March 13, 2020

To State Boards of Pharmacy:

We are aware of, and concerned about, likely garbing and personal protective equipment (PPE) shortages as a result of the COVID-19 outbreak, recently designated by the World Health Organization as a pandemic. CDC has released Interim Guidance on preventing COVID-19 from spreading, which includes Strategies for Optimizing the Supply of N95 Respirators and Healthcare Supply of Personal Protective Equipment. See https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html. FDA is working with PPE manufacturers to help facilitate mitigation strategies. See FDA’s statement at https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns.

As you know, USP’s Compounding General Chapters include provisions on garbing and PPE. These provisions, along with the rest of the USP compounding chapters, are science-based, reflect good clinical practice, and are a part of the broader federal and state government framework to help ensure that patients have access to quality compounded preparations.

While USP develops science-based standards that help ensure the quality of compounded drug preparations, it is not an enforcement body. Accordingly, we recognize that State Boards and other regulators may need to make risk-based determinations on the implementation of USP standards, as well as myriad of other choices to address broad public health needs as a result of the COVID-19 pandemic. We support appropriate risk-based enforcement discretion during the COVID-19 pandemic, in the interest of conserving garbing and PPE.

As always, protecting and advancing public health is USP’s priority, and we are committed to working with State Boards and other stakeholders during this crucial time. If you have any questions, please contact USP Healthcare Quality and Safety staff at CompoundingSL@usp.org.

Sincerely,

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