SECRETARY OF PUBLIC SAFETY AND HOMELAND SECURITY

Commonwealth of Virginia COVID-19 PPE Retooling Playbook

INFORMATION CURRENT AS OF APRIL 2020 UNLESS OTHERWISE NOTED

HOMELAND SECURITY DIVISION

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 Commonwealth of Virginia to address the COVID-19 crisis. **This document is a tool; it is NOT a commitment that the Commonwealth 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 Virginia manufacturers with a guide to producing PPE for COVID-19

Objectives

- **Share critical Personal Protective Equipment (PPE) needs** with Virginia manufacturers
- **Share need-to-know information on regulations and requirements** for the production and distribution of PPE
- **Assist Virginia manufacturers with navigating the path to producing PPE** in support of the Commonwealth of Virginia

Playbook contents

- Description of PPE product types required by Virginia healthcare workers, first responders, public workers, and general population
- High-level perspective on industries that are well-suited to produce certain types 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
- 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

Commonwealth of Virginia COVID-19 PPE Retooling Playbook contents

1. **Descriptions of critical PPE types in demand by the Commonwealth of Virginia**
2. Overview of regulatory and approving agencies for medical devices and considerations for manufacturers
3. End-to-end process map for Virginia manufacturers
4. Resources to leverage for additional assistance

1 The Commonwealth is in need of five types of medical use PPE to support healthcare workers, first responders and public works

General level of FDA regulation: High ↑ Low

Critical PPE needed	Definition[1]	Quantity Commonwealth is procuring in next tranche (subset of total planned procurement)
	• **N95 respirators:** A disposable half-face-piece intended to help reduce wearer to exposure to pathogenic biological airborne	• 5,000,000 units
	• **Patient/Isolation masks[2]:** A loose-fitting, disposable device that provides a physical barrier to particulate materials	• 5,000,000 units
	• **Exam gloves**: A hand covering intended for medical use to prevent contamination	• Vinyl exam gloves: 5,000,000 units • Nitrile gloves: 4,000,000 units • Latex gloves: 4,000,000 units
	• **Gowns, non-surgical**: A disposable or reusable product intended to protect the user from the transfer of materials in the wearer's environment	• Isolation gowns: 5,000,000 units • Hair caps: 5,000,000 units • Boot covers: 2,000,000 units • Medical coveralls: 900,000 units
	• **Eye protection**: A device used to protect the user's eyes and / or face from bodily fluids, liquid splashes, or infectious materials	• Medical goggles: 1,000,000 units • Face shields: 1,000,000 units

Who the PPE will help

Hospitals and Healthcare workers

First responders

Public works

1. Sourced from FDA Enforcement Policies for PPE during COVID-19 (April 2020): Face masks and respirators; Gowns, other apparel, and gloves
2. Here forward considered Face masks intended for a Medical Purpose that are NOT intended to provide liquid barrier protection

1 Demand for non-medical use PPE is also increasing as the economy reopens

Non-medical use PPE needed	Definition
	• **Filtering facepiece respirators:** A filtering facepiece respirator (FFR) offering protection from particulate materials[1]
	• **Face masks:** A mask that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels[1]
	• **Gloves**: A hand covering for the hand for protection against dirt (e.g., nitrile industrial grade gloves)

PPE intended for non-medical use is not regulated by the FDA – meaning manufacturers can start producing immediately

Indicators of increased demand

- **Global respirator consumption has increased 1,900% since 2019** – from 5B to 100B
- The **US PPE market size is expected to grow at a compound annual growth rate (CAGR) of 5.2%** - reaching ~$18B by 2026[2]
- **US states are increasingly requiring residents to cover their faces** when in public during the COVID-19 pandemic
- **Potential that face covers will be required for foreseeable future** based on current expert opinions and press search

Who the non-medical use PPE will help

General population

First responder

Public works

1. FDA Enforcement Policies for PPE during COVID-19 (April 2020): Face masks and respirators; Gowns, other apparel, and gloves
2. Grand View Research; Statista estimates; ID 895706; Daedal Research estimates a slightly larger market at ~$15bn

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

	Types of PPE needed by use		Raw materials needed
FDA regulated	Medical use	N95 respirators	• Spun-bonded polypropylene
		Isolation/patient masks	• Polypropylene
		Exam gloves	• Nitrile, natural rubber, polychloroprene
		Gowns, non-surgical	• Nonwovens (Spunlace, SMS, wet-laid)
		Eye protection	• Polycarbonate, PETG, PVC
Not FDA regulated	Non-medical use	Filtering facepiece respirators	• Various
		Face masks	• Various
		Gloves	• Nitrile, natural rubber, latex

Message for manufacturers:

Producing medical use 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

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2 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 April)
Food and Drug Administration (FDA)	Protect public health by ensuring the safety, efficacy, and security 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

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

Less

General level of FDA regulation

More

Device Class	Regulatory requirements[1]	PPE items in category[2]
Class I	• Exempt from 510(k) marketing approval and design controls	• Non-surgical gowns • Exam gloves[3] • Scrubs and coveralls • Head and shoe covers
Class II	• 510(k) – required if marketing a device for the first time	• Surgical gloves • Patient/isolation masks • Surgical gowns • Surgical N95 respirators
Class III	• Premarket approval (PMA) – the most stringent regulatory category for medical devices	• None

- 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

1. https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing
2. CDC PPE COVID-19 guidance (23-Mar-2020)
3. Class I (reserved) – subject to premarket notification marketing 510(k) requirements

2 FDA requirements are significantly different during the COVID-19 pandemic compared to "normal" conditions

FDA requirements[1]	During normal conditions	High-priority Class I/II PPE as of April 2020[2]
FDA pre-market notification 510(k)	Depends[3]	✗
Registration and listing	✓	✗
Quality System Regulation	✓	✗
Reports or corrections/removals	✓	✗
Unique Device Identification	✓	✗
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[2]**
- **Demonstrated ability to meet applicable manufacturing and design requirements[2]**

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

For the most updated information, visit the FDA's COVID-19 page: https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

1. Electronic Code of Federal Regulations, Title 21, Subchapter H – Medical devices
2. FDA COVID-19 Public Health Emergency Enforcement Policies for (a) Face Masks and Respirators and (b) Gowns, Other Apparel, and Gloves
3. Class I – 510(k) exempt Medical devices do not require a pre-market notification under normal conditions

2 Product information sheet: disposable surgical N95 respirators

Product Information

Product description: Surgical N95 respirators, e.g., 3M 8210 and 9210

Product group: Personal Protective Equipment

Demand

Usage guidance: Designed for single use.[1] Limited single-wearer re-use considered in contingency scenarios[2]

Current availability: Very low

Manufacturing

Technologies required to manufacture: Polypropylene spunbond and meltblown extrusion, heat press & assembly

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

FDA Classification: Class 2, if surgical[3] – may be 510(k) exempt

Regulatory & compliance validation process difficulty: Medium

Raw material availability: High quality polypropylene likely available; intermediate Spunbond Meltblown Spunbond (SMS) nonwoven, especially the quality meltblown in short supply

Raw material shortages: N95 quality meltblown nonwoven

Design requirements[2]

- Grade N95
- Good breathability with a design that does not collapse against the mouth (e.g. duckbill, cup-shaped).

Standards: Minimum "N95" respirator according to FDA Class II, under 21 CFR 878.4040; evaluated, tested, and approved by NIOSH as per 42 CFR Part 84

Message for manufacturers:

N95 respirators for medical purposes are likely more difficult to produce for non-medical manufacturers at this time for the following reasons:

- Existing global supply chains are low on raw materials
- After the EUA, regulatory and compliance validation process can be difficult

The FDA authorized all respirators approved by the NIOSH for use by medical personnel during the COVID-19 outbreak

1. https://www.cdc.gov/niosh/npptl/pdfs/UnderstandingDifference3-508.pdf 2. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/contingency-capacity-strategies.html
3. Per WHO technical guidance COVID-19 v4 (11-Mar-2020) 4. Non-healthcare N95 respirators (e.g., for use in construction and industrial settings) are regulated by the NIOSH in the US

Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html; https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html; image courtesy of 3M

2 Product information sheet: Surgical masks

Product Information

Product description: Surgical masks (these are 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 a 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[2]

Raw material availability: polypropylene, polystyrene, polycarbonate, polyethylene

Raw material shortages: High quality meltblown nonwoven

Design requirements[1]

	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 - 3 µm)	≥95%	≥98%	≥98%	Ability of the mask to prevent the passage of aerosolized bacteria
PFE (particle filtration efficiency standard – 0.1 µm)	≥95%	≥98%	≥98%	Filtration test using unnaturalized 0.1 micron Polystyrene Latex Spheres

Message for manufacturers:

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

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

The Commonwealth 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.

1. ASTM levels determined by ASTM F2100-11 standards, ASTM F1862, ASTM F2299
2. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions

Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html; https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html; image courtesy of 3M; Image source: 3M.com

2 Product information sheet: Patient examination gloves

Product Information

Product description: Patient examination gloves (21 CFR 880.6250)

Product group: Personal Protective Equipment

Demand

Usage guidance: Single use, hand hygiene and proper don/doff are critical

Current availability: Moderate

Manufacturing

Technologies required to manufacture: Chemicals (co-polymerization, monomers, plasticizers, Calcium Carbonate/Nitrate baths), rubber molding, ceramic molds, vulcanization, chlorination

Degree of automation: Fully automated by large players, but for smaller players stripping ceramic molds typically done manually

FDA Classification: Class I – 510(k) exempt

Regulatory & compliance validation process difficulty: Low

Raw material availability: Uncured nitrile, natural rubber, chemicals, polymers likely available

Design requirements[1]

- Examination gloves (non surgical / non sterile, unless for medical intervention)
- Disposable, thin (3mm), common sizes: S, M, L (M, L typically sufficient)
- Nitrile (unpowdered with finishing to remove chemicals is most common), Latex / natural rubber, polychloroprene
- Unpowdered (mandatory if latex[2]) or powdered (good for use on wet hands); if unpowered, then finished with chlorination or polymer coating (improves donning and doffing, and reduces the allergen content in latex gloves)
- Length: ideally long cuffs up to mid-forearm (not mandated by CDC currently)
- Double-gloving not mandated by CDC for COVID-19 care

Standards:

- ASTM D6319, D3578, D5250, D6977 or equivalent

Based on Acceptable Quality Limits (AQL) set by the FDA

- Tensile strength
- Elongation
- Leak test

Message for manufacturers

- Given examination gloves are Class I – 510(k) exempt, **PPE manufacturers can begin making and selling almost immediately**
- These are different from surgical gloves – Class II – requires 510(k)
- **These are different from non-medical use gloves, which are also likely to see an increase in demand**

1.CDC PPE COVID19 guidance (23-Mar-2020) 2. FDA prohibits powder with Latex gloves because of concerns on impairing wound healing
Source: Derived from manufacturing expert interviews; https://www.fda.gov/media/90612/download; image courtesy of Cardinal Health

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

ANSI/ AAMI Standard barrier protection	Level 1	Level 2	Level 3	Level 4
	Minimal Risk	Low risk	Moderate risk	High risk
			Surgical gowns	
			Surgical isolation gowns	
	Non-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 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

Healthcare professionals (HCPs) can use non-surgical isolation gowns when performing routine care for COVID-19 patients[2]

Non-surgical gowns

- If gowns are running low, FDA[2] 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)[2]

Surgical gowns should **only be used in scenarios** where healthcare professionals will be at moderate to high risk of **exposure to fluid[2]**

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html 2.. https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers

2 Product information sheet: Non-surgical isolation gowns

Product Information

Product description: Non-surgical isolation gowns (disposable)

Product group: Personal Protective Equipment

Demand[1]

Usage guidance : Mostly single use, can be re-worn by healthcare professionals if treating known COVID-19 patients

Current availability: Low

Manufacturing

Technologies required to manufacture: Polypropylene spunbond and meltblown extrusion, heat press, and assembly

Degree of automation: Fully automated for most large manufacturers, smaller manufacturers may use labor (e.g., stitching and cutting)

FDA Classification: Class 1 – 510(k) exempt

Regulatory & compliance validation process difficulty: N/A

Raw material availability: Various (polypropylene, polyester, polyethylene, cotton, blends)

Raw material shortages: Intermediate Spun bond- Melt blown-Spun bond (SMS) nonwoven

Design requirements[2]

- Isolation gowns (non surgical / non sterile)
- Disposable, common sizes: S, M, L, XL
- Tear resistant, strong seams, low lint, breathability
- Length: ideally to mid-calf
- Back: open or closed (not mandated by CDC)

Standards:

- US: ANSI / AAMI PB70 Level 1 and Level 2 for liquid barrier performance
- European: EN13795, EN14126
- ASTM F4207 for testing of surgical gowns

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**

1 FDA Medical PPE for infection control 2 CDC PPE COVID-19 guidance (3/23/2020)

Source: CDC; FDA

2 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

FDA Classification: N/A[1]

Regulatory & compliance validation process difficulty: Low

Raw material availability: Available (polycarbonate, polyethylene, PVC)[2]

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 shield
- Shape: flexible across face of wearer

Standards:

- US: Meet specification of ANSI Z87.1-2015[3] (D3 splash marking, not impact resistant rated)

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**

1. Eye protection is not classified as a medical device by the FDA, Occupational Safety and Health Administration (OSHA) states that protective eye and face protection devices must comply with specification of ANSI Z87.1-2015, https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.133
2. ANSI Z87.1-2015 or additional details at: https://www.coopersafety.com/ansiz87-1

Source: Derived from expert manufacturing interviews; images courtesy of 3M, Pyramex

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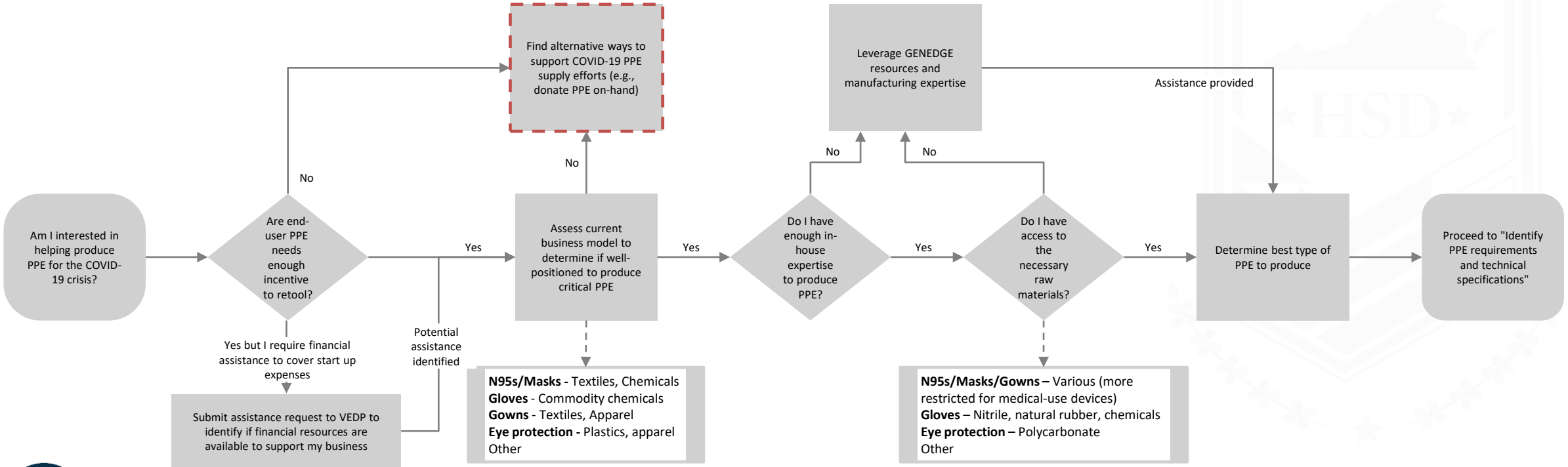
3 Understanding end-user PPE needs and assessing internal capabilities will inform the decision to produce PPE

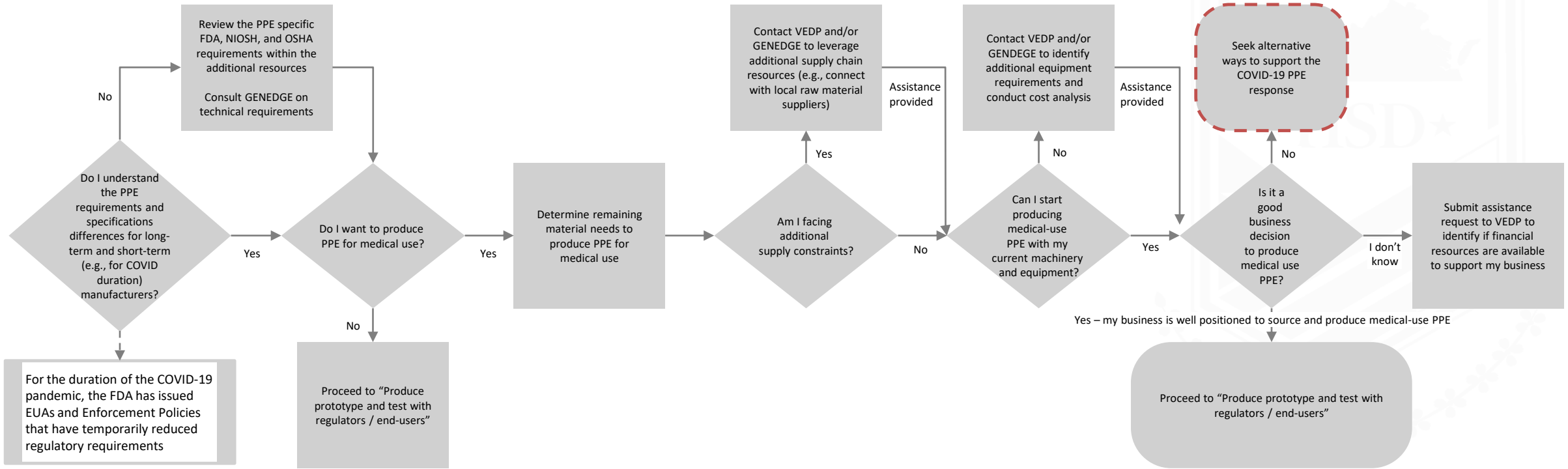
Understand end-user PPE needs | **Determine what PPE we are best positioned to produce** | **Identify PPE requirements and technical specifications** | **Produce prototype and test with regulators / end-users** | **Connect with buyers and scale production**



Start / end | Decision point | Action | Sub-action

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

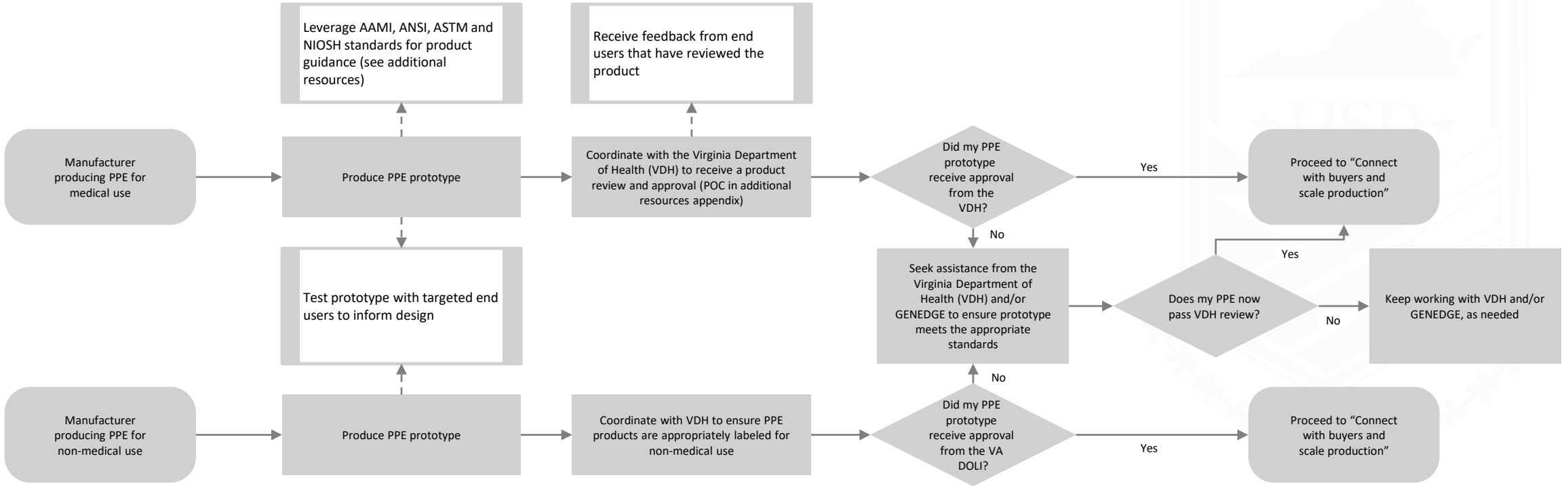
Understand end-user PPE needs → **Determine what PPE we are best positioned to produce** → **Identify PPE requirements and technical specifications** → **Produce prototype and test with regulators / end-users** → **Connect with buyers and scale production**



Start / end | Decision point | Action | Sub-action

3 Retooling manufacturers should incorporate targeted end-user feedback and contact Virginia DOLI as early in the process as possible

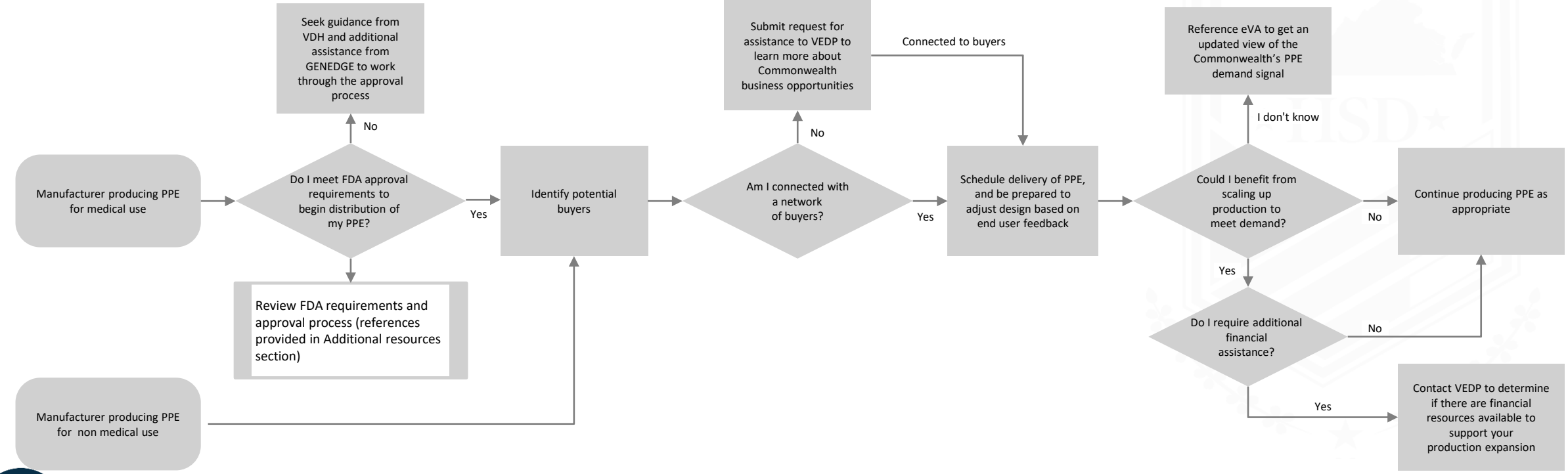
Understand end-user PPE needs → **Determine what PPE we are best positioned to produce** → **Identify PPE requirements and technical specifications** → **Produce prototype and test with regulators / end-users** → **Connect with buyers and scale production**



Start / end | Decision point | Action | Sub-action

3 The Commonwealth and partnering organizations can assist manufacturers with connecting 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**



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4 Commonwealth of Virginia resources to support retooling manufacturers with product development and expansion

Resource	Role	COVID-19 PPE manufacturer resources available	Point of contact
VEDP	The **Virginia Economic Development Partnership supports Commonwealth manufacturers with site selection and incentive** services for expansion opportunities	Performance-based incentives, including workforce training, to support companies that expand operations with new capital investment and job growth[1]	vbarnett@vedp.org 804.545.5815
GENEDGE	**GENEDGE**, Virginia's public resource to help manufacturing & industry innovate, compete and grow, is part of the Manufacturing Extension Partnership (MEP) National Network **offering tailored and expert business solutions for growth**	Comprehensive collection of COVID-19 Resources for Virginia Manufacturers Video link to Webinar to assist with understanding medical devices during the COVID-19 pandemic	dyoung@genedge.org 804.801.6000 acerilli@genedge.org 804.517.1235
VMA	The **Virginia Manufacturers Association** serves as an advocate for Commonwealth businesses and **a resource for training, education, and consulting services to help businesses grow**	The VMA COVID-19 Resource Center, including daily updates and best practices, a COVID-19 Model Action Plan for manufacturers, and the PPE Sourcing Center – a joint effort with McClung Companies	804.643.7489 http://www.vamanufacturers.com/contact-us/

Any entity seeking to sell PPE in Virginia should register at the Private Sector Portal to receive updates PPE-related update from Virginia's Emergency Support Team during the COVID-19 pandemic

1. Companies must meet minimum thresholds

4 Commonwealth of Virginia resources to assist PPE end-users and manufacturers with testing and evaluation

Resource	Role	COVID-19 PPE manufacturer resources available	Point of contact
VDH Virginia Department of Health – Protecting You and Your Environment	The **Virginia Department of Health is leading Commonwealth efforts** to increase COVID-19 testing, awareness, and **evaluating PPE products for medical use during the state of emergency**	Daily-updated COVID-19 dashboard containing locality information on cases, hospitalizations, and deaths Guidance for cloth face covers *(making and wearing)*	804.864.7035 questions@vdh.virginia.gov
Department of Labor and Industry	The **Virginia Department of Labor and Industry administers the Occupation Safety and Health program**, ensuring employers are complying with relevant laws, standards, and regulations	Virginia Occupational Safety and Health's COVID-19 resources Guidance from the Division of Registered Apprenticeship	804.371.2327 Justin.Paxton@doli.virginia.gov covid19questions@doli.virginia.gov

The Commonwealth's latest COVID-19 executive actions and press releases identify manufacturing operations as "essential services" – meaning businesses seeking to retool are able to return to work

4 Additional resources to support retooling manufacturers

State and local

- The **Virginia 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
- The **Virginia Small Business Financing Authority** is the Commonwealth of Virginia's business and economic development financing arm. It has several programs that may interest retooling manufacturers seeking financial support

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

The information provided herein does not, and is not intended to, constitute legal advice; instead, all information, content, and materials provided are for general information purposes only and suggested guidance based on the best available information at this time