below is no longer NIOSH approved. The NIOSH Certified Equipment List no longer includes these two approval numbers:

Approval Number	Part / Model
19C-0400	Series CF2300, Mask / Hood 5400, Protection SA/CF
19C-0401	Series CF2300, Mask / Hood 5400, Protection SA/CF

About the Supply Chain Resource Council (SCRC)

The Supply Chain Resource Council (SCRC) is comprised of over 90 supply chain and health care leaders from across the health care field with the goal of understanding the extent and impact supply shortages and disruptions are having within the hospital and patient care settings, as well as a capturing and documenting solutions to these challenges. Information collected during these calls is drafted into a report and shared with AHA, AHRMM and Professional Management Group (PMG) senior leaders, the White House Response Team, various Federal Agencies and the broader health care field. *The content of this report represents information, strategies and solutions from SCRC members but does not necessarily reflect policy positions of the AHA.*