
# COVID-19 PPE Retooling Playbook

INFORMATION CURRENT AS OF MAY 2020

- This document is meant to provide a summarized fact base on potential immediate supply strategies, including manufacturer retooling, for increasing critically needed PPE across the State of Alaska to address the COVID-19 crisis. This document is a tool; it is NOT a commitment that the State of Alaska, Alaska MEP or others will purchase PPE offers of assistance. This document does not limit the government's policy on where and how to purchase PPE or medical devices in response to COVID-19.
- Given the urgency of the situation, this document seeks to rapidly synthesize information in a timeline that would not be appropriate in other circumstances. For all formal guidance, manufacturers and healthcare systems and professionals can find up-to-date information at FDA's COVID-19 website, with a section specific to industry: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/medical-devices-and-covid-19-coronavirus-pandemic.

# The purpose of this playbook is to provide Alaska manufacturers with a guide to producing PPE for COVID-19

| OBJECTIVES | PLAYBOOK CONTENTS |
|---|---|
| • Share Critical Personal Protective Equipment needs with Alaska manufacturers | • Description of PPE product types required by Alaska healthcare workers, first responders, public workers, and general population |
| | • High-level perspective on industries that are well-suited to produce certain types of PPE |
| • Share need-to-know information on regulations and requirements for the production and distribution of PPE | • Synthesis of the FDA Enforcement Policy for PPE during COVID-19 and implications for manufacturers |
| | • Product information sheets for each type of PPE |
| • Assist Alaska manufacturers with navigating the path to producing PPE | • Process maps and example courses of action for non-medical manufacturers to retool for PPE production |
| | • Additional resources and assistance for each step of retooling |

# Alaska MEP COVID-19 PPE Retooling Playbook Contents

1. Descriptions of critical PPE types
2. Overview of regulatory and approving agencies for medical devices and considerations for manufacturers
3. End-to-end process map for Alaska manufacturers
4. Resources to leverage for additional assistance

# The decision to produce medical or non-medical use PPE has different implications for manufacturers



| | |
|---|---|
| **FDA Regulated** | **Medical Use** |

| Types of PPE needed by use | Raw materials needed |
|---|---|
| N95 Respirators | Spun-bonded polypropylene |
| Isolation patient masks | Polypropylene |
| Gowns, non surgical | Nonwoven (Spunlace, SMS, wet-laid) |
| Eye protection | Polycarbonate, PETG, PVC |

| | |
|---|---|
| **Not FDA Regulated** | **Non-Medical Use** |

| Types of PPE needed by use | Raw materials needed |
|---|---|
| Filtering facepiece respirators | Spun-bonded polypropylene |
| Face masks | Polypropylene |

**Message for Manufacturers:**

- Producing Medical PPE requires additional expertise and access to narrow supply chains
- Producing non-medical use PPE is currently subject to fewer FDA regulatory requirements with appropriate labeling, manufacturers can start production immediately for the majority of PPE items needed
- In certain cases (e.g., Class II medical devices), testing may be required, which can take 2 – 4 weeks for approval

# The FDA, NIOSH and OSHA are the primary agencies involved in the certification, approval, and enforcement of PPE regulations



| Agency | Mission | Role relative to PPE | COVID-19 PPE manufacturer resources available (as of May) |
|---|---|---|---|
| **Food and Drug Administration (FDA)** | Protect public health by ensuring the safety, efficiency, and securing of foods and drugs, including medical devices | Sets the regulations and specific performance standards for the majority of PPE | Enforcement Policy for PPE during COVID-19: Immediately in effect Guidance |
| **National Institute for Occupational Safety and Health (NIOSH)** | Develop new knowledge in the field of occupational safety and health | The CDC agency responsible for the certification and approval of respiratory devices for occupational use | Guidance for Businesses and Employers to Plan and Respond to COVID-19 |
| **Occupation Safety and Health Administration (OSHA)** | Assure safe and healthy working conditions by setting and enforcing standards | Sets and enforces standards and provides training to ensure safe and healthful working conditions for employees that may require the use of PPE | Guidance on Preparing Workplaces for COVID-19 |

# The FDA categorizes medical devices across three regulatory classes based on the level of control necessary to assure device effectiveness



| Device Class: | Regulatory Requirements: | PPE items in category: |
|---|---|---|
| **Class I** | Exempt from 510(k) marketing approval and design controls | • Non-surgical gowns<br>• Exam gloves<br>• Scrubs and coveralls<br>• Head and shoe covers |
| **Class II** | 510(k)- required if marketing a device for the first time | • Surgical gloves<br>• Patient/ isolation masks<br>• Surgical gowns<br>• Surgical N95 respirators |
| **Class III** | Premarket Approval (PMA)- the most stringent regulatory category for medical devices | • None |

**Message for Manufacturers:**

- The FDA has made exceptions under Emergency Use Authorizations (EUA) to minimize regulatory hurdles to production
- The FDA regulates devices based on claims made by the manufacturer (e.g., regulated if infection prevention is claimed)
- PPE products marketed to the public for general, non-medical purposes will not require FDA marketing authorization (510(k)); they must be labeled accordingly

# FDA requirements are significantly different during the COVID-19 pandemic compared to “normal” conditions

| FDA Requirments | During normal conditions | High-priority Class I/II PPE as of May 2020 |
|---|---|---|
| FDA Pre-market notification 510(k) | Depends | X |
| Registration and listing | √ | X |
| Quality System Regulation | √ | X |
| Reports or corrections/ removals | √ | X |
| Unique Device Identification | √ | X |
| Labeling accurately describing intended use | √ | √ |

**Message for Manufacturers:**

The FDA does not intend to object to the distribution of certain items during the public health emergency IF they do not create “such an undue risk.”

This risk can be mitigated through:
- Appropriate labeling
- Demonstrated ability to meet applicable manufacturing and design requirements

Given frequent policy changes, manufacturers should visit the FDA’s COVID-19 website.

# Product Information Sheet: Surgical masks

2.

## Product information

**Product description:** Surgical masks (NOT the same as patient. Isolation masks and face masks

**Product group:** Personal Protective Equipment

## Demand

**Usage guidance:** Not intended to be used more than once; discard if damaged, soiled or if breathing through mask becomes difficult

**Current availability:** Very low

## Manufacturing

**Technologies required to manufacture:** Polypropylene, typically 2-3 layers; usually in SMS form

**Degree of automation:** Fully automated by large players, but for smaller players the final assembly may be manual (seamstresses)

**Regulatory & compliance validation process difficult:** Moderate
**FDA Classification:** Class II

**Raw material availability:** Polypropylene, polystyrene, polycarbonate, polyethylene

**Raw material shortages:** High quality meltblown nonwoven

## Message for Manufacturers:

Surgical masks **must be FDA approved** as Class II device

- Manufacturing standards **must meet ASTM F2100-19 standard**

The state expects an **extended demand for surgical masks, patient/isolation masks and non-medical use face masks**

**Standards:** Surgical masks are regulated under 21 CFR 878.4040

## Design Requirements

| | Level 1 | Level 2 | Level 3 | Description |
|---|---|---|---|---|
| **Fluid protection resistance** | **>80 mmHg** | **>120 mmHg** | **>160 mmHg** | **Resistance to penetration by synthetic blood** |
| **Differential pressure test** | **<4.0** | **<5.0** | **<5.0** | **Breathing pressure difference across the mask** |
| **BFE (bacteria filtration efficiency standard- 3µm)** | **≥95%** | **≥98%** | **≥98%** | **Ability of the mask to prevent the passage of aerosolized bacteria** |
| **PFE (particle filtration efficiency standard- 0.1µm)** | **≥95%** | **≥98%** | **≥98%** | **Filtration test using unnaturalized 0.1 micron Polystyrene Latex Spheres** |

# CDC guidance states that Level 1 isolation gowns are appropriate PPE for routine COVID-19 patient care



**ANSI / AAMI Standard barrier protection**

| | Level 1 | Level 2 | Level 3 | Level 4 |
|---|---|---|---|---|
| | Minimal risk | Low risk | Moderate risk | High risk |
| | Non-surgical isolation gowns | Non-surgical isolation gowns | Surgical isolation gowns | Surgical isolation gowns |
| **Standard use** | Basic care, standard isolation, standard medical unit | Blood draw, suturing, ICU, or pathology lab | Arterial blood draw, inserting an IV, in the ER, or for the trauma cases | Surgery, fluid intense procedures, surgery, infectious diseases suspected |
| **COVID-19 applicability** | Routine potential and current COVID patient care | Routine potential and current COVID patient care | Environments that will expose wearer to fluid (e.g., intubations, vomiting patient, etc.) | Surgical purposes and environments that will expose wearer to fluid |
| | Minimum requirement for COVID | | | |

## Message for Manufacturers:

**Healthcare professionals (HCPs) can use non-surgical isolation gowns when performing routine care for COVID-19 patients**

**Non-surgical gowns**

- **If gowns are running low, FDA indicates that HCPs can extend the use of disposable gowns without changing between COVID-19 patients. If the gown becomes contaminated, it should be changed**
- **Reusable gowns (those specifically constructed to be cleaned) should be washed after each patient is treated; can also spray gowns after use with decontamination fluid (ethanol based spray)**

**Surgical gowns should only be used in scenarios where healthcare professionals will be at moderate to high risk of exposure to fluid**

# Product information sheet: Non-surgical isolation gowns

2.

| | |
|---|---|
| **Product information** | **Product description:** Non-surgical isolation gowns (disposable)<br>**Product group:** Personal Protective Equipment |
| **Demand** | **Usage guidance:** Mostly single use, can be re-worn by healthcare professionals if treating known COVID-19 patients<br>**Current availability:** low |
| **Manufacturing** | **Technologies required to manufacture:** Polypropylene spun-bond and melt blown extrusion, heat press and assembly<br>**Degree of automation:** Fully automated by large players, smaller players may use labor (stitching and cutting)<br>**Regulatory & compliance validation process difficult:** N/A<br>**FDA Classification:** Class I – 510(k) exempt<br>**Raw material availability: Various (p**olypropylene, polyethylene, polyester, cotton blends)<br>**Raw material shortages:** Intermediate spun-bond- melt blown- spun-bond (SMS) nonwoven |
| **Design Requirements** | • Isolation gowns (non surgical / non sterile)<br>• Disposable, common sizes: S, M, L, XL<br>• Tear resistant, strong seams, low lint, breathability<br>• **Length: ideally to mid-calf**<br>• Back: open or closed (not mandated by CDC) |

**Message for Manufacturers:**

**Non surgical isolation gowns are Class I** - 510(k) exempt, meaning they **can be made and sold almost immediately**- including head and shoe covers

Comparatively, gowns are **less difficult from a regulatory and compliance validation perspective**

**Standards:**

- US: ANSI / AAMI PB70 Level 1 and Level 2 for liquid barrier performance
- ASTM F4207 for testing of surgical gowns

# Product information sheet: Eye protection



## Product information

**Product description:** Eye protection

**Product group:** Personal Protective Equipment

## Demand

**Usage guidance:** Multi-use, proper don/doff are critical

**Current availability:** Medium

## Manufacturing

**Technologies required to manufacture:** Injection molding (polycarbonate, polyethylene, PVC)

**Degree of automation:** Partially automated

**Regulatory & compliance validation process difficult:** low
**FDA Classification:** N/A

**Raw material availability:** Available (polycarbonate, polyethylene, PVC)

**Message for Manufacturers:**

**Given the FDA does not provide guidance for PPE,** manufacturers should refer to **ANSI Z87.1-2015 standards** and feedback from targeted end users

Common **technologies to produce include injection molding**

## Design Requirements

### Goggles:

Functional: splash protection for eyes; in-directly vented to prevent fogging

Technical: scratch resistant lenses

Shape: snug fit for various face sizes/ shapes

### Face shields:

Functional: splash protection for face/eyes; clear unobstructed viewing

Technical: scratch resistant

Shape: flexible across face of wearer

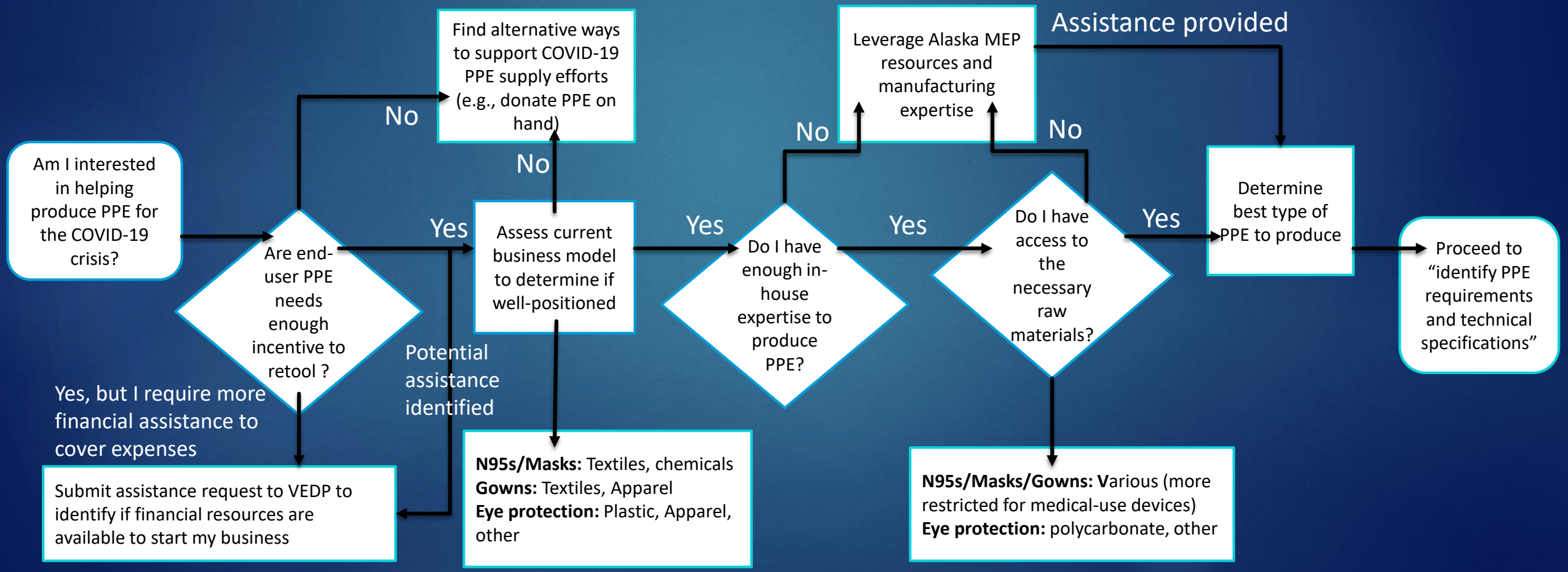
### Standards:

US: Meet specifications of ANSI Z87.1-2015 (D3 splash marking, not impact resistant rated)

# Understanding end-user PPE needs and assessing internal capabilities will inform the decision to produce PPE



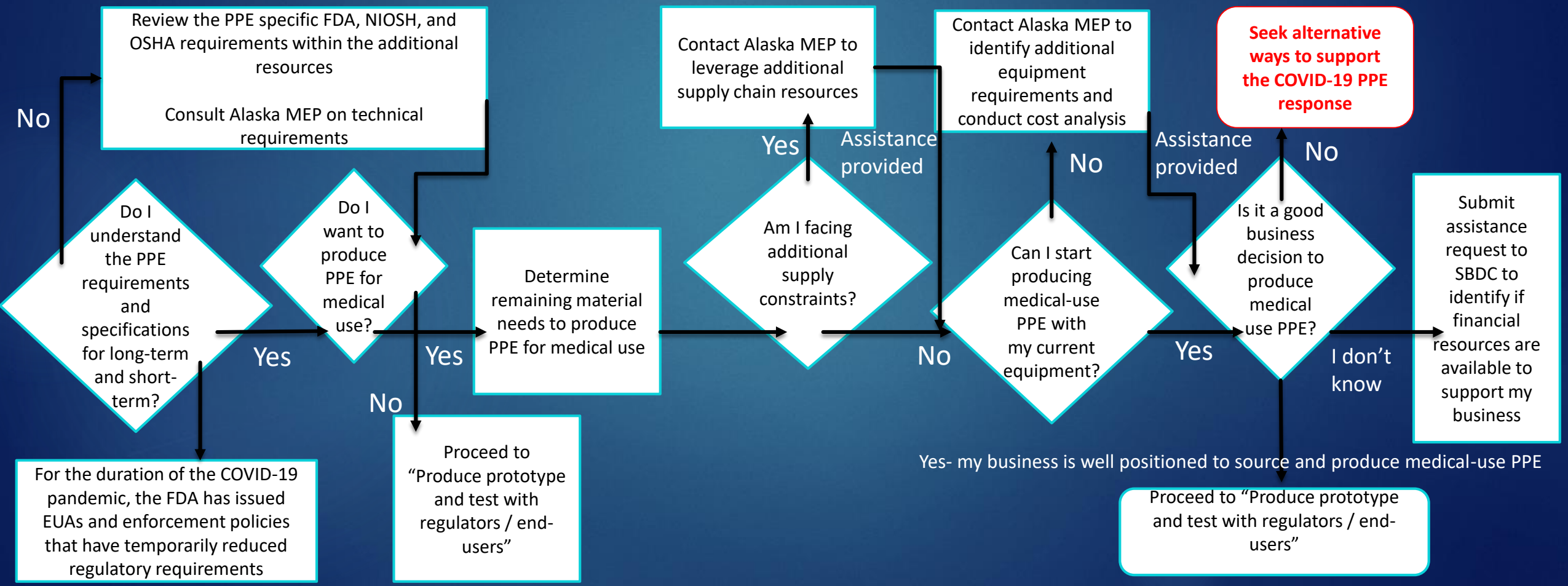
| Understand end-user PPE needs | Determine what PPE we are best positioned to produce | Identify PPE requirements and technical specifications | Produce prototype and test with regulators / end-users | Connect with buyers and scale production |
|---|---|---|---|---|



# Proper interpretation of specific manufacturing requirements will help to identify supply chain constraints ahead of time



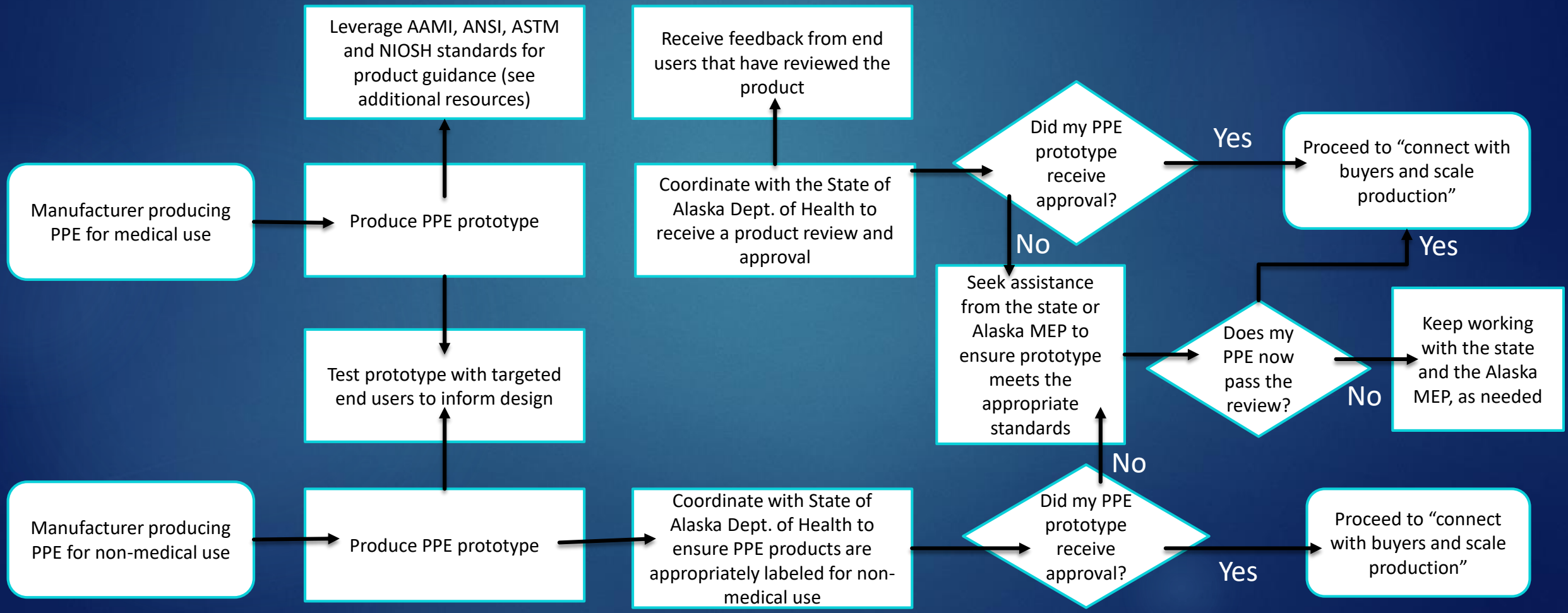
| Understand end-user PPE needs | Determine what PPE we are best positioned to produce | Identify PPE requirements and technical specifications | Produce prototype and test with regulators / end-users | Connect with buyers and scale production |
|---|---|---|---|---|



# Retooling manufacturers should incorporate targeted end-user feedback and contact available resources early in the process



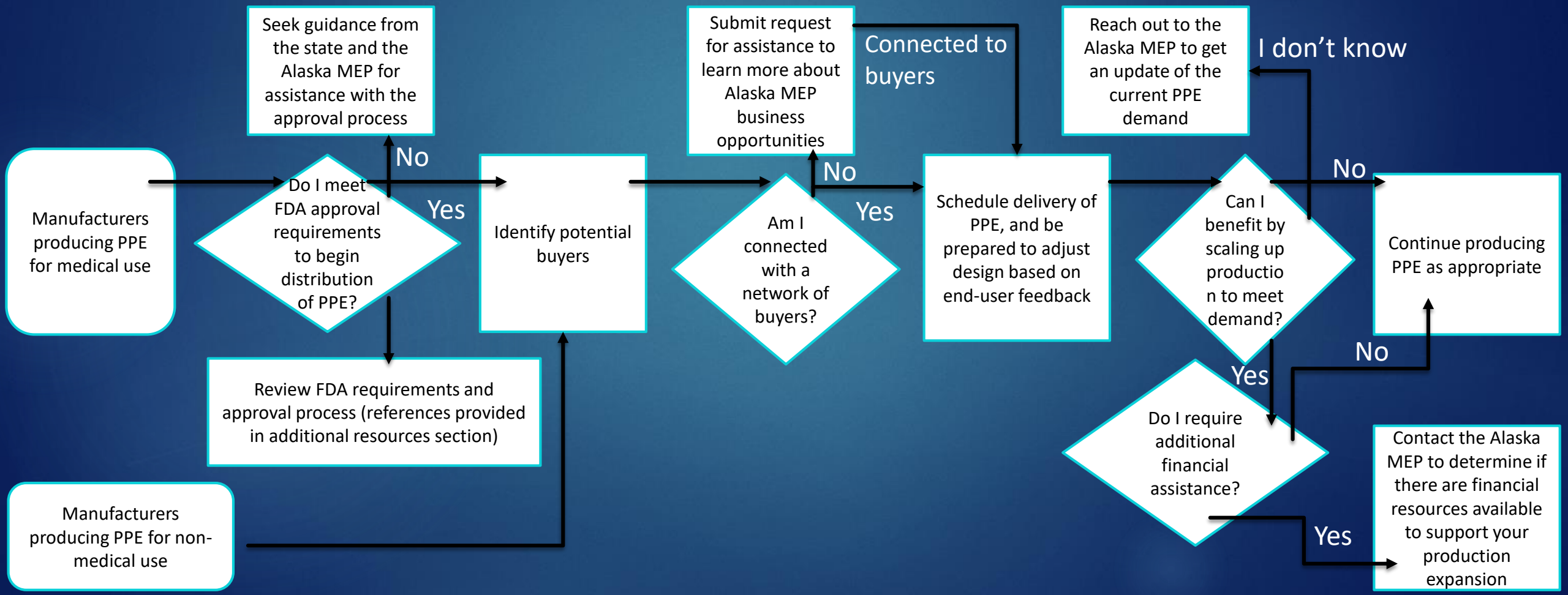
| Understand end-user PPE needs | Determine what PPE we are best positioned to produce | Identify PPE requirements and technical specifications | Produce prototype and test with regulators / end-users | Connect with buyers and scale production |
|---|---|---|---|---|



# The Alaska MEP and partnering organizations can assist manufacturers with PPE-end users



| Understand end-user PPE needs | Determine what PPE we are best positioned to produce | Identify PPE requirements and technical specifications | Produce prototype and test with regulators / end-users | Connect with buyers and scale production |
|---|---|---|---|---|

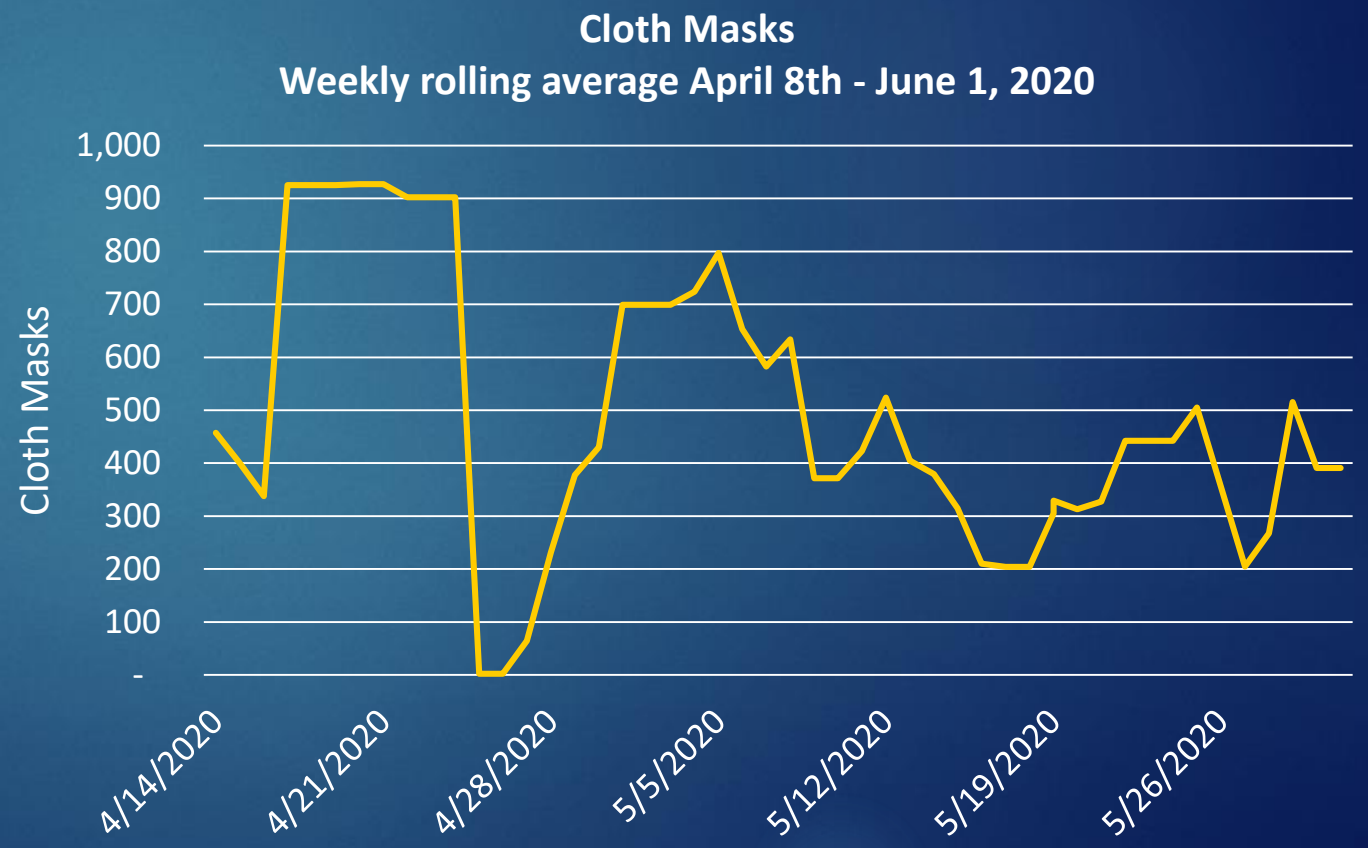


# Noteworthy PPE trends for the state of Alaska:

Our PPE needs across the state have changed since our first positive COVID-19 test. The graphs outline the changes in PPE types demanded on a rolling weekly average since the Alaska MEP began its PPE matchmaking services.

## Cloth Masks:

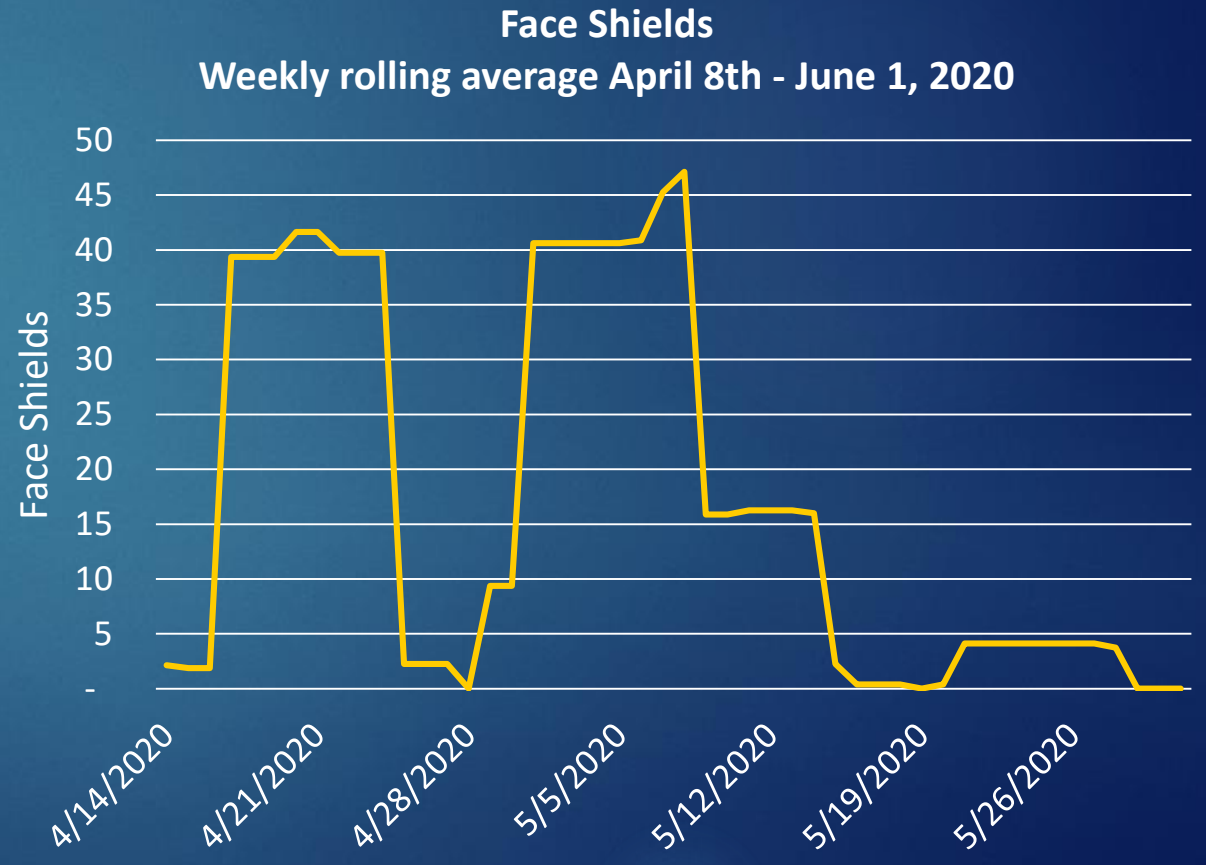
Demand for cloth masks rose quickly, declined during the heat of “hunker down” and rebounded as people began going out in public again. Demand for cloth masks is still significant.



# Noteworthy PPE trends for the state of Alaska:

## Face Shields:

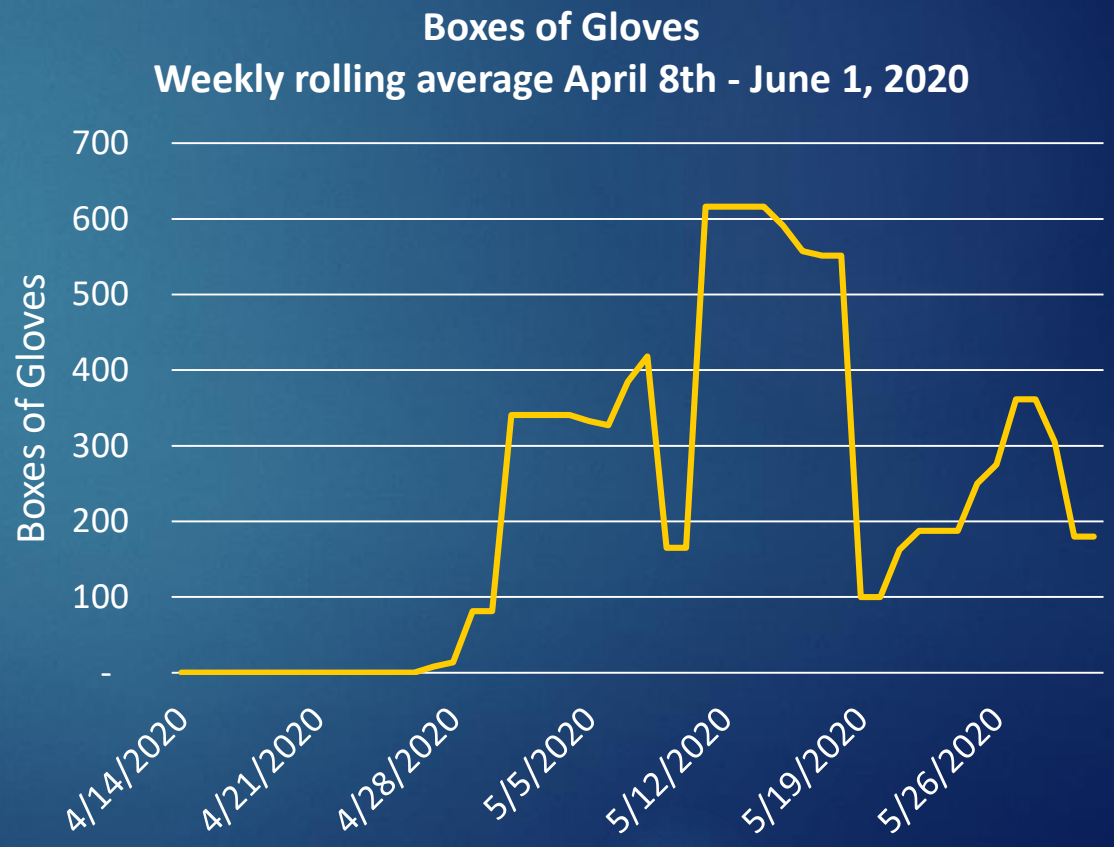
Demand for face shields rose as availability of face shields declined in the medical arena. The demand for face shields has been on the decline since the beginning of May. Demand for face shields is at an all-time low since the beginning of the pandemic.



# Noteworthy PPE trends for the state of Alaska:

## Gloves:

Demand for disposable gloves lagged the onset of COIVD-19 in Alaska. Demand increased as supplies dwindled in the medical field. A second wave of demand rose as restrictions on public movement and businesses eased. Demand for disposable gloves is still positive.

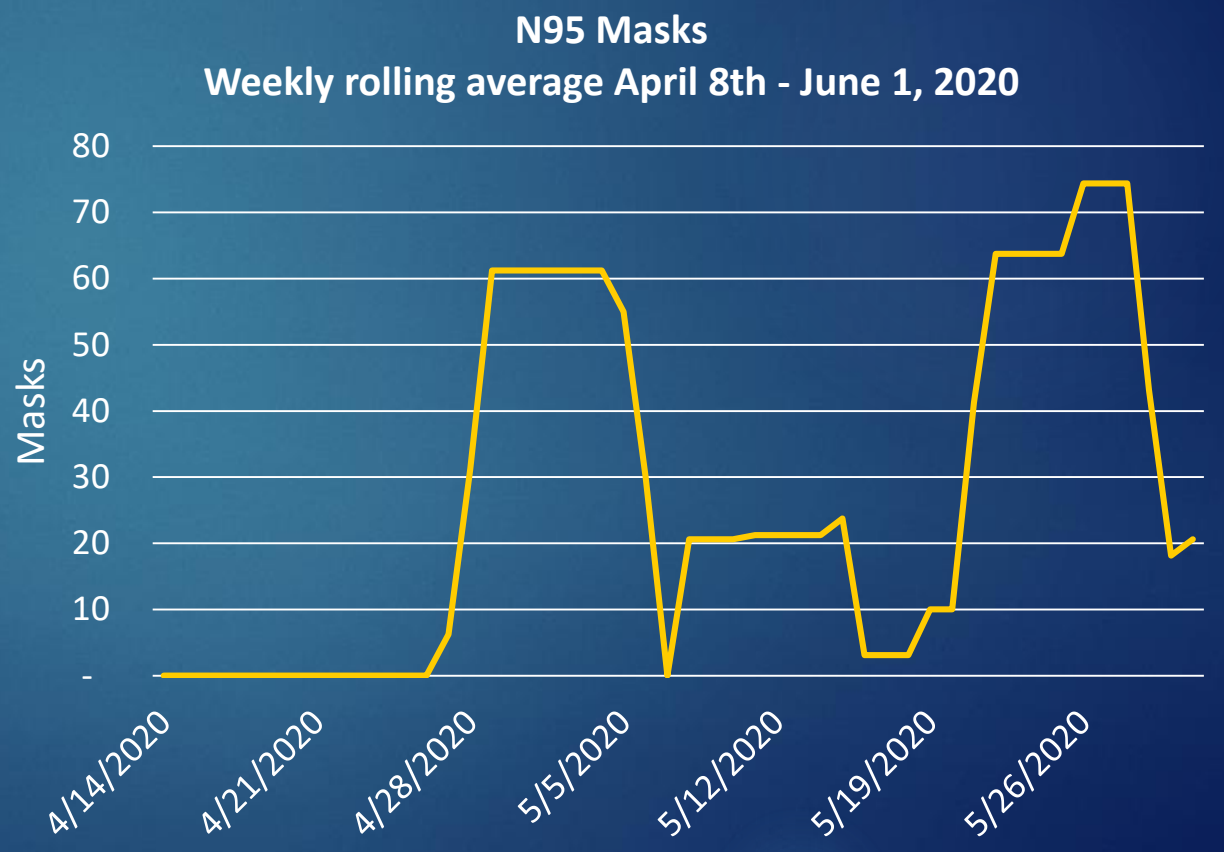


# Noteworthy PPE trends for the state of Alaska:



**N95 Masks:**

Demand for N95 masks lagged the beginning of the pandemic, but has increased over time as supplies dwindled. Demand for N95 masks is on the rise.

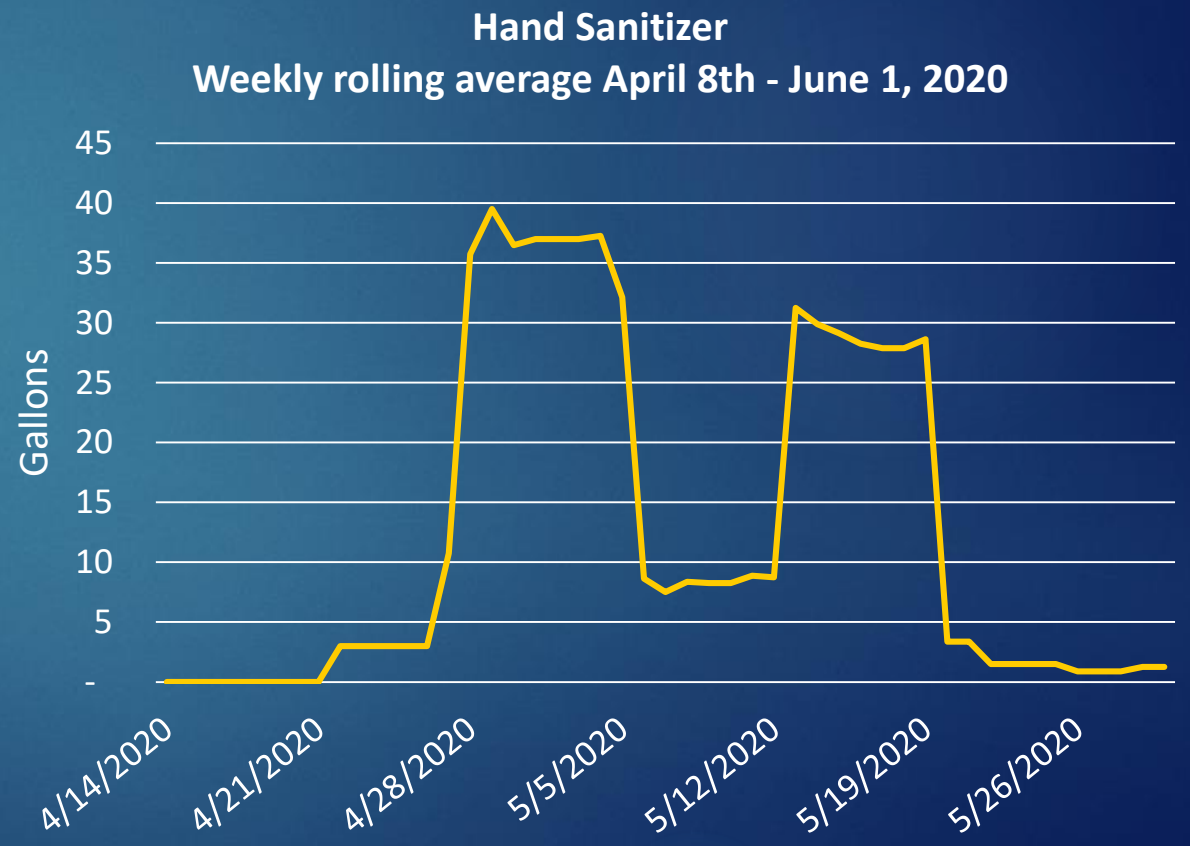


# Noteworthy PPE trends for the state of Alaska:



**Hand Sanitizer:**

Demand for hand sanitizer lagged the initial start of the COVID-19 pandemic. The initial increase in demand reflects demand for healthcare organizations that were allowed to be open during the pandemic. The second wave of demand reflects preparations for reopening of the economy and reduced restrictions on businesses. Demand for hand sanitizer has decreased, but remains slightly positive.

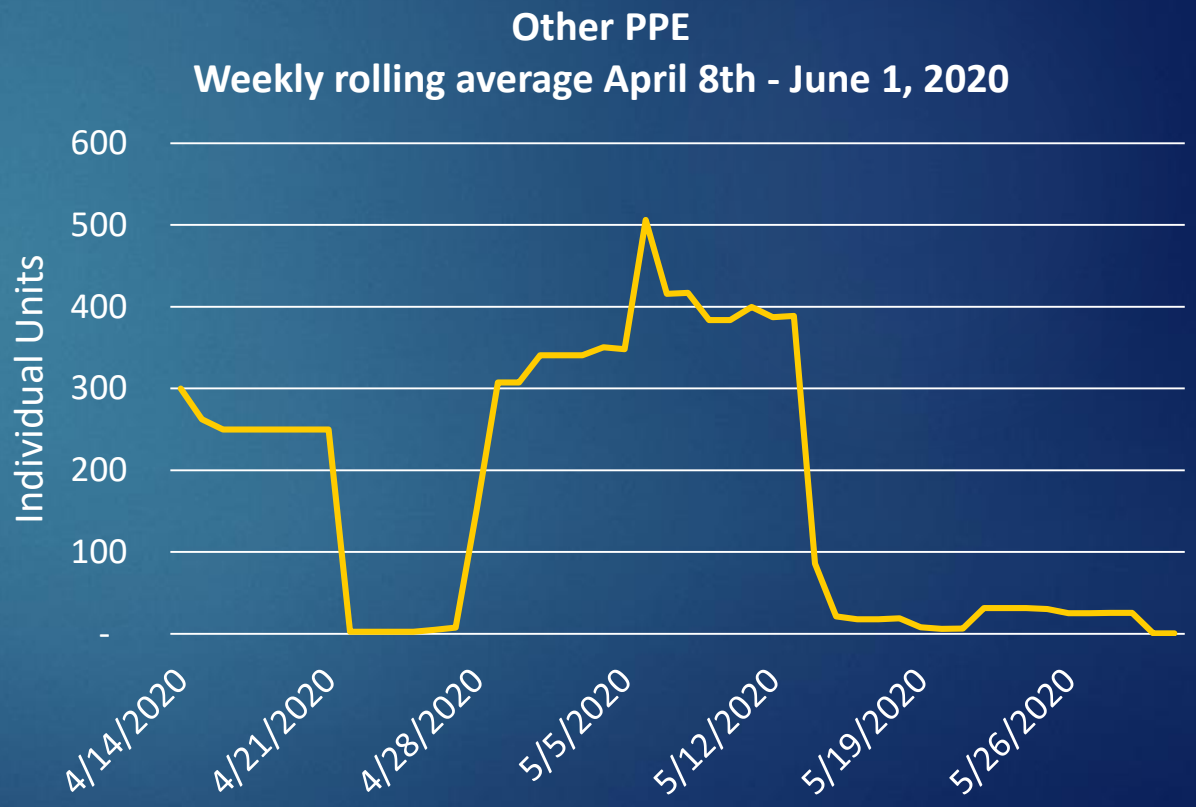


# Noteworthy PPE trends for the state of Alaska:



**Additional (other) PPE:**

Other PPE includes ventilators, ventilator helmets, bouffants, booties, goggles, gowns, Tyvek suits, PAPRs, plexiglass counter shields, and HEPA filters. Demand began with ventilators and Tyvek suites and then moved on to, primarily, gowns and disinfectant wipes. Demand for other types of PPE has dwindled to very low levels reflecting minimal demand for gowns.



# Resources to support retooling manufacturers



**State and local**

- **The Alaska Small Business Development Center provides COVID-19 resources for small businesses, including the Small Business Debt Relief Program (part of the CARES Act) and industry specific guidance for companies during the Pandemic**
- **U.S Chamber of Commerce Emergency Loans**

**Additional resources for manufacturers**

- **State of Alaska Vendor FAQ**
- **RFI**
- **Statewide Approved Face Mask Design**
- **Supplier Scouting Form**
- You can register to become a vendor for the State here: https://iris-vss.alaska.gov/webapp/PRDVSS1X1/AltSelfService.

**Federal and national**

- The Department of Health and Human Services published supplementary information regarding the PREP Act for Medical Countermeasures Against COVID-19, which provides liability immunity to certain individuals for related actions
- The FDA's enforcement policies for PPE (face masks and respirators, gowns, gloves and other apparel) during the COVID-19 Public Health Emergency serve as important guidance for industry
- The CDC's National Institute of Occupational Safety and Health (NIOSH) provided Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19
- The Department of Labor's Occupational Safety and Health Administration (OSHA) released Guidance on Preparing Workplaces for COVID-19 for employers to reference

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**The Alaska MEP Center serves manufacturers seeking to improve the quality, productivity, and competitiveness of their operations.**