Clinical Briefing USA

Implementing everyday practice

A hierarchical approach to selecting guidelines and standards for developing infection prevention and control policy

- The Centers for Medicare and Medicaid Services (CMS) develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that health care organizations (HCOs) must meet in order to participate in the Medicare and Medicaid programs.[1-3]
- State survey agencies or CMS approved accreditation organizations (e.g. The Joint Commission, TJC) conduct surveys to determine if the HCO meets mandatory CoPs and CfCs.[4,5]

> According to the CoPs, hospitals must demonstrate "adherence to **nationally recognized infection prevention and control guidelines**, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms."[3]

The Joint Commission recommends the following hierarchical approach to HCOs selecting standards and guidelines to incorporate into their device disinfection and sterilization policies (Figure 1).[6]

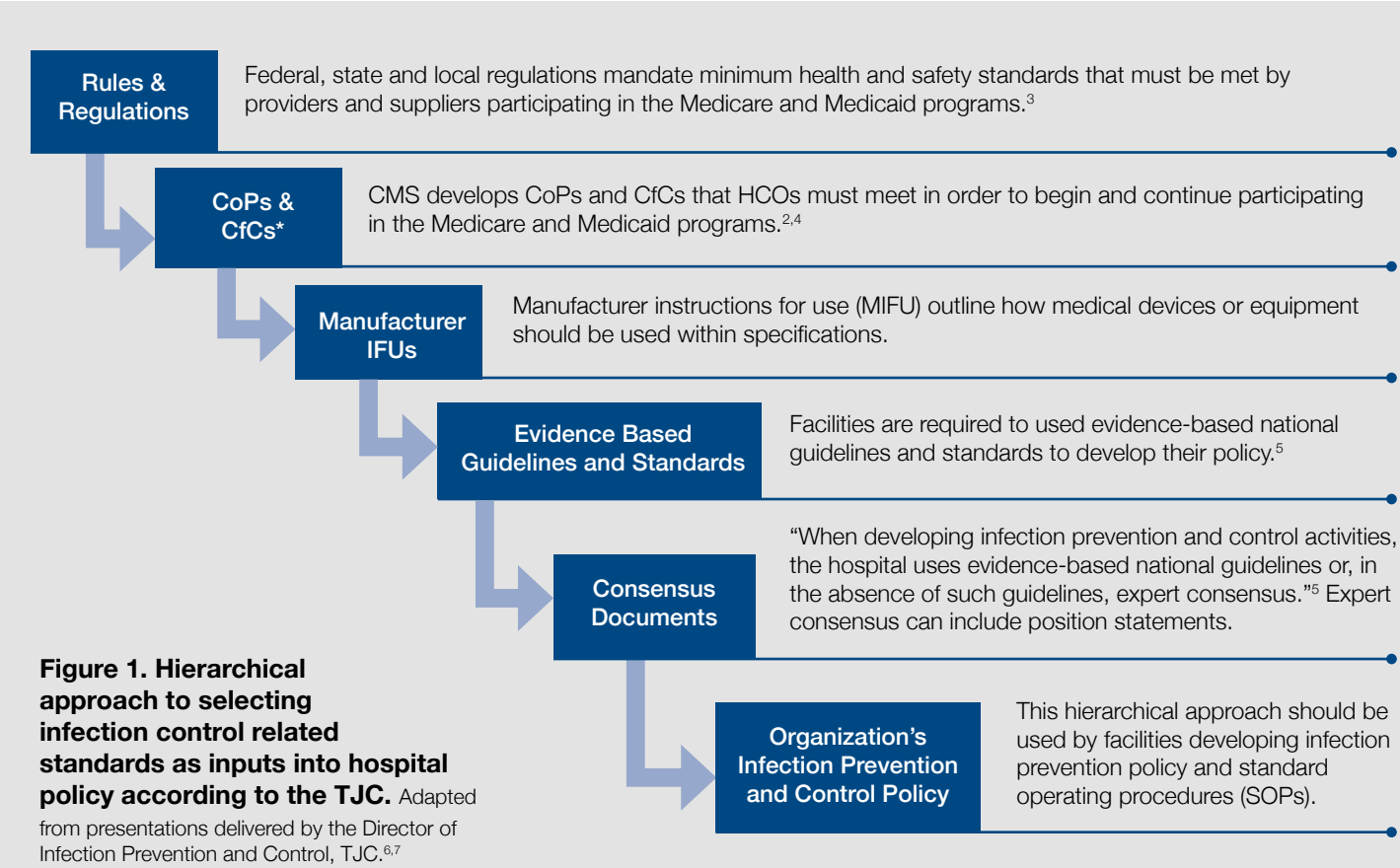

Figure 1. Hierarchical approach to selecting infection control related standards as inputs into hospital policy according to the TJC. Adapted from presentations delivered by the Director of Infection Prevention and Control, TJC.[6,7]

Rules, regulations, evidence based national guidelines and standards

Rules, regulations, evidence based national guidelines and standards consistently apply the Spaulding classification to disinfectant regulation and to reusable medical device disinfection. Below is a list of some of these key documents that HCOs should take into consideration when developing their ultrasound probe reprocessing policies.

Code of Federal Regulations: 21 CFR 880.6885 (revised April 1, 2019)
Title 21 Chapter 1 – Food and Drug Administration Department of Health and Human Services; Subchapter H-Medical Devices; Sec. 880.6885 Liquid chemical sterilants/high level disinfectants.
Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=880.6885

Centers for Medicare & Medicaid Services (CMS), 2015
Hospital Infection Control Worksheet
Available at:
https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf

Food and Drug Administration (FDA), 2019
Marketing Clearance of Diagnostic Ultrasound Systems and Transducers
Available at:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-clearance-diagnostic-ultrasound-systems-and-transducers

Centers for Disease Control and Prevention (CDC), 2008
Guideline for Disinfection and Sterilization in Healthcare Facilities
Available at: https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

Association for the Advancement of Medical Instrumentation (AAMI), 2013
AAMI ST58 Chemical sterilization and high-level disinfection in health care facilities
Available at: https://standards.globalspec.com/std/13068409/AAMI%20ST58

ECRI Institute (ECRI), 2018
Cleaning and Disinfecting Diagnostic Ultrasound Transducers: Our Recommendations
Available at: https://www.ecri.org/components/HDJournal/Pages/Recommendations-for-Disinfecting-Ultrasound-Transducers.aspx?tab=1

Association of perioperative Registered Nurses (AORN), 2018
AORN Guidelines for perioperative practice
Available at: https://aornguidelines.org/

References: **1.** Centers for Medicare and Medicaid Services (CMS). CMS Hospital Infection Control Worksheet 2015, Sections 3A and 3B. Date accessed: 03/05/2021 Available at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf **2.** Centers for Medicare and Medicaid Services (CMS). Conditions for Coverage (CfCs) & Conditions of Participation (CoPs). 2020. Date accessed: 03/05/2021. Available at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs **3.** Code of Federal Regulations (CFR). PART 482 - CONDITIONS OF PARTICIPATION FOR HOSPITALS. Date accessed: 03/05/2021. Available at: https://ecfr.federalregister.gov/current/title-42/chapter-IV/subchapter-G/part-482 **4.** The Joint Commission (TJC). Federal deemed status and state recognition. 2018. Date Accessed: 03/05/2021. https://www.jointcommission.org/-/media/tjc/idev-imports/topics-assets/facts-about-federal-deemed-status-and-state-recognition/federal_deemed_status_12_12_181pdf.pdf **5.** The Joint Commission (TJC). Comprehensive Accreditation Manual for Hospitals (CAMH). 2019. Available at: https://store.jcrinc.com/2021-comprehensive-accreditation-manuals/ **6.** The Joint Commission (TJC). Presentation by Garcia-Houchins S, TJC. 'Disinfection and Sterilization: Dispelling the Myths' Presentation. 2018. Date accessed: 03/05/2021. Available at: https://www.jointcommission.org/-/media/tjc/documents/resources/hai/dispelling_the_myths_final_to_present1.pdf **7.** The Joint Commission (TJC). Presentation by Garcia-Houchins S, TJC. 'Leading the Way to Zero Through Infection Prevention' at APIC OHIO 2019 Conference. Date accessed: 03/05/2021. Available at: https://higherlogicdownload.s3.amazonaws.com/APIC/c05cd876-d549-42d9-a5cc-bdb3723376ef/UploadedFiles/CIlkY2gjR6aJVNLpngB7_APIC%20OHIO%20Leading%20the%20Way%20to%20Zero-GarciaS-TTJC%20(002).pdf

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Nanosonics, Inc.
(USA & Canada)
7205 E 87th Street, Indianapolis, IN 46256, United States
T: 1-844-TROPHON T: 1-844-876-7466 E: info@trophon.com www.nanosonics.us