MINNESOTA
BOARD OF DENTISTRY

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Guidance on Resuming Elective Care

The Governor is expected to make a statement later today related to elective medical and dental procedures. The MDH will also release a final guidance statement on resuming elective care. It will include a requirement for a facility plan, a category which includes dental clinics. Dental clinics do not have to use our template plan, but we will issue one later today as an example. Since dental clinics will be required to have one, we wanted to provide this resource As previously stated, the phase back to care will rely on continued prioritization of urgent dental needs. The Board is not recommending routine hygiene procedures that use ultrasonic scalers or air polishers at this time unless all other risk mitigation strategies can be employed. This would include N95 or KN95 masks and face shields and utilizing high volume evacuation, which may involve the use of a dental assistant. Dental hygiene and periodontal procedures can continue to be prioritized and considered for treatment using hand scaling techniques.

Some helpful resources:
ADA Interim Guidance on Returning to Work
ADHA Interim Guidance on Returning to Work

The use of a handpiece will continue to be necessary in many circumstances treating urgent care needs. Consider all other risk mitigation strategies when using a handpiece due to aerosol generation. See Board of Dentistry Information on Infection Control, PPE, and N95 Use.

Dental professionals need to continue to connect with PPE suppliers. The Board is also seeking out PPE resources that dentists and clinics can use to make purchases. Please be aware that the marketplace has recently been flooded with counterfeit N95 and KN95 PPE.

Please see FDA Guidance

Non-NIOSH-approved Imported FFRs Made in China
On April 3, 2020, in response to continued respirator shortages, the FDA issued an updated Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency and issued a new EUA for non-NIOSH-approved N95 respirators made in China. The new EUA makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic.

Non-NIOSH FFRs from China that are intended for medical use should be listed on the CDC webpage or in Appendix A of the EUA. For those respirators listed on CDC's Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies or Appendix A (during the Covid-19 Public Health Emergency), premarket approval, registration, and listing are **not**

required. For the duration of the pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA, including KN95 respirators. Although not required, if a N95 respirator is not listed in Appendix A of the EUA, importers may want to take appropriate steps to verify the authenticity of these products.

If the product you are importing is manufactured to a standard that is not listed on the CDC's Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies or is not listed in Appendix A of the EUA, an EUA request should be submitted to the FDA. Send an email notification to the FDA with the subject line "FFRS Made in China" to CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov. See this EUA letter for information that should be provided to the FDA for review.

Although not required, if a KN95 or other respirator does not have an EUA, the FDA encourages importers to take appropriate steps to verify the product's authenticity prior to importing. For information specific to KN95 masks, see the FAQs on Shortages of Surgical Masks and Gowns.

ACE Transmission Requirements for Non-NIOSH-Approved Imported FFRs Made in China:

Program Code:	DEV
Processing Code:	NED
Intended Use Code:	940.000 if the product is listed in Appendix A
	081.006 Enforcement Discretion if the product is manufactured to standard listed on the CDC website only
Product Code:	80Q--KU if listed in Appendix A of EUA
	80N--ZJ if listed on the CDC website and meets the enforcement policy
	Use the Product Classification and Product Code Builder

***Under these IUCs, the A of Cs for medical devices (such as the Registration, Listing or Premarket numbers) are optional in ACE during the COVID-19 Public Health Emergency, if listed in EUA Appendix A, or if conditions of the enforcement policy are met and manufactured to a standard listed on the CDC website.