May 19, 2025

Jonathan B. Perlin, MD, PhD, MSHA, MACP, FACMI, FAMIA
President and Chief Executive Officer
The Joint Commission
Office of Federal Relations
1099 14th Street NW, Suite 500
Washington DC 20005

Dear Dr. Jonathan Perlin,

The Association for Professionals in Infection Control and Epidemiology (APIC) has enjoyed a long collaboration with The Joint Commission (TJC) over our shared goal of keeping patients and healthcare facilities safe and free from healthcare-associated infections (HAIs). APIC appreciates TJC's leadership in prioritizing infection prevention and control in both facility surveys and education. As you know, APIC is a nonprofit, multidisciplinary organization representing 15,000 infection preventionists (IPs) whose mission is to advance the science and practice of infection prevention and control. The purpose of this letter is to share feedback APIC has received from our membership regarding the focus on manufacturers' instructions for use (IFUs) during Joint Commission surveys, and to work together to find a solution that gets us to the end result of improving patient safety while minimizing administrative burden.

APIC members have reported that IFU-related findings are frequently cited during TJC surveys, and that these findings result in significant follow-up and response that at times is not in alignment with an actual risk to patient safety. As you may recall, APIC released a report in 2024 entitled "Modernizing Medical Device Instructions for Use (IFUs): Infection Preventionists Speak up for Patient Safety". This report outlines a multimodal approach at documenting infection preventionists' (IP) concerns regarding their experiences with accessing, interpreting, and utilizing IFUs. Two focus groups were held in 2022 to identify themes that were then used to develop a membership survey. One thousand one hundred ninety-eight APIC members responded to that survey and overwhelmingly indicated that the current IFU system adds complexity to their practice and reduces reliability of cleaning, disinfection, and sterilization processes.

Forty-two percent of participants indicated that their facility had been cited by a surveyor for failure to follow an IFU (including both regulatory and accrediting surveys). Fifty-four percent of those who had been cited reported not being able to successfully challenge the citation by providing evidence for their practice. Eighty-four percent of respondents indicated that they had reached out to a manufacturer for clarification on an IFU in the past, and eight percent went as far as reaching out to the U.S. Food and Drug Administration (FDA) directly.

These numbers are concerning and indicate a much larger problem than simple process non-compliance. Rather, IPs report a variety of barriers that exist within the current IFU system, many of which involve the quality, complexity, difficulty, clarity, consistency, feasibility, availability of products, and availability of the IFUs themselves.

The APIC report was an initial attempt at uncovering the size and scope of the IFU problem, and APIC continues to partner with other organizations to further improvement efforts within this space. A holistic approach will be required to fully address the magnitude of the barriers listed above.

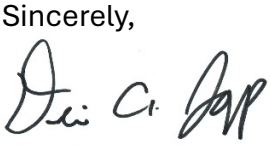
With that in mind, APIC would like to recommend some modifications to TJC's approach to assessing IFU compliance during surveys to ensure that everyone's efforts are focused on keeping patients and the healthcare environment safe. The recommendations below should allow continued alignment with CMS's Conditions of Participation, as they do not conflict with any of the verbiage listed in 482.42.

First, APIC requests that a differentiation be made between simple non-compliance with policy or stated practice and a commonly-used approach where a facility has conducted a risk assessment and determined that an alternative cleaning, disinfection, and/or sterilization method is appropriate. Given the aforementioned issues, especially those regarding technical feasibility or availability of products, APIC recommends that some degree of flexibility be given to facilities to determine safe, effective alternatives when compliance with the manufacturer's IFUs is not feasible or does not meet infection prevention standards.

Second, APIC recommends that IFU-related findings no longer be assessed under the "Infection Prevention and Control" chapter of the TJC standards and instead be housed under either "Environment of Care" or "Leadership". Often, the burden of reconciling IFUs falls to the Infection Prevention and Control department, rather than the team that owns, operates, and maintains the equipment. While collaboration between these two teams is critical, IP time spent on deciphering IFUs related to device/equipment maintenance, cleaning, disinfection, and sterilization diverts IP attention from other infection prevention-related responsibilities, including focused interventions that impact patient safety.

While we understand that adherence to strict cleaning, disinfection, and sterilization practices is essential for patient safety, we also understand that the current IFU process is inherently flawed. APIC and our 15,000 infection preventionist members appeal to TJC to consider thoughtful revisions to survey practices, and we look forward to the opportunity to work with TJC to improve the overall process of surveying compliance with IFUs. Please feel free to reach out to me directly Dr. Perlin if you have any questions. APIC and its members stand ready to assist as needed.

Sincerely,



Devin Jopp, EdD
Chief Executive Officer
Association for Professionals in Infection Control & Epidemiology