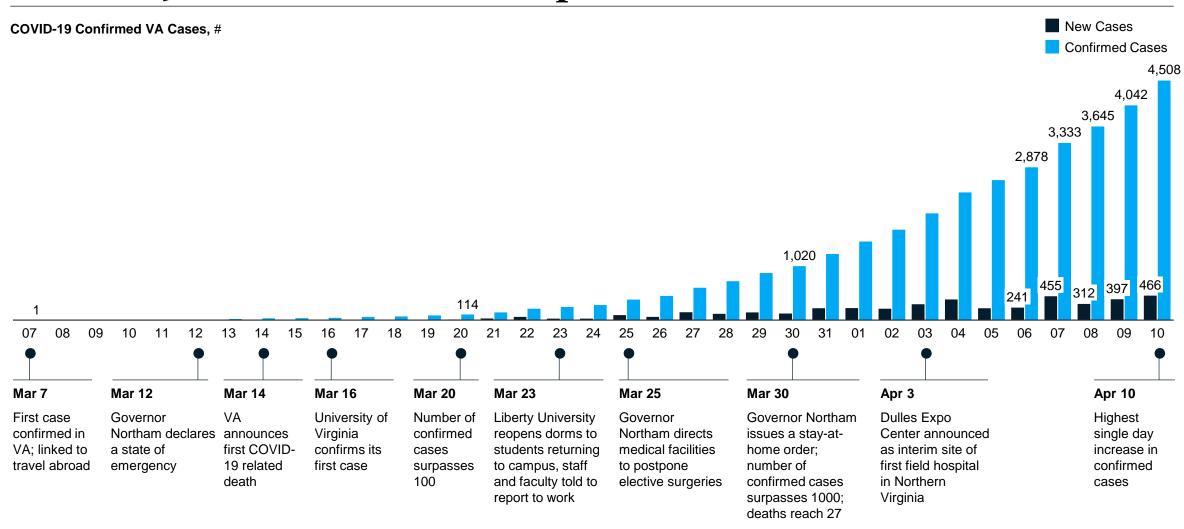
McKinsey & Company

## Commonwealth of Virginia COVID-19 Response

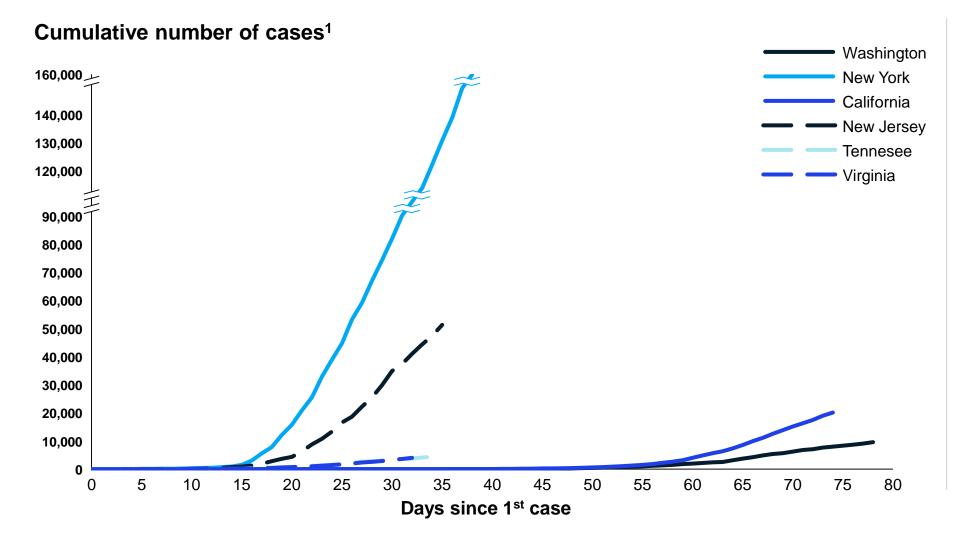
State of Play Fact Pack
10 April 2020



## **COVID-19** in VA: Timeline of Important Events



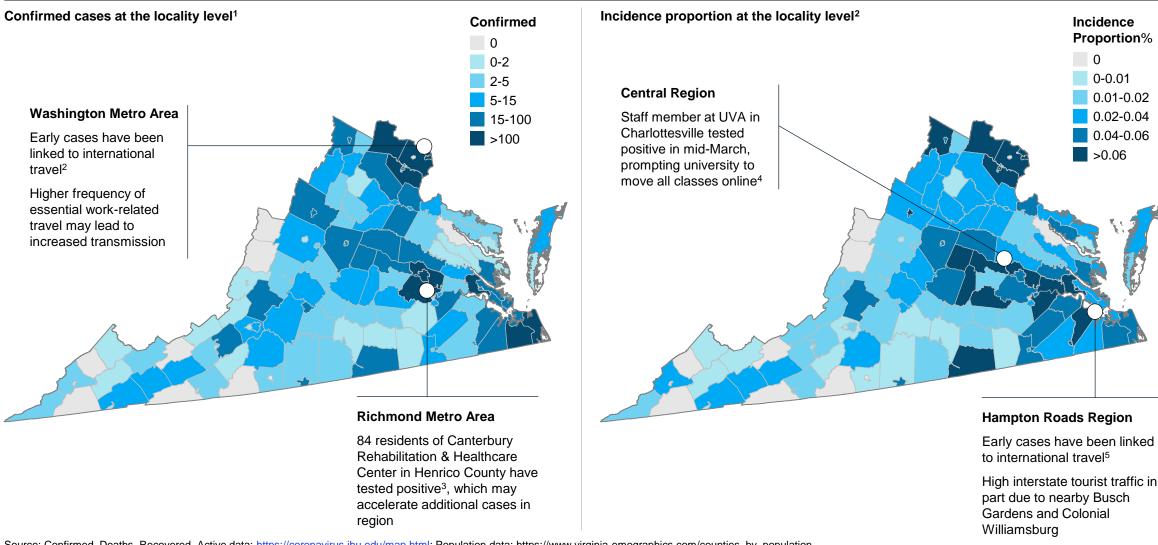
## Early data suggests Virginia is currently on a less aggressive trajectory than New York or New Jersey



### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- California: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

## Case volume is high in counties surrounding DC & Richmond, but incidence is particularly high in Central & Hampton Roads regions



Source: Confirmed, Deaths, Recovered, Active data: <a href="https://coronavirus.jhu.edu/map.html">https://coronavirus.jhu.edu/map.html</a>; Population data: <a href="https://www.virginia-emographics.com/counties\_by\_population">https://coronavirus.jhu.edu/map.html</a>; Population data: <a href="https://www.virginia-emographics.com/counties\_by\_population">https://coronavirus.jhu.edu/map.html</a>; Population data: <a href="https://coronavirus.jhu.edu/map.html">https://coronavirus.jhu.edu/map.html</a>; Population data: <a href="https://coronavirus.jhu.edu/map.

https://www.wtkr.com/iames-citv-county-continues-to-lead-region-in-number-of-cases

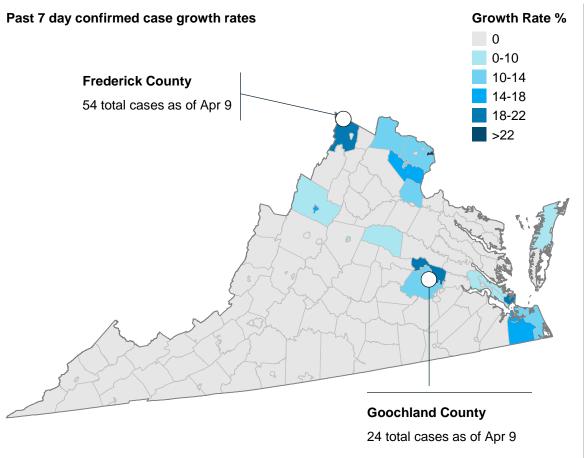
<sup>.</sup> Incidence Proportion = Confirmed Cases / Estimated Population

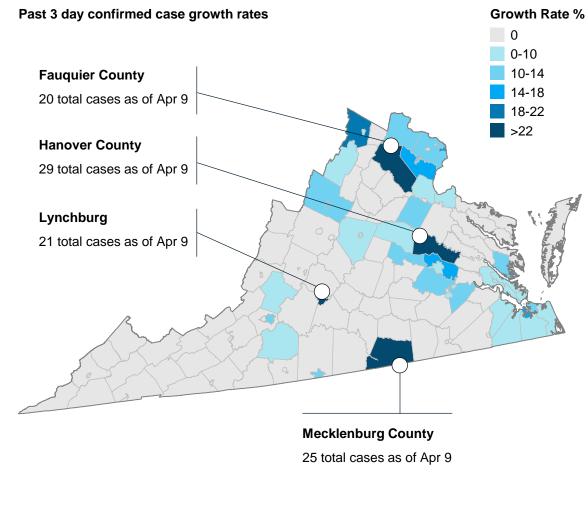
http://www.vdn.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/

https://www.nbc12.com/2020/04/09/more-deaths-overnight-virginia-long-term-care-center-bringing-total/

https://www.dailyprogress.com/news/local/uva-employee-tests-positive-for-covid/article\_578b39be-77d6-5391-80dc-7fcf0277be69.html

## Confirmed cases have grown particularly rapidly in the Central and Northern Regions over the past few days



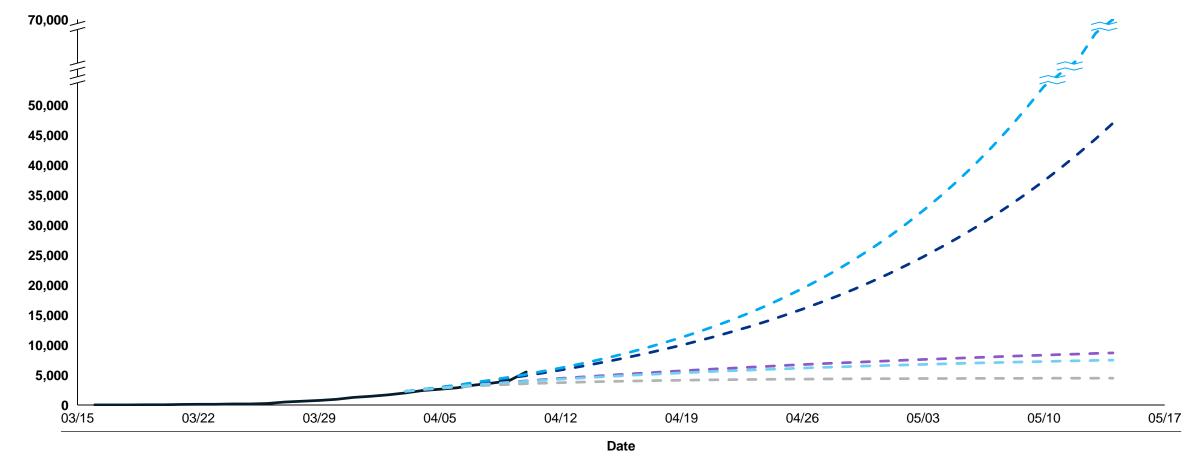


Source: Confirmed, Deaths, Recovered, Active data: https://coronavirus.jhu.edu/map.html

## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia



### **Cumulative number of cases**



Gloves

N95s

### Initiatives target an expanded sourcing strategy and reprocessing equipment to address immediate PPE gap Face shield/ goggles Surgical masks Gowns

**PPE** Initiative Progress/next steps **Targeted PPE inventory** Sub-lever **Status** Key stakeholders HQ, Commerce, Top 40 CEO/SVP Ghost email and contact information 10 10 10 50M+ **VDEM** distributor outreach provided to Cabinet Steering Committee **Expand** Received 4/7; VDEM reviewing and sourcing National Association VDEM. VEDP. 12 ~25M<sup>1</sup> strategy and conducting outreach; Database outlining of Manufacturers **GENEDGE** identify database PPE inventories within the US alternatives Received 4/8; DGS reviewing; Lead 3 8M **Regulus Global LLC** HQ. VDEM provided from former Congressman Scott Taylor; known supplier to Sentara 5-7k masks / N95s per room per day VCU and Volvo are working on UV Ultraviolet VDH, VHHA decontamination kits for Virginia (nfi) decontamination Can be reprocessed 3-10 times HQ, VDEM, VDH, Battelle system Re-use / Purchases are made through FEMA; Up to 80k masks / N95s per day **GENEDGE** acquisition for VA reprocess signed and submitted a request for four Can be reprocessed up to 20x PPE units across the Commonwealth Up to 80k masks / N95s per day Considering a white paper to with HQ, VDEM, VDH, Rent space in non-GENEDGE support to use a system IVO Can be reprocessed up to 20x **GENEDGE VA Battelle system** Washington DC ~\$3.45 per N95 (excl. logistics)

<sup>1.</sup> Based on PPE inventory volume listed in the data base

## Cross-cutting enablers will decrease the time it takes to identify and implement PPE initiatives and increase PPE capture rates

Sub-lever	Cross-cutting enabler	Status	Key stakeholders	Description	Opportunity
	Streamline PPE sourcing process		VDEM, VEDP, VDH	Increase private sector outreach team by additional ~7 FTEs and implement prioritized review and outreach	<ul><li>Capture promising opportunities in less time</li><li>Leverage available capacity in VEDP</li></ul>
Expand sourcing strategy and identify alternatives	VA manufacturing base for retooling		VDEM, VEDP, VMA, GENEDGE	Requesting VA manufacturing capabilities database to size PPE opportunity	<ul> <li>Equip local manufacturers with expertise to begin production to address PPE need and economy</li> </ul>
alternatives	Diversity sourcing partners across geographies		VDEM, VEDP	Outreach to China Council for the Promotion of International Trade, as well as Taiwan and China ambassadors	<ul><li>Gain perspective on global supply chain PPE inventories</li><li>Identify long-term providers</li></ul>
Control and balance inventory	Implement min/max PPE Qty purchase threshold		HQ, VDH, VDEM, VEDP	Broadcast clear demand requirements to provide non-medical manufacturers with incentive to being production	<ul> <li>Increased engagement from local and national manufacturers</li> </ul>
Prioritize and extend PPE usage	Proactive rebalancing and redistribution	•	HQ, VDEM, VDH, GENEDGE	Gather data from Virginia healthcare providers on daily basis to identify burn rate and projected gaps	<ul> <li>Obtain necessary burn rate data to receive SNS PPE shipments</li> <li>Informed demand signal</li> </ul>
Adjust care team guidelines	Communicate CDC PPE guidelines		HQ, VDEM, VDH, GENEDGE	Engage with hospitals to understand their current conservation techniques, and ensure awareness of guidelines	<ul> <li>Informed demand signal</li> <li>Share top-down best practices, and lessons learned across healthcare systems</li> </ul>

### The Unified Command's PPE sourcing process now quickly prioritizes leads and leverages VEDP subject matter expertise

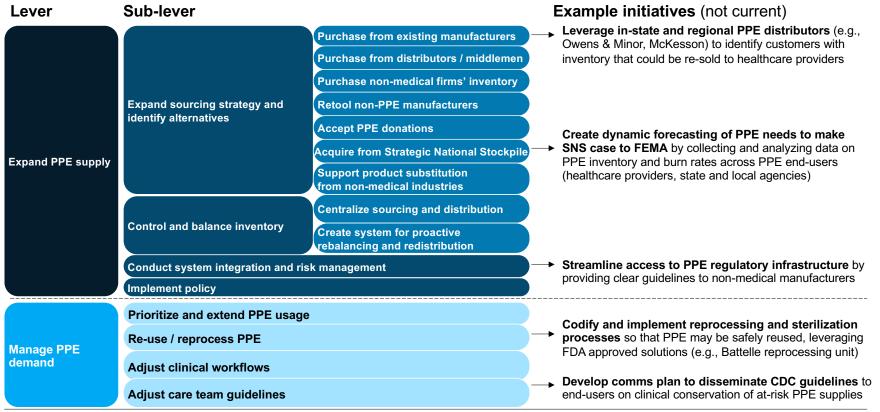
Process change Route all offers of assistance to COVID-19 Filter leads based on requirements **Unified Command** Survey data collection **Prioritization** Follow-up Reconciliation Initial vetting Screening & Procurement Offers of assistance are addressed by: Supplier HQ/ Distribution center location **✓** PPE product offered VEDP updates dataset /PPE quantities via Google Sheets for offered ✓ All private sector outreach **VDEM EM team runs VEDP Business Retention** VDEM to pull dataset to leads are directed to reconcile ArcGIS at COB company through and Expansion team (~7FTEs) complete VDEM survey in BBB. FTC. and conducts follow-ups to order to maintain **VSCC** databases determine if offer should be consolidated database forwarded to DGS VEDP Virginia Economic Development Lead



## **Appendix**

### Framework of PPE Levers

Commonwealth of Virginia COVID-19 PPE Capacity



Gloves

N95s

## Initiatives target an expanded sourcing strategy and reprocessing equipment to address immediate PPE gap Face shield/ goggles Surgical masks Gowns

**PPE Targeted PPE inventory** Initiative **Progress/next steps Sub-lever Key stakeholders Status** HQ. Commerce. Top 40 CEO/SVP Ghost email and contact information 50M+ **VDEM** distributor outreach provided to Cabinet Steering Committee **Expand** Received 4/7; VDEM reviewing and sourcing National Association VDEM, VEDP, 2 12 ~25M1 strategy and of Manufacturers conducting outreach; Database outlining **GENEDGE** identify database PPE inventories within the US alternatives Received 4/8; DGS reviewing; Lead 3 2 8M provided from former Congressman **Regulus Global LLC** HQ. VDEM Scott Taylor; known supplier to Sentara 5-7k masks / N95s per room per day VCU and Volvo are working on UV **Ultraviolet** VDH, VHHA decontamination kits for Virginia (nfi) decontamination Can be reprocessed 3-10 times HQ, VDEM, VDH, **Battelle system** Re-use / Purchases are made through FEMA; Up to 80k masks / N95s per day **GENEDGE** acquisition for VA reprocess signed and submitted a request for four Can be reprocessed up to 20x units across the Commonwealth PPE Up to 80k masks / N95s per day Considering a white paper to with HQ, VDEM, VDH, Rent space in non-GENEDGE support to use a system IVO Can be reprocessed up to 20x **GENEDGE VA Battelle system** Washington DC ~\$3.45 per N95 (excl. logistics)

## Cross-cutting enablers will decrease the time it takes to identify and implement PPE initiatives and increase PPE capture rates

Sub-lever	Cross-cutting enabler	Status	Key stakeholders	Description	Opportunity
	Streamline PPE sourcing process		VDEM, VEDP, VDH	Increase private sector outreach team by additional ~7 FTEs and implement prioritized review and outreach	<ul><li>Capture promising opportunities in less time</li><li>Leverage available capacity in VEDP</li></ul>
Expand sourcing strategy and identify alternatives	VA manufacturing base for retooling		VDEM, VEDP, <b>VMA, GENEDGE</b>	Requesting VA manufacturing capabilities database to size PPE opportunity	<ul> <li>Equip local manufacturers with expertise to begin production to address PPE need and economy</li> </ul>
aiternatives	Diversity sourcing partners across geographies		VDEM, VEDP	Outreach to China Council for the Promotion of International Trade, as well as Taiwan and China ambassadors	<ul><li>Gain perspective on global supply chain PPE inventories</li><li>Identify long-term providers</li></ul>
Control and balance inventory	Implement min/max PPE Qty purchase threshold		HQ, VDH, VDEM, VEDP	Broadcast clear demand requirements to provide non-medical manufacturers with incentive to being production	<ul> <li>Increased engagement from local and national manufacturers</li> </ul>
Prioritize and extend PPE usage	Proactive rebalancing and redistribution		HQ, VDEM, VDH, GENEDGE	Gather data from Virginia healthcare providers on daily basis to identify burn rate and projected gaps	<ul> <li>Obtain necessary burn rate data to receive SNS PPE shipments</li> <li>Informed demand signal</li> </ul>
Adjust care team guidelines	Communicate CDC PPE guidelines		HQ, VDEM, VDH, GENEDGE	Engage with hospitals to understand their current conservation techniques, and ensure awareness of guidelines	<ul> <li>Informed demand signal</li> <li>Share top-down best practices, and lessons learned across healthcare systems</li> </ul>

## The Unified Command's PPE sourcing process now quickly prioritizes leads and leverages VEDP subject matter expertise

✓ Process change

Route all offers of assistance to COVID-19 **Unified Command** 

Filter leads based on requirements

Survey data collection

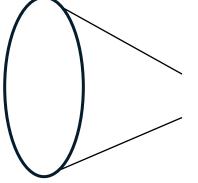
**Initial vetting** 

**Prioritization** 

Follow-up

Reconciliation

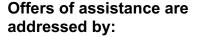








**VDEM EM team runs** company through BBB, FTC, and **VSCC** databases



- **✓** Supplier HQ/ **Distribution center** location
- **✓** PPE product offered
- /PPE quantities offered



**VEDP Business Retention** and Expansion team (~7FTEs) conducts follow-ups to determine if offer should be forwarded to DGS





**VEDP** updates dataset via Google Sheets for **VDEM** to pull dataset to reconcile ArcGIS at COB





consolidated database









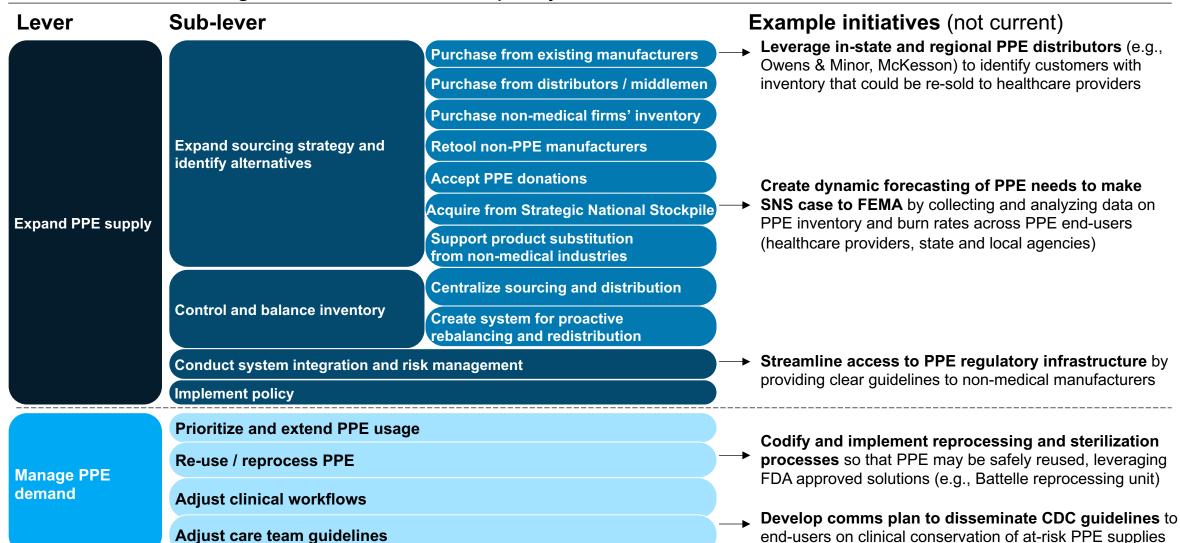


Screening & Procurement

## **Appendix**

### Framework of PPE Levers

Commonwealth of Virginia COVID-19 PPE Capacity



McKinsey & Company

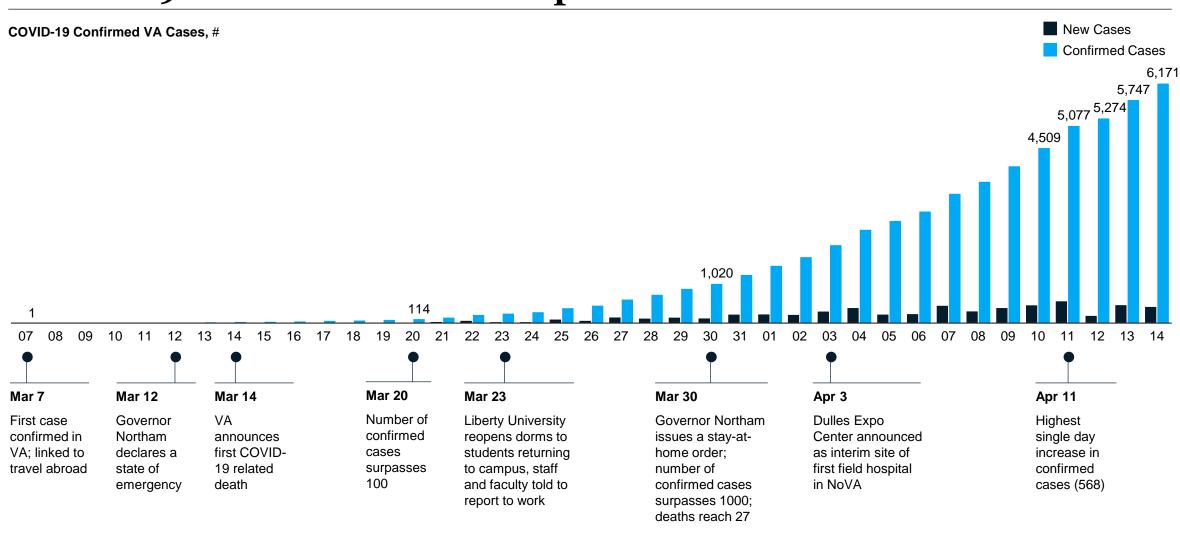
## Commonwealth of Virginia COVID-19 Response

State of Play Fact Pack
14 April 2020

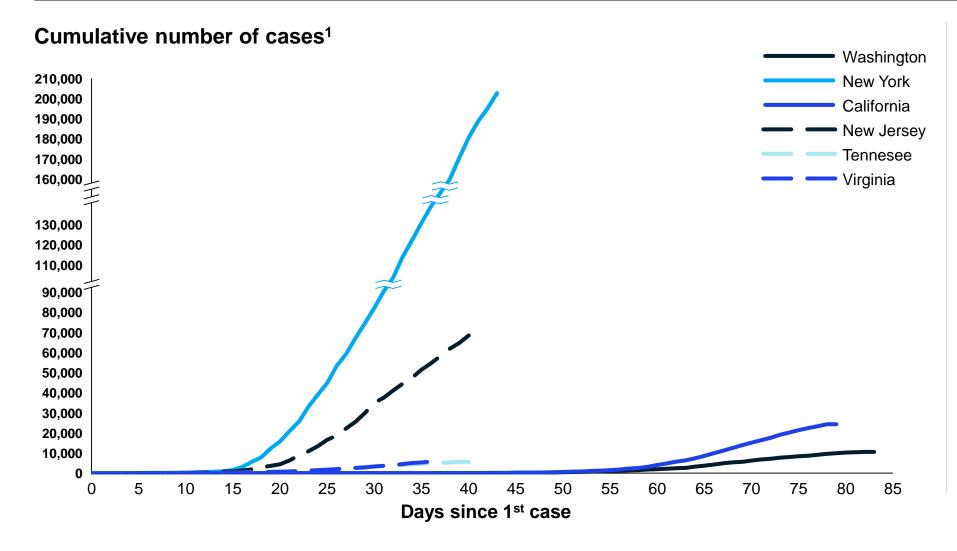


CONFIDENTIAL AND PROPRIETARY
Any use of this material without specific permission of McKinsey & Company is strictly prohibited

## **COVID-19** in VA: Timeline of Important Events



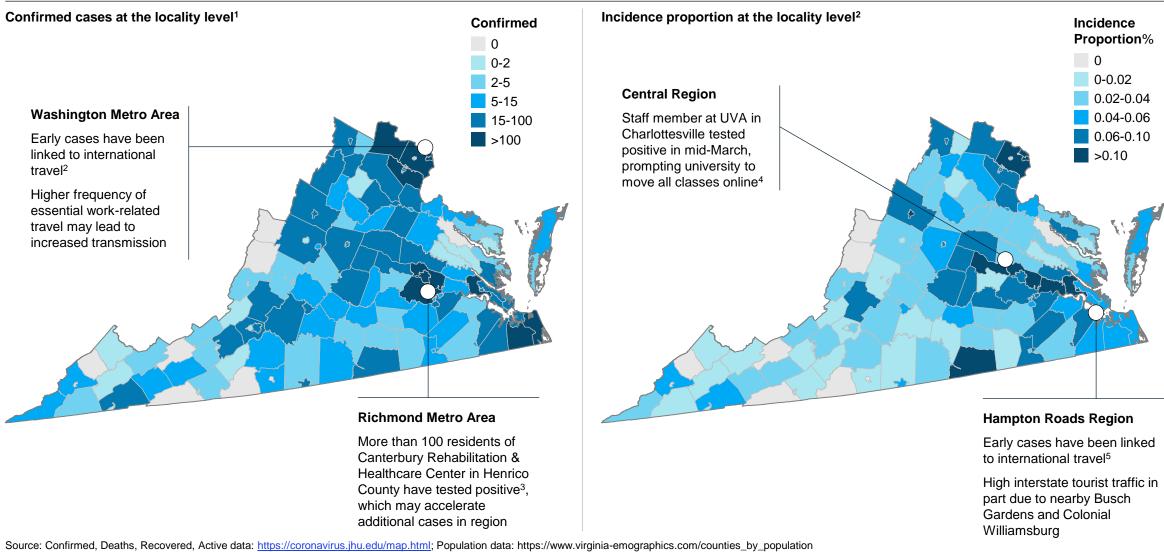
## Virginia is currently on a less aggressive trajectory than New York or New Jersey



### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- California: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

## Case volume is high in counties surrounding DC & Richmond, but incidence is also high in Central & Hampton Roads regions



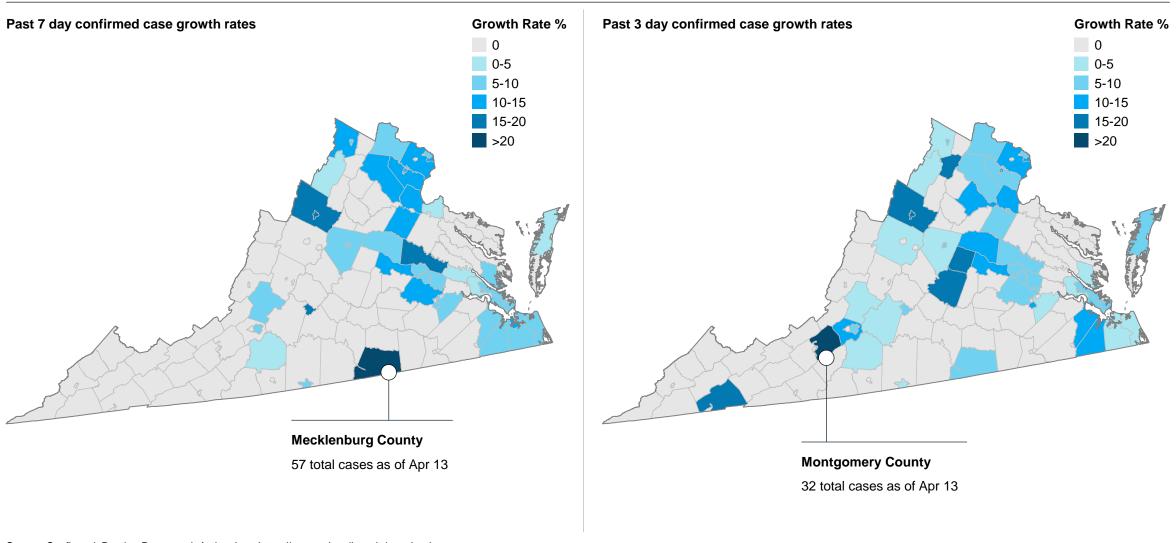
Incidence Proportion = Confirmed Cases / Estimated Population

http://www.vdh.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/

<sup>3.</sup> https://www.wric.com/news/local-news/45-dead-in-coronavirus-outbreak-at-canterbury-rehabilitation-healthcare-center/

https://www.dailyprogress.com/news/local/uva-employee-tests-positive-for-covid/article\_578b39be-77d6-5391-80dc-7fcf0277be69.html
 https://www.wtkr.com/james-citv-county-continues-to-lead-region-in-number-of-cases

## Confirmed cases have grown particularly rapidly in the Central and Northern Regions over the past few days

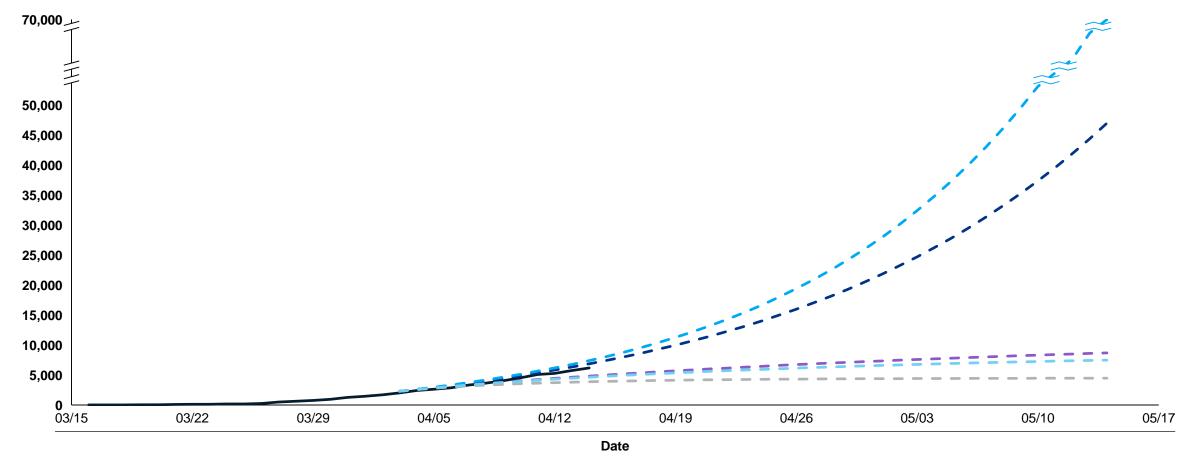


Source: Confirmed, Deaths, Recovered, Active data: https://coronavirus.jhu.edu/map.html

## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia



### **Cumulative number of cases**



McKinsey & Company

## Commonwealth of Virginia COVID-19 PPE Capacity Project

Procurement requirements & initiatives update
April 14, 2020

**Deliberative Process Privileged Document** 

CONFIDENTIAL AND PROPRIETARY
Any use of this material without specific permission of McKinsey & Company is strictly prohibited

### **Today's objectives**

- Align on initial procurement requirements for PPE in Virginia
- Provide update and receive input on in-flight PPE initiatives

### Creating a central PPE demand signal is critical to driving PPE procurement and informing distribution

Focus of this document

Develop a high-level view on PPE needs **Establish top-down PPE** ☐ Priority PPE types for COVID-19 requirements to provide demand signal to ☐ Future-looking scenarios of estimated PPE needs suppliers ☐ PPE segmentation by end user (e.g., acute care, long-term care, first responder, etc) Stakeholders to engage for a regular stream of PPE data: Establish infrastructure to □ VDEM (public hospitals, first responders, utilities) collect PPE usage data

from end users

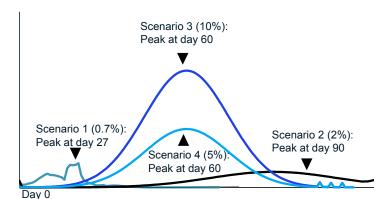
- ☐ VHHA (private hospital systems and independent hospitals)
- ☐ Other points of contact to establish a comprehensive view of PPE use landscape

**Continually adjust** procurement / distribution based on end-user needs

Utilize PPE use data enable mindful decision-making:

- ☐ Understand gaps between supply and anticipated demand at the regional / hospital system level
- Distribute PPE to end-users in need
- ☐ Adjust distribution over time to reflect changing needs

## Modeling of COVID-19 progression informs four scenarios that Virginia should consider



Scenario 1: 0.7% infection rate (observed) – Empirical Wuhan scenario

Represents a curve with Wuhanlike measures, where no measures are put in place at the beginning, resulting in a quick ramp-up, however, followed by a very rigorous and strict lockdown, leading to a lower infection rate and quicker rampdown

NOTE: 0.7% of the population has been infected over 70 days

Note: End of curve occurs when therapeutics and vaccines are available

Scenario 2:

2% infection rate with a 90 day peak

Represents a curve where initial epidemic uptick results in moderate measures (e.g., physical distancing) are put into place, resulting in a very slow rise, with more robust action over a certain amount time to slowly bring infection rates down

NOTE: 2% of the population has been infected over 180 days

rection rates down

NOTE: 10% of the population has been infected over 120 days

Represents the "worst case"

scenario where very limited

measures are put into place.

resulting in a severe peak and

a high (10%) infection rate

over a 120 day period

Scenario 3:

peak

NOTE: 5% of the population has been infected over 120 days

Scenario 4:

period

10% infection rate with a 60 day 5% infection rate with a 60 day

scenario. where limited measures

are put in place, leading to a 5%

infection rate over a 120 day

Represents a mid-point

Day 180

DRAFT WORKING DOCUMENT – DELIBERATIVE PROCESS PRIVILEGED

The development of multiple epidemiology scenarios across external and internal McKinsey models reflects the amount of variability in the data, assumptions, and differences in local measures and corresponding impact

Based off of these models, we have created four scenarios to create a range which should be considered as "book ends" for planning purposes, particularly given the need to mobilize with the understanding that changes occur on a daily basis, therefore having a range to enable contingency planning

McKinsey & Company
Proprietary and confidential

### **Preliminary Analysis - For Discussion**

## These four epidemiological scenarios provide insight into incremental COVID-19 PPE demand in acute care hospital settings

Incremental PPE D	Demand in acute care hospital settings <sup>1</sup> , # units <sup>2</sup>	0.7% infection rate (Empirical Wuhan scenario)	2% infection rate, day 90 peak	10% infection rate, day 60 peak	5% infection rate, day 60 peak
Ventilators <sup>3</sup>	Up to 7.5k ventilators	1.2k	1.0k	7.5k	3.8k
Masks (N95)	Up to 43.7M N95 respirators	16k – 4.4M	39k – 9.8M	150k – 43.7M	81k – 22.3M
Masks (surgical) <sup>4</sup>	Up to 1.8M surgical masks	212k	529k	1.8M	1.0M
Nitrile gloves (pairs)	Up to 43.7M nitrile gloves	1.9M – 4.4M	4.2M – 9.8M	18.9M – 43.7M	9.7M – 22.3M
Gowns, disposable	Up to 43.7M disposable gowns	5k – 4.4M	24k – 9.8M	31k – 43.7M	19k – 22.3M
Gowns, linen <sup>5</sup>	Up to 51k linen gowns	0 – 8k	0 – 7k	0 – 51k	0 - 25k

<sup>1.</sup> These values do not consider supplies needed to sustain pre-acute sites, post-acute sites, and non-healthcare sites to treat COVID patients (e.g., first responders, law enforcement, utility workers)

<sup>2.</sup> Values in ranges represent three PPE use case scenarios: conventional (standard clinical practices), contingency (e.g., re-using a face shield throughout the day), and crisis (e.g., re-using a face shield until damaged or soiled)

<sup>3.</sup> Ventilator values are not shown in ranges because they are reusable in every use case scenario

<sup>4.</sup> Surgical mask values are not shown in ranges because they are used on patients so their utilization is consistent in every use case scenario

<sup>5.</sup> Utilization of linen gowns increases in a "crisis" use case scenario as it replaces utilization of disposable gowns

# require significant quantities of N95 respirators, masks, and gloves Non-hospital PPE users are included in the demand signal as they

Significant demand expected from end user

considered by demand scenarios

End user segments not

Gowns, linen	Gowns, disposable	Nitrile gloves (pairs)	Masks (surgical)	Masks (N95)	Ventilators	Supply Type
0 – 51k	4.4M – 43.7M	4.4M – 43.7M	212k - 1.8M	4.4M – 43.7M	1.0k – 7.5k	Acute-Care Facilities (conventional PPE use <sup>1</sup> )
	<	<	<	<		Long-Term Care Facilities
	<	<	<	<		Other Healthcare Providers
		<	<	<		First Responders
		<	<			Other Essential Gov't Workers and Contractors
0%	30%+2	30%+2	Variable	30%+2	0%	Estimated % Need From Non-Acute Care Users
0 – 51k	6 Million +	6 Million +	212k+ for only patients 4M+ for gov't workers <sup>3</sup>	6 Million +	1.2k – 7.5k	Estimated Total Incremental Demand Signal

ων.→ PPE utilization following standard clinical practices (e.g. dispose consumable after every patient interaction)
Experiences in governments (state, local, federal, foreign) suggest ~70% of PPE consumed in acute care setting and ~30% consumed by other end-users
Assumes 20% of Virginia's ~180,000 state and local employees wear one face mask a day for 120 days

## issuing a request for proposal Recommendation: publish a clear demand signal to industry by

## ☐ When is the earliest we can complete this request for proposal? □ Do we want to set minimum / maximum quantities per supplier? For Discussion: ☐ Commit to EOD Thursday deadline ☐ Name POC responsible for drafting requests for proposal ☐ Agree to publish a clear demand signal **Decisions:** □ Do we want to submit this as a public demand signal or share with □ Agree on quantities to request for critical PPE / supplies key vendors? (N95s, surgical masks, gowns, gloves, ventilators)

## tracking tools in order to validate demand and address gaps High utilization end users require daily inventory and burn rate

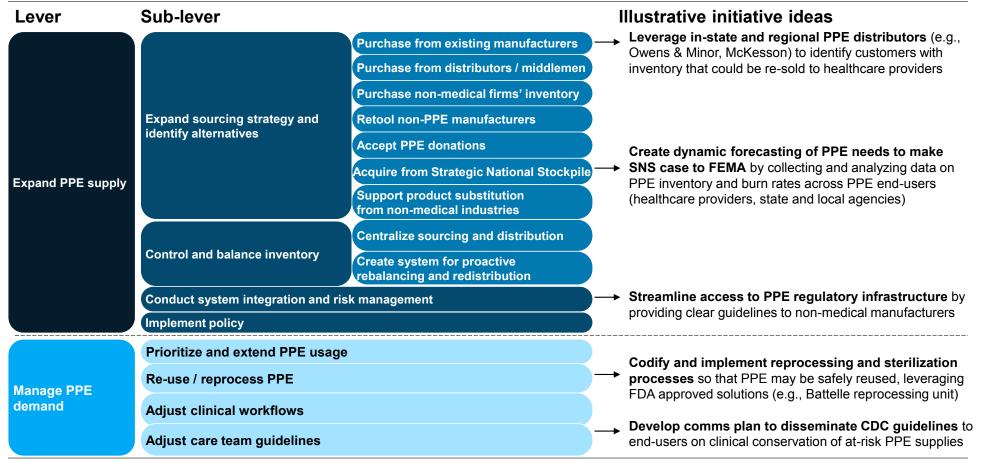
For Discussion

## Today's objectives

- Align on initial procurement requirements for PPE in Virginia
- Provide update and receive input on in-flight PPE initiatives

### PPE initiatives are being identified along a holistic set of PPE levers

Framework for increasing net PPE



Gloves

N95s

### Initiatives target an expanded sourcing strategy and reprocessing equipment to address immediate PPE gap (1/2) Face shield/ goggles Surgical masks

Detail follows Leadership No issues Work required **PPE** quidance required Key **Targeted PPE inventory** Progress/next steps Sub-lever Initiative **Status** stakeholders Email sent 4/10: initial discussion with HQ, VEST Engage top 40 10 50M+ MSC Industrial yielded promising distributors via CEOs sourcing of bulk PPE supply Leverage NAM<sup>1</sup> Received 4/7; Database outlining PPE VDEM, VEDP, inventories within the US; Awaiting ~25M<sup>2</sup> database to target **GENEDGE** potential PPE vendors **VDEM** review Received 4/8: approved and PO being Procure from distributor: VDEM, VEST executed; lead provided by former Rep.  $\sim$ 8M by 5/2 **Expand** Regulus Global LLC Scott Taylor; known Sentara supplier sourcing strategy and identify Salem, VA-based company; masks and Procure via retooling alternatives Level IV gowns; awaiting product review 100k 100k ~200k by ~5/7 VDEM. VDH manufacturer: ITS for procurement to move forward Received 4/10; Offering FDA-approved Procure via retooling 1M+ by ~4/20 VDEM, VHA, face shields for delivery as early as late manufacturer: Ford Motor **VEST** April; shipped samples to VHA Company Dr. Leonardo distributing ~275/wk face Drive local production: VDEM, VDH shields from Loudon County; seeking 1.7k per week Janelia Research Campus, HHMI support to increase capacity

<sup>1.</sup> National Association of Manufacturers

<sup>2.</sup> Based on PPE inventory volume listed in the data base

## DRAFT WORKING DOCUMENT - DELIBERATIVE PROCESS PRIVILEGED

## equipment to address immediate PPE gap (2/2) Initiatives target an expanded sourcing strategy and reprocessing

	Den	nand		
	PPE	Re-use /		Sub-lever
Leverage complimentary Micron ventilator refurbishment	Rent space in non- Virginia Battelle systems	Acquire in-state Battelle system for Virginia	Acquire UV Germicidal decontamination system	PPE Initiative
				Status
VDEM, VDH, VHHA	HQ, VEST, VDH, GENEDGE	HQ, VEST, VDH, GENEDGE	VDH, VHHA, VMA	Key stakeholders
Offering service to re-certify and test decommissioned ventilators; requires model/inventory info of VA ventilators	NCR system coming online by end of month. Planning implementation. Need to determine VA share of NCR system	Purchases made through FEMA; VA signed and submitted a request for 3 units across the Commonwealth	Exploring feasible options within VA; VCU and Volvo are working on UV decontamination kits; tracking Project Shining Light through VMA	Progress/next steps
<ul> <li>Micron partnering with Bloom Energy to collect, refurbish, certify and test, and deliver ventilators back to hospitals</li> </ul>	<ul> <li>10k to 80k masks / N95s per day</li> <li>Can be reprocessed up to 20x</li> <li>FEMA will cover expenses</li> </ul>	<ul><li>10k to 80k masks / N95s per day</li><li>Can be reprocessed up to 20x</li></ul>	<ul><li>5-7k masks / N95s per room per day</li><li>Can be reprocessed 3-10x</li></ul>	No issues

## PPE initiatives and increase PPE capture rates (1/2)Cross-cutting enablers decrease the time it takes to implement

				H	
Sub-lever	Cross-cutting enabler	Status	Key stakeholders	Description	No issues
	Streamline PPE sourcing process for ~180 priority offers of assistance		VDEM, VEDP, VDH	Increased private sector outreach team by additional ~7 FTEs and implementing prioritized review and outreach	<ul> <li>Capture promising opportunities in less time, using VEDP capacity</li> <li>Develop view of procurement pipeline</li> </ul>
Expand sourcing strategy and identify alternatives	Create simple step-by- step retooling process for manufacturers		VDEM, VEDP, GENEDGE, VDH	Creating plain-English version of CDC/FDA guidance to communicate to non-medical manufacturers	<ul> <li>Equip local manufacturers with expertise to begin production to address PPE need and economy</li> </ul>
	Develop Chinese PPE supplier network through CCPIT		VDEM, VEDP	Outreach to China Council for the Promotion of International Trade POC via VEDP; contacted 4/11 and waiting for response	<ul> <li>Gain perspective on global supply chain PPE inventories</li> <li>Identify long-term providers</li> </ul>
Control and balance inventory	Broadcast clear demand requirements for PPE procurements		VDH, VDEM, VEST	Provide minimum/maximum PPE quantity purchase thresholds and accepted prices from vendors	<ul> <li>Increase incentive for retooling manufacturers to being production</li> <li>Increase engagement from local and national manufacturers</li> </ul>

and extend

reallocation strategy burn-rate data to inform

## Cross-cutting enablers decrease the time it takes to implement PPE initiatives and increase PPE capture rates (2/2)

DRAFT WORKING DOCUMENT - DELIBERATIVE PROCESS PRIVILEGED

Sub-lever **Prioritize Cross-cutting enabler** Gather comprehensive Status VDEM, VDH, VHHA stakeholders Key Description Gather data from Virginia healthcare No issues Opportunity Obtain necessary burn rate data to Work required guidance required Leadership

providers on daily basis to identify burn

rate and projected inventory gaps

PPE usage Adjust care

Communicate CDC PPE guidelines

guidelines

VDH, VHHA HQ, VDEM,

and ensure awareness of guidelines their current conservation techniques Engage with hospitals to understand

Informed demand signal

Informed demand signal

receive SNS PPE shipments

systems Share top-down best practices, and lessons learned across healthcare

# **Integrated Textile Solutions**

Initiative

# Status: Leadership guidance required

# Solutions

# Initiative description

- VA-based company with factories in Salem, VA and South Boston
- Secured necessary materials to **produce face** masks (ramping up from 50k per week to ~100k per
- Currently selling masks into local markets via emergency services, hospitals, nursing facilities, and first responders
- Exploring options for N95 certification (Yale and WV labs)
- standards Can produce gown and hood at Level 4

# Initiative Aspiration

### PPE target

- Face masks 100k (\$3.19/mask)
- Gowns (Level 4) TBD

## Time to impact

- Face masks: NLT 5/8 based on quote
- Gowns: TBD

# Actions to date

- 4/3: Quote received for face masks 4/8: Forwarded to DGS

producing Level 4 gowns and hoods 4/12: Received notification that ITS is

# Initiative Milestones

Milestone

Deadline

•	_	_	_	-	
Face masks delivered	Purchase order completed	VDH written product (masks and gowns) approval provided	VDEM procurement review completed	DGS investigation completed	Sourcing review completed
• 5/8	• TBD	• 4/16	• 4/15 <i>\</i>	• 4/14 <i>\</i>	• 4/5 <i>\</i>
				Ì	Ì

# **Accountabilities**

Organization Name - Description

•
VDEM • Stacie Neal - Source lead

# Leadership Decisions and/or Actions Required

Identify VDH representative responsible for approving/disapproving ITS requirements for masks and gowns

# Simply step-by-step retooling process Enabler

Status: Leadership guidance required

Detail follows

# **Enabler description**

- Manufacturers seeking to retool for PPE production lacking clarity on legal/FDA/OSHA requirements
- GENEDGE is currently offering services to VA FDA recently released COVID-19 PPE guidance for industry
- manufacturers (e.g., technical expertise consulting) Limited communication between VEST, VDH and VDEM to align on requirements communication strategy

# **Enabler Aspiration**

### PPE target

- N95s: 1M+
- Surgical masks: 1M+
- Gloves: 1M+
- Face shields/goggles: 1M+
- Gowns: 1M+
- (Includes PPE for non-medical use)

## Time to impact

Less than 4 weeks given significant outreach from non-medical manufacturers to VDEM, VDH, and DGS

# Actions to date

	•
Commonwealth	4/2: GENEDGE and VMA offer assistance to the   •
Emergency	the • 4/7: FDA webinar on upc
y Use Authorization procedures	vebinar on updated guidelines and

# **Enabler Milestones**

_	Milestone	Deadline
	<ul> <li>Identify lead POCs from necessary organizations</li> </ul>	• 4/14
	Align on FDA/CDC guidance for non-medical retooling manufacturers	• 4/15
	<ul> <li>Establish and formalize partnership with GENEDGE for retooling expertise</li> </ul>	• 4/17

Deadline

# Accountabilities

Organization	Name - Description
• VDH	Roxanne Erhardt
• VHHA	• TBD
<ul> <li>VDEM</li> </ul>	Stacie Neal
GENEDGE	Bill Donohue - Retooling technical expertise
• VMA	Brett Vassey – Manufacturing base expertise

# Leadership Decisions and/or Actions Required

- Agree to proceed with the development of retooling guide to share with non-medical manufacturers of PPE
- Identify VHHA POC and confirm VDH POC for coordinating on development of guidance

# manufacturers to reference for consolidated FDA/CDC guidance We are building a clear, plain-English resource for non-medical

### Enabler

## Situation

VEST, VDEM and VDH fields numerous requests from non-medical manufacturers for guidance to inform their PPE retooling process

# Complication

- Highly complex regulations make it difficult for manufacturers to navigate unchartered territory
- VEST, VDH, and VDEM lacking unified response language/guidance to affected non-medical manufacturers

# Potential course of action

 Leverage VDH regulation guidance is providing manufacturers

Incorporate additional FDA guidance — for industry



 Direct businesses to GENEDGE for additional retooling expertise

What does this look like from a



What does this look like from a manufacturer's perspective?

- Clear and consistent retooling reference material across Unified COVID-19 Command
- Simple document that points manufacturers to only necessary guidance
- Reference material packaged in a manner that could be shared with VMA and GENEDGE for expanded dissemination to VA manufacturing base

# **Next steps**

# Publish clear demand signal to industry

- Continue refining epidemiological modeling with available data to inform leadership decision-making and PPE demand scenarios
- Release demand signal document by collaborating with VDH and VDEM
- Leverage completed and in-flight procurement data to inform remaining PPE needs, including launching VHHA PPE data collection

# Produce step-by-step retooling playbook

- Obtain VDEM, VDH, and VEST alignment on synthesized CDC/FDA PPE guidance for non-medical manufacturers
- Coordinate with GENEDGE to share PPE retooling best practices with manufacturers
- Make playbook available to manufacturers through VEST, GENEDGE and additional channels

# **PPE** initiatives

- Create simple view to track progress along 180+ prioritized PPE opportunities from VDEM's offers of assistance
- Identify additional opportunities for immediate PPE procurement from external databases
- Rapidly determine opportunity for MSC Industrial to serve as a bulk supplier of PPE
- Prioritize leads from the National Association of Manufacturer's based on available PPE inventory
- Target additional suppliers that are suited to be retooling manufacturers from McKinsey suppliers database

# **PPE** demand management

Share best practices for prioritizing and extending PPE usage with PPE end-users through VHHA and MSV

McKinsey & Company

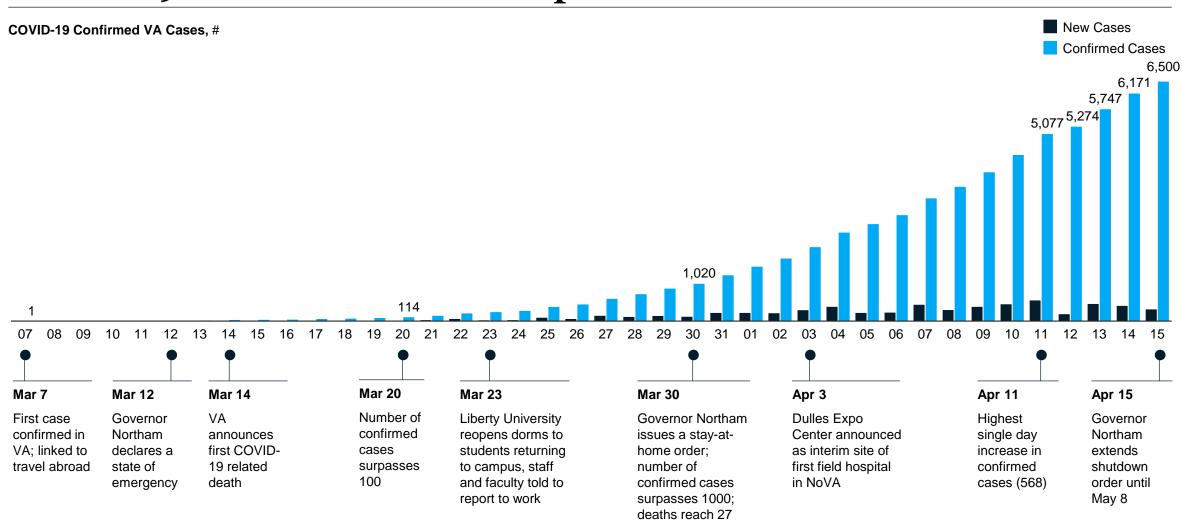
### Commonwealth of Virginia COVID-19 Response

State of Play Fact Pack
14 April 2020

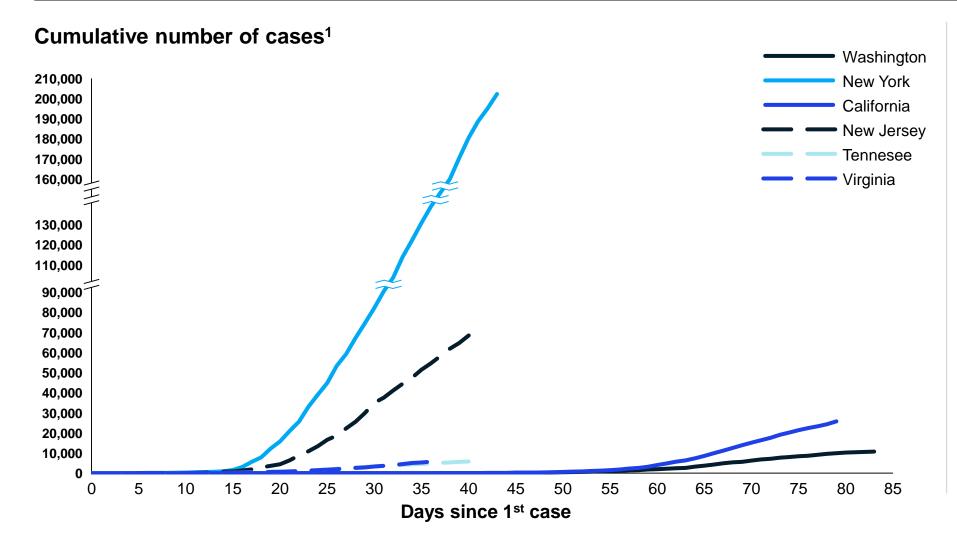


CONFIDENTIAL AND PROPRIETARY
Any use of this material without specific permission of McKinsey & Company is strictly prohibited

#### **COVID-19** in VA: Timeline of Important Events



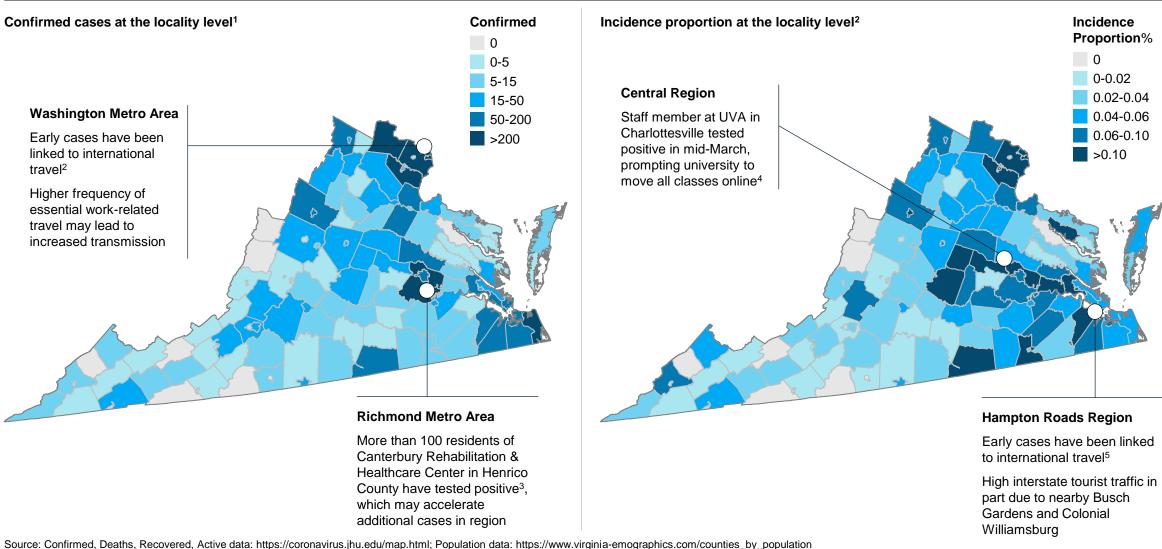
## Virginia is currently on a less aggressive trajectory than New York or New Jersey



#### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- California: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

## Case volume is high in counties surrounding DC & Richmond, but incidence is particularly high in Central & Hampton Roads regions

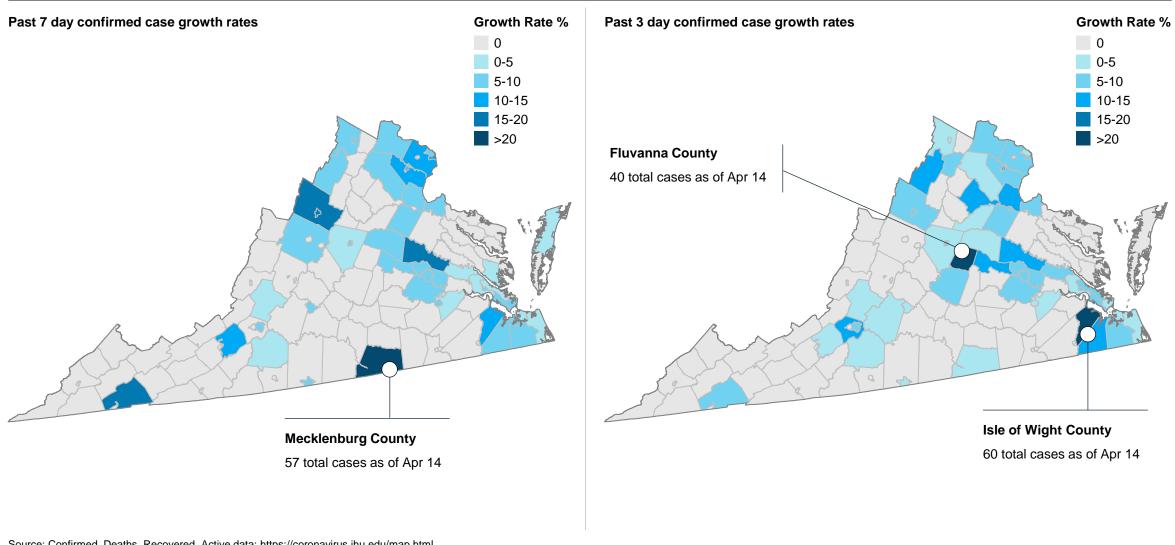


1. Incidence Proportion = Confirmed Cases / Estimated Population

http://www.vdh.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/https://www.wric.com/news/local-news/45-dead-in-coronavirus-outbreak-at-canterbury-rehabilitation-healthcare-center/

https://www.dailyprogress.com/news/local/uva-employee-tests-positive-for-covid/article\_578b39be-77d6-5391-80dc-7fcf0277be69.html
 https://www.wikr.com/iames-city-county-continues-to-lead-region-in-number-of-cases

#### Confirmed cases have grown particularly rapidly in the Central and **Hampton Roads Regions over the past few days**

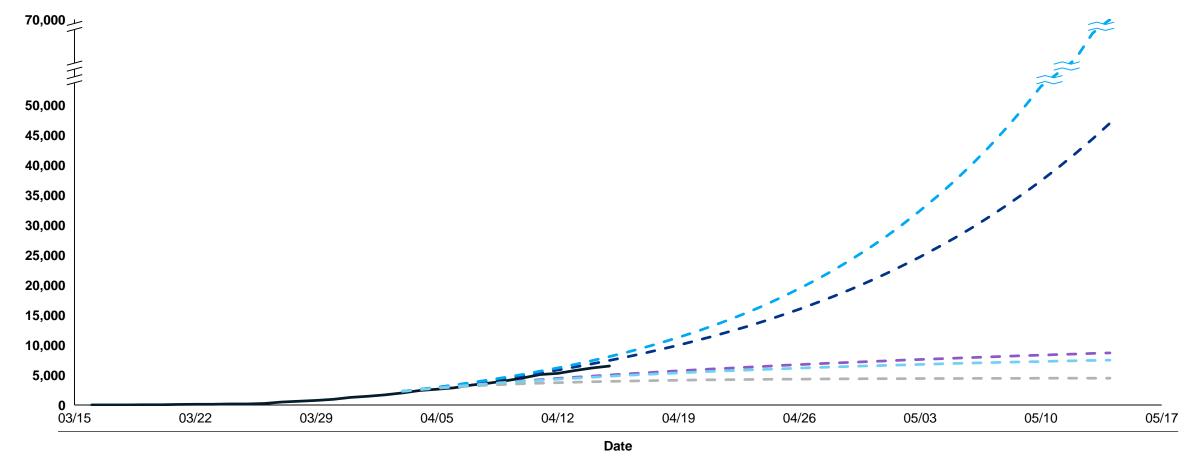


Source: Confirmed, Deaths, Recovered, Active data: https://coronavirus.jhu.edu/map.html

## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia



#### **Cumulative number of cases**



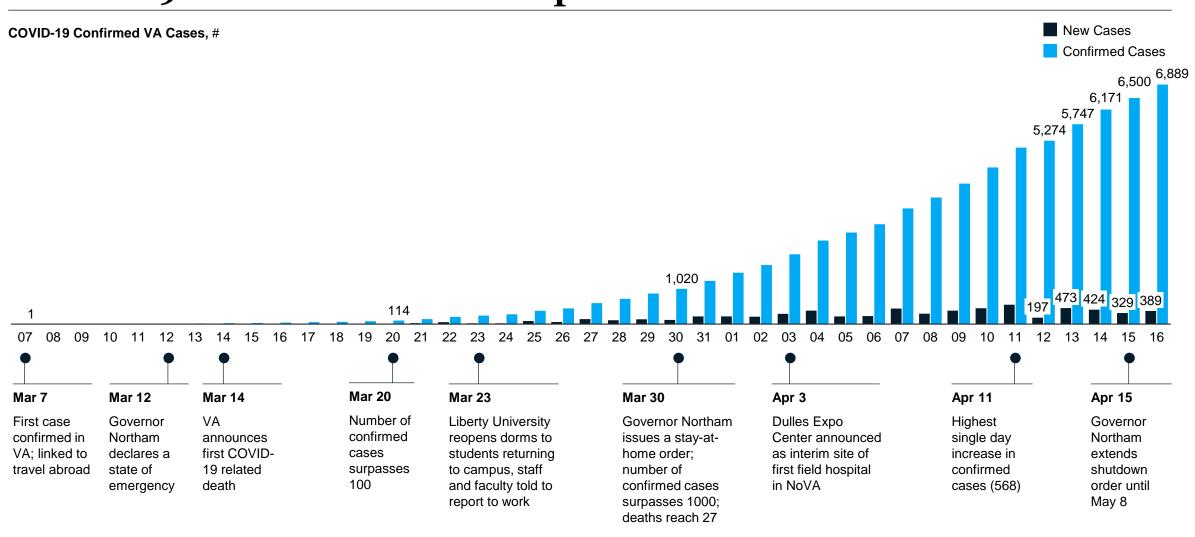
McKinsey & Company

### Commonwealth of Virginia COVID-19 Response

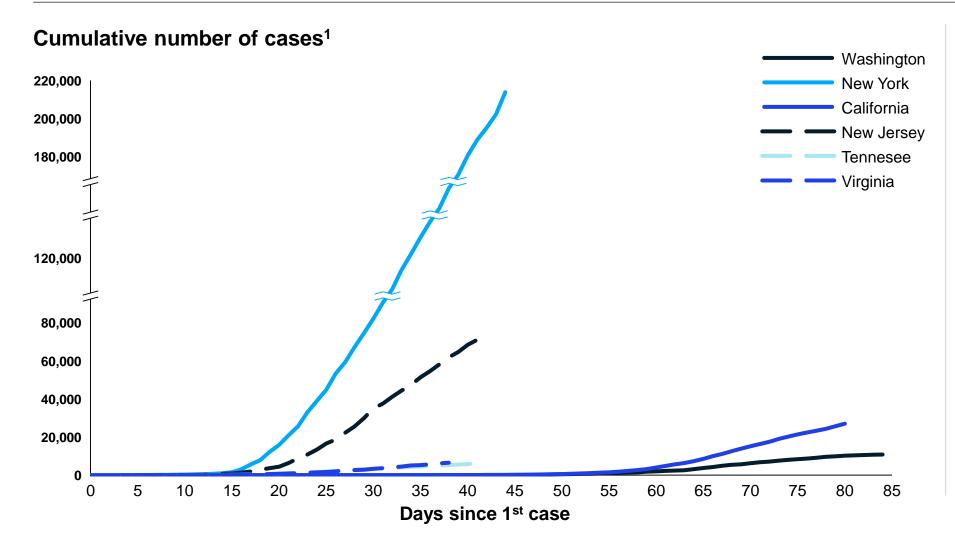
State of Play Fact Pack
16 April 2020



#### **COVID-19** in VA: Timeline of Important Events



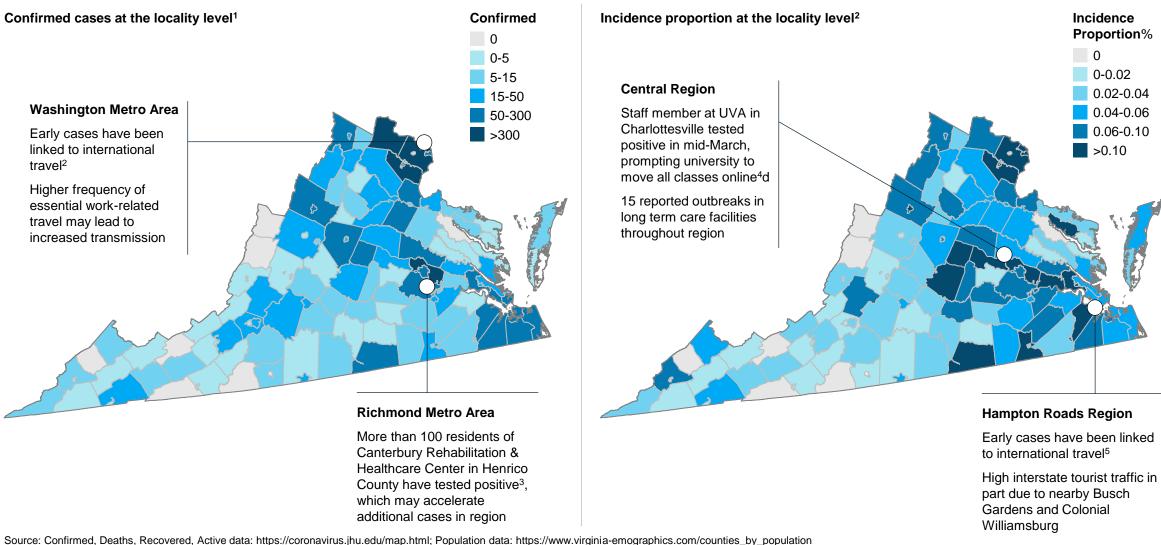
## Virginia is currently on a less aggressive trajectory than New York or New Jersey



#### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- California: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

#### Case volume is high in counties surrounding DC & Richmond, but incidence is particularly high in Central & Hampton Roads regions



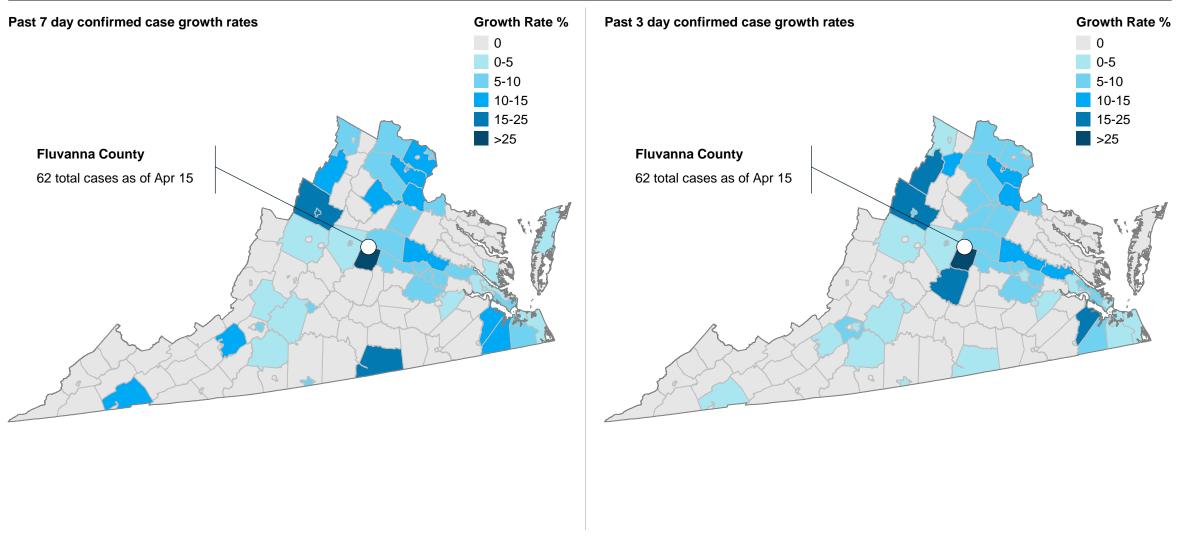
Incidence Proportion = Confirmed Cases / Estimated Population

http://www.vdh.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/ https://www.wric.com/news/local-news/45-dead-in-coronavirus-outbreak-at-canterbury-rehabilitation-healthcare-center/

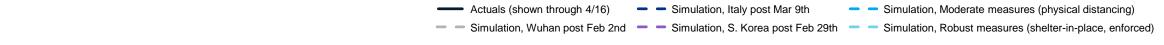
https://www.dailyprogress.com/news/local/uva-employee-tests-positive-for-covid/article\_578b39be-77d6-5391-80dc-7fcf0277be69.html

https://www.wtkr.com/james-city-county-continues-to-lead-region-in-number-of-cases

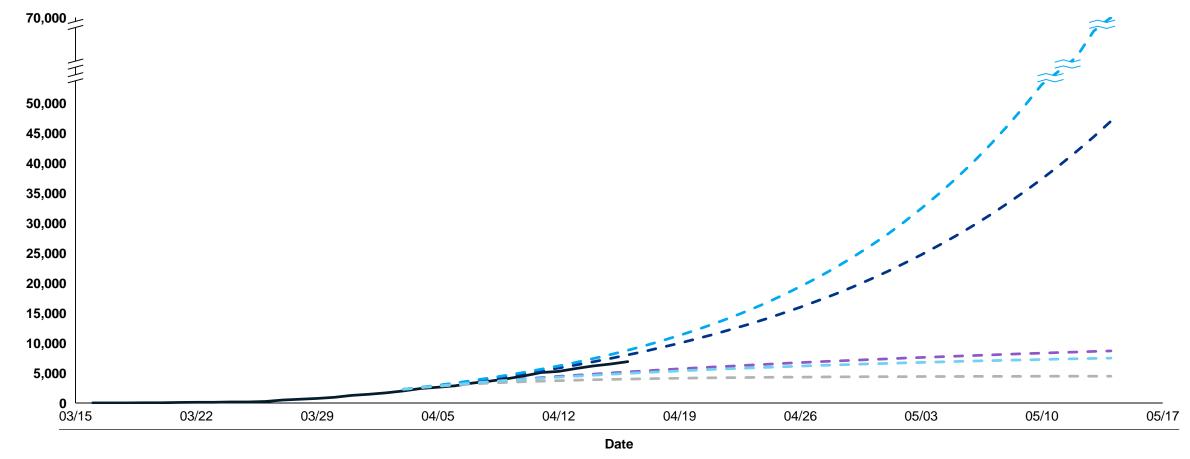
#### Confirmed cases have grown particularly rapidly in the Central Region over the past few days



## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia



#### **Cumulative number of cases**



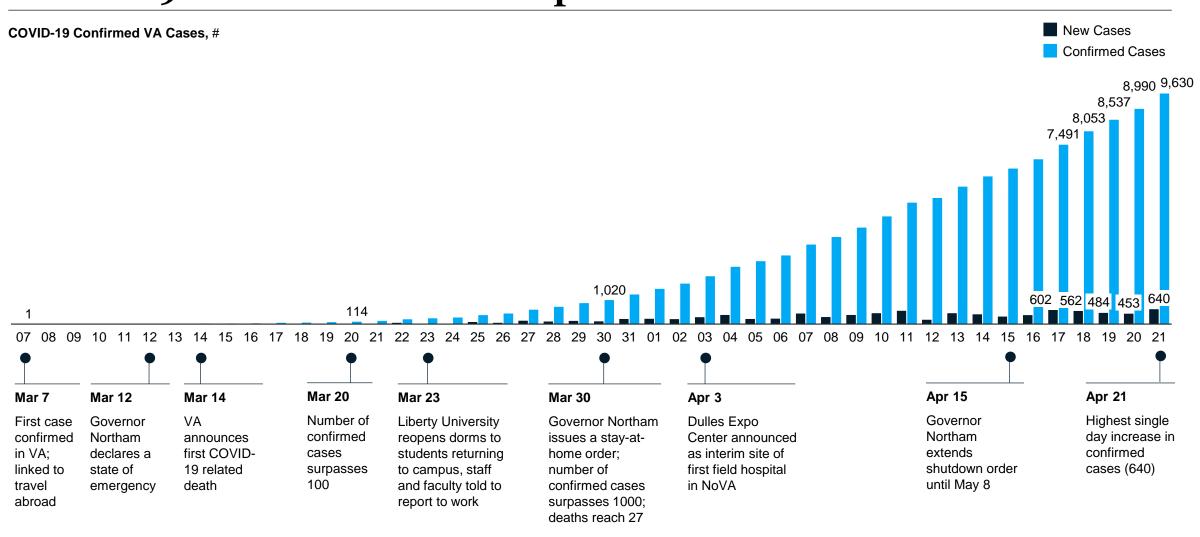
McKinsey & Company

### Commonwealth of Virginia COVID-19 Response

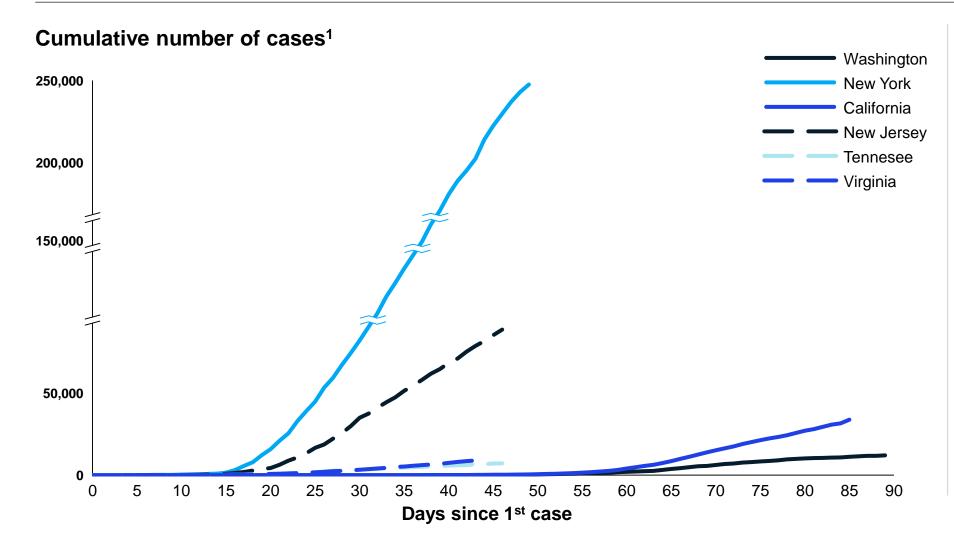
State of Play Fact Pack
21 April 2020



#### **COVID-19** in VA: Timeline of Important Events



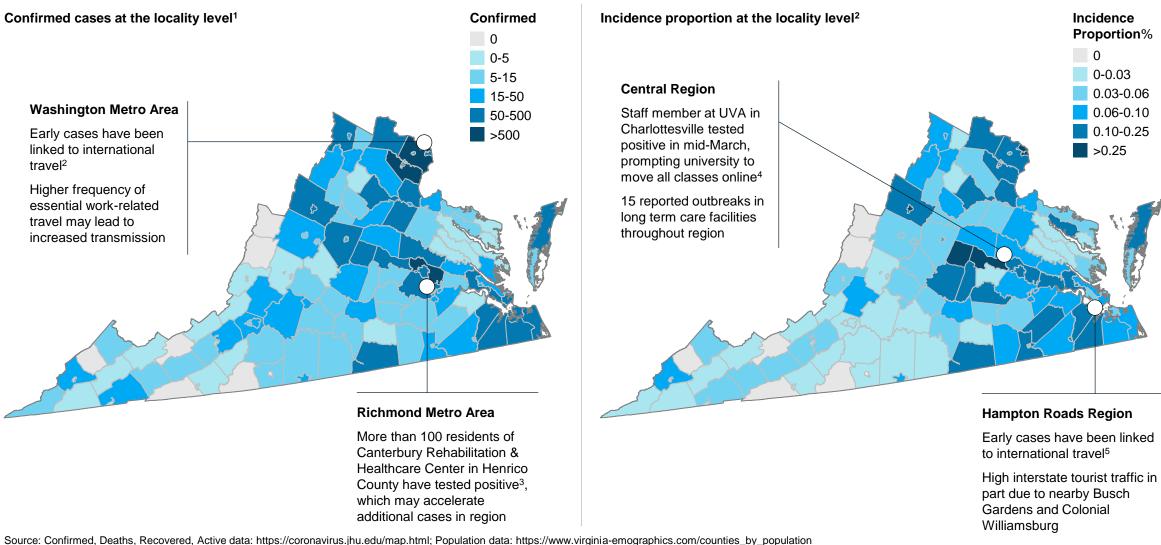
## Virginia is currently on a less aggressive trajectory than New York or New Jersey



#### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- California: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

## Case volume is high in counties surrounding DC & Richmond, but incidence is particularly high in Central & Hampton Roads regions



Source. Committed, Deaths, Necovered, Active data. https://coronavirus.jnd.edu/map.mm, Population data. https://www.virginia-emographics.cc

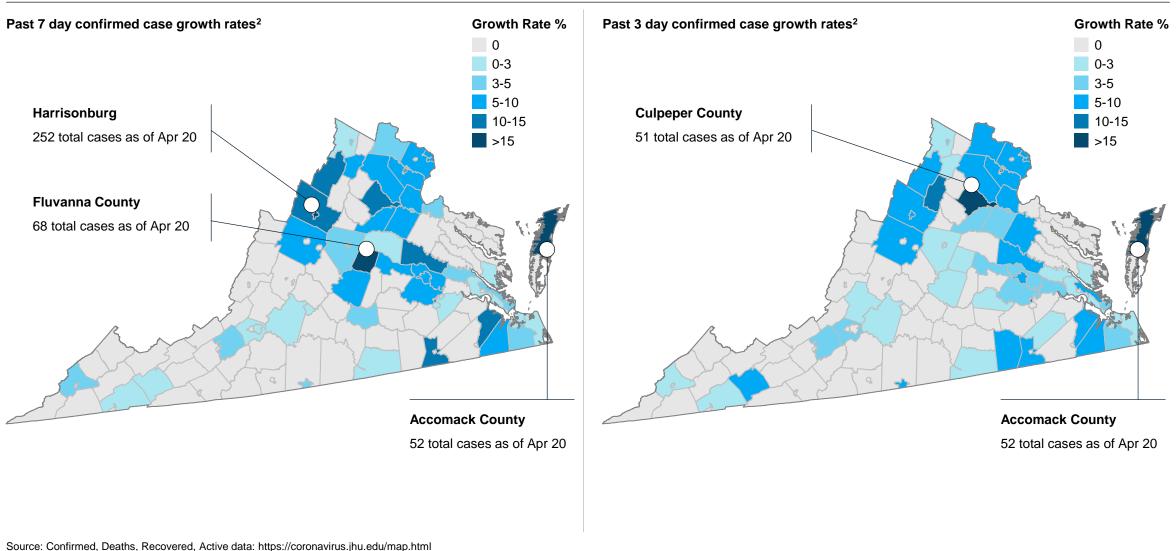
https://www.wtkr.com/james-city-county-continues-to-lead-region-in-number-of-cases

<sup>.</sup> Incidence Proportion = Confirmed Cases / Estimated Population

http://www.vdn.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/https://www.wric.com/news/local-news/45-dead-in-coronavirus-outbreak-at-canterbury-rehabilitation-healthcare-center/

<sup>4.</sup> https://www.dailyprogress.com/news/local/uva-employee-tests-positive-for-covid/article\_578b39be-77d6-5391-80dc-7fcf0277be69.html

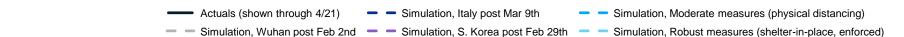
## Confirmed cases have grown particularly rapidly in the Central and Eastern Regions over the past few days<sup>1</sup>



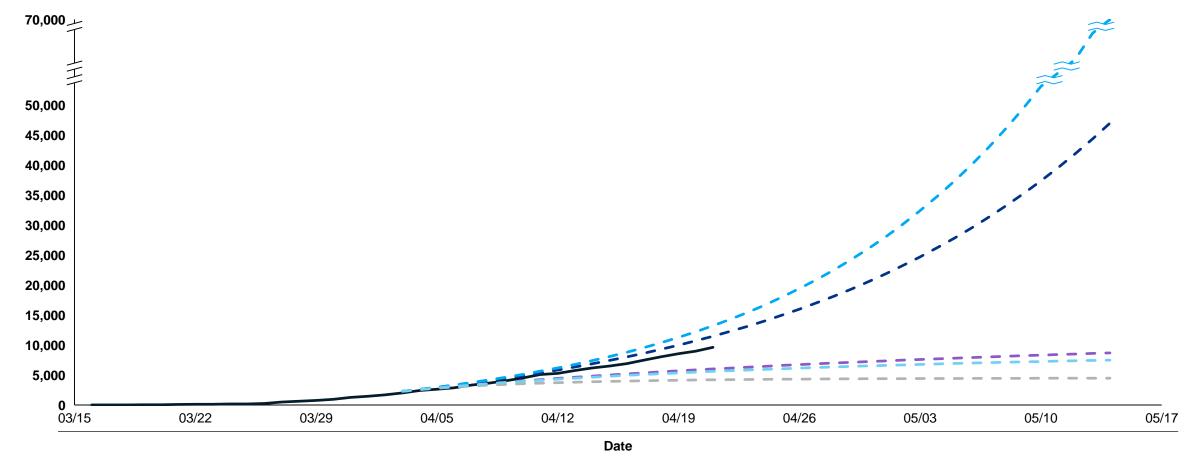
burce. Committed, Deaths, Recovered, Active data. https://coronavirus.jhd.edd/map.html

Outbreak has been recently reported in Fluvanna County long-term care facility (https://www.cbs19news.com/story/42017121/fluvanna-county-monitoring-outbreak-at-envoy-at-the-village)

## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia



#### **Cumulative number of cases**





SECRETARY OF PUBLIC SAFETY AND HOMELAND SECURITY

### COMMONWEALTH OF VIRGINIA 22 APRIL PPE PROBLEM SOLVING



#### Today's objectives

- Discuss key PPE initiatives and next steps
- Refine PPE delivery pipeline visualization
- Share current state of PPE Retooling Playbook for Manufacturers
- Discuss PPE Evaluation Working Group members and process



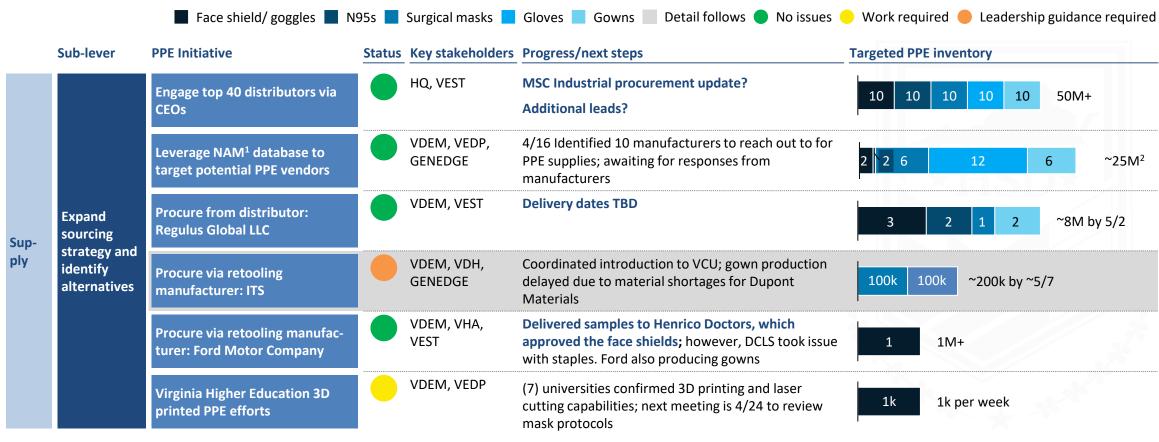
#### PPE initiatives are being identified along a holistic set of PPE levers

#### Framework for increasing net PPE

Lever	Sub-lever		Illust	rative initiative ideas	
		Purchase from existing manufacturers		<b>Leverage in-state and regional PPE distributors</b> (e.g., Owens & Minor, McKesson) to identify customers with inventory that could be re-sold to healthcare providers	
		Purchase from distributors / middlemen	iden	thy customers with inventory that could be re-sold to healthcare providers	
		Purchase non-medical firms' inventory			
	Expand sourcing strategy and identify alternatives	Retool non-PPE manufacturers			
		Accept PPE donations			
Expand PPE supply		Acquire from Strategic National Stockpile		te dynamic forecasting of PPE needs to make SNS case to FEMA by collecting and yzing data on PPE inventory and burn rates across PPE end-users (healthcare providers,	
		Support product substitution from non-medical industries	-	and local agencies)	
	Control and balance inventory	Centralize sourcing and distribution			
	Control and balance inventory	Create system for proactive rebalancing and redistribution			
	Conduct system integration and	risk management	•	amline access to PPE regulatory infrastructure by providing clear guidelines to non- ical manufacturers	
	Implement policy		mean	ical manatactarers	
Manage PPE demand	Prioritize and extend PPE usage				
	Re-use / reprocess PPE			Codify and implement reprocessing and sterilization processes so that PPE may be safely reused, leveraging FDA approved solutions (e.g., Battelle reprocessing unit)	
	Adjust clinical workflows			eu, leveraging FDA approveu solutions (e.g., Battelle reprocessing unit)	
	Adjust care team guidelines			elop comms plan to disseminate CDC guidelines to end-users on clinical servation of at-risk PPE supplies	



# Initiatives target an expanded sourcing strategy and reprocessing equipment to address immediate PPE gap (1/2)





No issues 🛑 Work required 🛑 Leadership guidance required

# Initiatives target an expanded sourcing strategy and reprocessing equipment to address immediate PPE gap (2/2)

	Sub-lever	PPE Initiative	Status	Key stakeholders	Progress/next steps	Targeted PPE inventory
De- mand		Acquire UV Germicidal decontamination system		VDH, VHHA, VMA	Identified feasible options within VA (e.g., VCU and Volvo UV decontamination kits, Project Shining Light through VMA); appetite for this technology?	<ul><li>5-7k masks / N95s per room per day</li><li>Can be reprocessed 3-10x</li></ul>
		Acquire in-state Battelle system for Virginia		HQ, VEST, VDH, GENEDGE	No updates re: 3 purchase requests; Need to confirm implementation/logistics plan	<ul> <li>10k to 80k masks / N95s per day</li> <li>Can be reprocessed up to 20x</li> </ul>
	Re-use / reprocess PPE	Rent space in non-Virginia Battelle systems		HQ, VEST, VDH, GENEDGE	NCR system coming online by end of month. Need to determine VA share of NCR system and confirm implementation/logistics plan	<ul> <li>10k to 80k masks / N95s per day</li> <li>Can be reprocessed up to 20x</li> <li>FEMA will cover expenses</li> </ul>
		Leverage complimentary Micron ventilator refurbishment		VDEM, VDH, VHHA	No action since 4/14; offering service to re-certify and test decommissioned ventilators; requires model/inventory info of VA ventilators	<ul> <li>Micron partnering with Bloom Energy to collect, refurbish, certify and test, and deliver ventilators back to hospitals</li> </ul>
		Acquire select Emergency Use Authorization reprocessing medical devices		VDEM, VDH, VHHA	Since 4/9 three additional sterilization systems for decontaminating PPE have received FDA EUAs; appetite for this technology / request price quote?	<ul> <li>STERRAD: 480 N95s per day (~10k hospitals)</li> <li>STERIS: ~360 N95s per day (~2k hospitals)</li> </ul>



## Cross-cutting enablers decrease the time it takes to implement PPE initiatives and increase PPE capture rates

					Detail follows No issues	Work required Leadership guidance required
	Sub-lever	Cross-cutting enabler	Status	Key stakeholders	Description	Opportunity
Su- pply	Expand sourcing strategy and identify alternatives	Streamline PPE sourcing process for ~180 priority offers of assistance		VDEM, VEDP, VDH	Completed outreach to all priority offers of assistance and 9 forwarded to DGS; continuous refinement of survey to sharpen data collection and refined collaboration with DGS	<ul> <li>Capture promising opportunities in less time, using VEDP capacity</li> <li>Develop view of procurement pipeline</li> </ul>
		Create simple step-by-step retooling process for manufacturers		VDEM, VEDP, DOLI, VDH, GENEDGE	Incorporating and synthesizing feedback from key stakeholders; preference to share playbook as online, dynamic content (e.g., webpage)?	<ul> <li>Equip local manufacturers with expertise to begin production to address PPE need and economy</li> </ul>
		PPE Evaluation process		VDEM, VEST, DOLI, VDH, VHHA(?)	Establish working group with relevant expertise to evaluate and approve/disapprove PPE products for procurement by various end-users	<ul> <li>Expedite review process to increase number of vendors supporting PPE efforts</li> <li>Share knowledge and best practices across VEST</li> </ul>
	Control and balance inventory	requirements for PPE		VDH, VDEM, VEST	Provide minimum/maximum PPE quantity purchase thresholds and accepted prices from vendors	<ul> <li>Increase incentive for retooling manufacturers to begin production</li> <li>Increase engagement from local and national manufacturers</li> </ul>

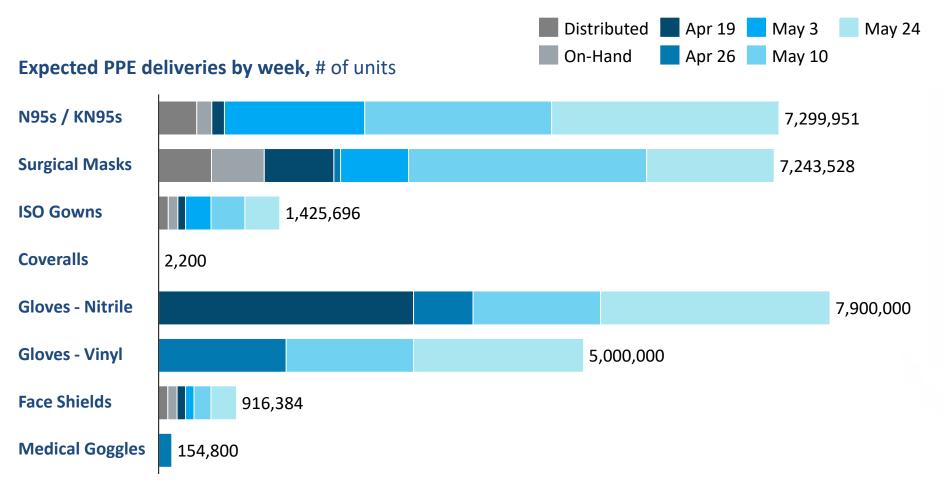


#### Today's objectives

- Discuss key PPE initiatives and next steps
- Refine PPE delivery pipeline visualization
- Share current state of PPE Retooling Playbook for Manufacturers
- Discuss PPE Evaluation Working Group members and process



#### Visualization of fulfilled and expected PPE shipments from VEST dashboards



Values for "On-Hand" and "Distributed" pulled from VEST Joint Inventory Logistics Dashboard

Values for expected PPE deliveries pulled from COVID-19 VEST Delivery Survey Dashboard – Logistics View

Are these two dashboards the full view of past and future PPE deliveries?



#### Today's objectives

- Discuss key PPE initiatives and next steps
- Refine PPE delivery pipeline visualization
- Share current state of PPE Retooling Playbook for Manufacturers
- Discuss PPE Evaluation Working Group members and process



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

#### **Objectives**



#### **Playbook contents**

Share critical Personal Protective Equipment
 (PPE) needs with Virginia manufacturers

- 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

 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

Assist Virginia manufacturers with navigating the path to producing PPE in support of the Commonwealth

- Product information sheets for each type of PPE
- Suggested process maps and course of action for non-medical manufacturers to retool for PPE production
- Additional resources and assistance for each step of the way



#### COVID-19 Virginia manufacturer's 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 greatest need of five types of medical-use PPE to support healthcare workers, first responders and public works

**Quantity Commonwealth is procuring in next Critical PPE** needed tranche (subset of total planned procurement) **Definition** N95 respirators: A filtering facepiece respirator 5,000,000 units (FFR) offering protection from particulate materials Surgical masks: A loose-fitting, disposable 5,000,000 units device that helps block large-particle droplets, splashes, sprays, or splatter **Exam gloves:** A hand covering intended for Vinyl exam gloves: 5,000,000 units medical use to prevent contamination Nitrile gloves: 4,000,000 units Latex gloves: 4,000,000 units Gowns, non-surgical: A disposable or reusable Isolation gowns: 5,000,000 units product intended to protect the user from the Hair caps: 5,000,000 units transfer of materials in the wearer's Boot covers: 2,000,000 units environment Medical coveralls: 900,000 units **Eye protection**: A device used to protect the Medical goggles: 1,000,000 units user's eyes and / or face from bodily fluids, Face shields: 1,000,000 units



Low

High

General level of FDA regulation



liquid splashes, or infectious materials

#### Similarly, non-medical use PPE demand is increasing as the economy reopens – presenting an opportunity for retooling manufacturers

Non-medical use PPE needed

#### Definition



Filtering facepiece respirators: A device
 that is a disposable half-face-piece intended
 for use to help reduce wearer to exposure
 to pathogenic biological airborne
 particulates



Face masks: A mask that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels

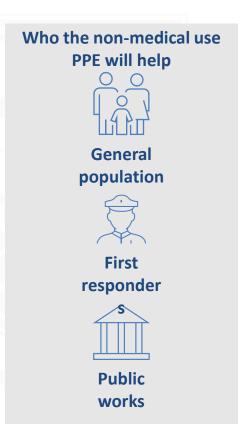


**Gloves**: A hand covering for the hand for protection against cold or dirt (e.g., nitrile industrial grade gloves)

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

#### Indicators of increased demand

- The Southeast Asia PPE market size is expected to grow at a compound annual growth rate (CAGR) of 8.0% reaching \$2.1B by 2025<sup>1</sup>
- As of 20-April, 5 states require all residents to cover their faces when going in public during the COVID-19 pandemic (NY, CT, HI, MD, NJ)<sup>2</sup>
- Potential that face covers will be required for foreseeable future based on current expert opinions and press search





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

#### **Agency**

Food and Drug
Administration (FDA)

#### **Mission**

Protect public healthy by ensuring the safety, efficacy, and security of foods and drugs, including medical devices

#### **Role relative to PPE**

Sets the regulations and specific performance standards for the majority of PPE

#### **COVID-19 PPE manufacturer** resources available

Enforcement Policy for PPE during COVID-19: Immediately in Effect Guidance (6-Apr)

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 assure safe and healthful working conditions for employees may require 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

**Device** Less Regulatory requirements<sup>1</sup> PPE items in category<sup>2</sup> Class Exempt from 510(k) marketing Non-surgical gowns approval and design controls Exam gloves<sup>3</sup> General level of FDA regulation Class I Scrubs and coveralls Head and shoe covers 510(k) – required if marketing Surgical gloves a device for the first time Surgical masks Class II Surgical gowns Surgical N95 respirators Premarket approval (PMA) – None

- The FDA has made exception under Emergency Use Authorizations 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)); must be labeled accordingly

the most stringent regulatory

category for medical devices

Class III

More

 $<sup>1.\</sup> https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing and the state of the stat$ 

<sup>2.</sup> CDC PPE COVID19 guidance (23-Mar-2020)

<sup>3.</sup> 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	During normal conditions	During COVID-19 pandemic  Depends	
FDA marketing approval	<b>✓</b>		
Special labeling for non-medical and	medical- use PPE 🗙		
State approval for testing kits	×	<b>V</b> HSD*	
Recall procedures in place	<b>✓</b>	X	
Diagnostic testing	✓	Depends	
Quality system procedures	<b>✓</b>	X	
Device listing	<b>✓</b>	X	
FDA facility registration	<b>✓</b>	X	



## Product information sheet: Non-surgical isolation gowns

**Product** Information **Product description:** Non-surgical isolation gowns (disposable)

**Product group:** Personal Protective Equipment

Demand<sup>1</sup>

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, assembly and sterilization

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 in short supply for converters

Design requirements<sup>2</sup>

- 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:**

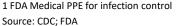
- US: ANSI / AAMI PB70 Level 1 and Level 2 for liquid barrier performance
- European: EN13795, EN14126
- ASTM F4207 for testing of surgical gowns



### 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



2 CDC PPE COVID-19 guidance (3/23/2020)

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

SECRETARY OF PUBLIC SAFETY AND HOMELAND SECURITY

**Determine what PPE we are Identify PPE requirements Produce prototype and test Connect with buyers and scale Understand end-user PPE needs** best positioned to produce and technical specifications with regulators / end-users production Add: Would financial Call out distinction: Find alternative ways to assistance (e.g., Leverage GENEDGE and support COVID-19 PPE VMA resources and produce LT or ST? loan/grant) support supply efforts (e.g., manufacturing expertise Assistance provided donate PPE on-hand) your company in producing PPE? No No Are end-Do I have Do I have Assess current user PPE Am I interested in enough inaccess to Proceed to "Identify business model to Yes Yes Yes Yes helping produce needs house the Determine best type of PPE requirements determine if well-PPE for the COVIDexpertise PPE to produce and technical enough necessary positioned to produce 19 crisis? incentive to produce specifications" critical PPE to retool? PPE? materials? N95s/Masks - Textiles, Chemicals N95s/Masks/Gowns - Polypropylene **Gloves** - Commodity chemicals **Gloves** – Nitrile, natural rubber, chemicals Gowns - Textiles, Apparel Eve protection - Polycarbonate Eye protection - Plastics, apparel



### Commonwealth of Virginia resources to support retooling manufacturers

### Resource

Virginia Department of **Emergency Management** 

Virginia Department of **Labor and Industry** 

**Virginia Department of** Health

**Virginia Economic Development Partnership** 

Virginia's Manufacturing **Extension Partnership** (GENEDGE)

Virginia Manufacturer's **Association** 

### Mission

Coordinate broader COVID-19 response efforts, including management of PPE supplies and outreach to private sector Administer Virginia Occupational Safety and Health program, ensuring employers adhere to best practices in the workplace

WIPts , including management of PPE

Provide tailored assistance to help manufacturers quickly develop and produce products, services, and equipment

WIPs, including management of PPE supplies and outreach to private sector

### Point of contact

Private Sector Portal: https://bit.ly/VaPrivateSector Email: private.sector@vdem.virginia.gov Mr. Justin Paxton

Email: justin.Paxton@doli.viginia.gov

Jeanne M. Grubbs, PHR Human Resources Manager

Email: jgrubbs@genedge.org

### **COVID-19 PPE manufacturer** resources available

Offers of assistance survey

eVA registration link

Occupational Safety and Health standards

**Job Hazard Analysis** 

COVID-19 Resources for Virginia Manufacturers



### Today's objectives

- Discuss key PPE initiatives and next steps
- Refine PPE delivery pipeline visualization
- Share current state of PPE Retooling Playbook for Manufacturers
- Discuss PPE Evaluation Working Group members and process



## The COVID-19 PPE Evaluation Working Group includes key representatives to rapidly assess and approve PPE for medical usage

Proposed future state PPE Evaluation WG organization and roles/responsibilities

### **Current situation**

- Retooling manufacturers are unfamiliar with PPE regulations and requirements
- Insufficient representation and input from various offices to evaluate new PPE products by new manufacturers
- Unclear process on assessing and approving PPE for medical usage

### Future state working group organization

### **VDEM**

**Role:** Identify requirements that can be introduced during sourcing and/or outreach

**POC:** Stacie Neal

### **VEST**

**Role:** Use insights from working group to inform subsequent PPE procurements

**POC:** Jason Eaton

POCs: Pete Stamps, Kelly Langley

### **VDH**

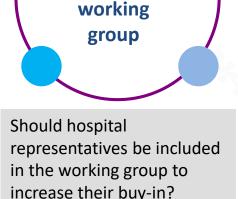
**Role:** Review for adherence to CDC and FDA guidance

**POCs:** Dr. Shaina Bernard, Dr. Rehab Abdelfattah, Roxanne Ehardt, Mike McMahon

### DOLI

**Role:** Ensure adherence to OSHA standards (e.g., job hazards analysis) associated with PPE production

**POC:** Justin Paxton



**PPE** 

evaluation



## DGS will flag cases requiring involvement from the PPE Evaluation WG, triggering a linear process to gather information and conduct assessment

FOR DISCUSSION: Proposed future state process for PPE evaluation

Route all offers of assistance to COVID-19
Unified Command

Filter leads based on requirements

**Screening and procurement** 

**Deliver to end customer** 

**Start:** PPE products requiring additional review flagged

**Critical actions** 

Collect key manufacturer and PPE product information

information requirements to

screening questionnaire to flag

manufacturers producing new,

Add VDH and DOLI

appropriate vendors

non-certified PPE

Maintain list of Virginian

Provide tailored CDC/OSHA/FDA guidance to manufacturer

- Share tailored and current CDC and FDA guidance to manufacturers
- Ensure employer awareness of OSHA standards for PPE

Evaluate manufacturers' product & operations to ensure regulatory compliance

- Assess PPE to determine suitability for medical use (prototype review)
- Review manufacturer's operations to complete updated Job Hazards Analysis

Align on PPE evaluation and forward to DGS for final review

- Discuss cases under review at weekly interagency meeting, with focus on how to accelerate to decision
- Leverage external expertise as required (e.g., VHHA, GENEDGE)

**End:** PPE products evaluated, enabling informed procurement decision

Question for discussion:

Will VDH assess PPE prototypes in-house or rely on 3<sup>rd</sup> party certification (e.g., UL)?

Key stakeholders by step





















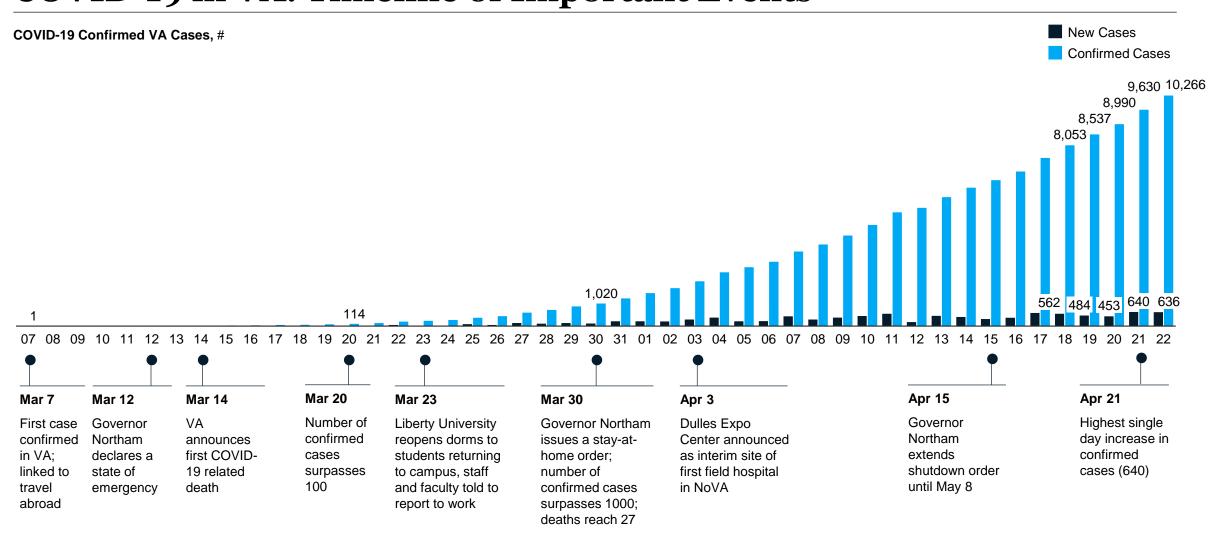
McKinsey & Company

## Commonwealth of Virginia COVID-19 Response

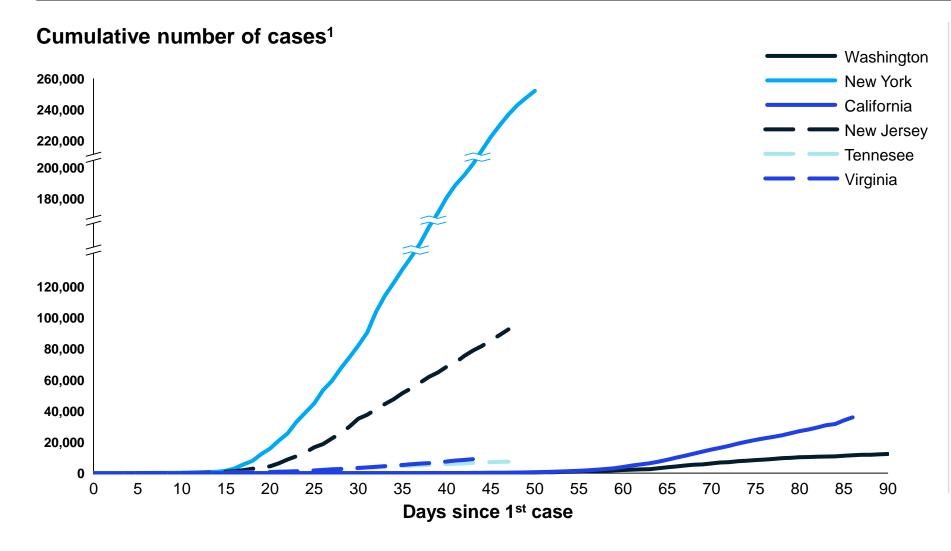
State of Play Fact Pack
22 April 2020



### **COVID-19** in VA: Timeline of Important Events



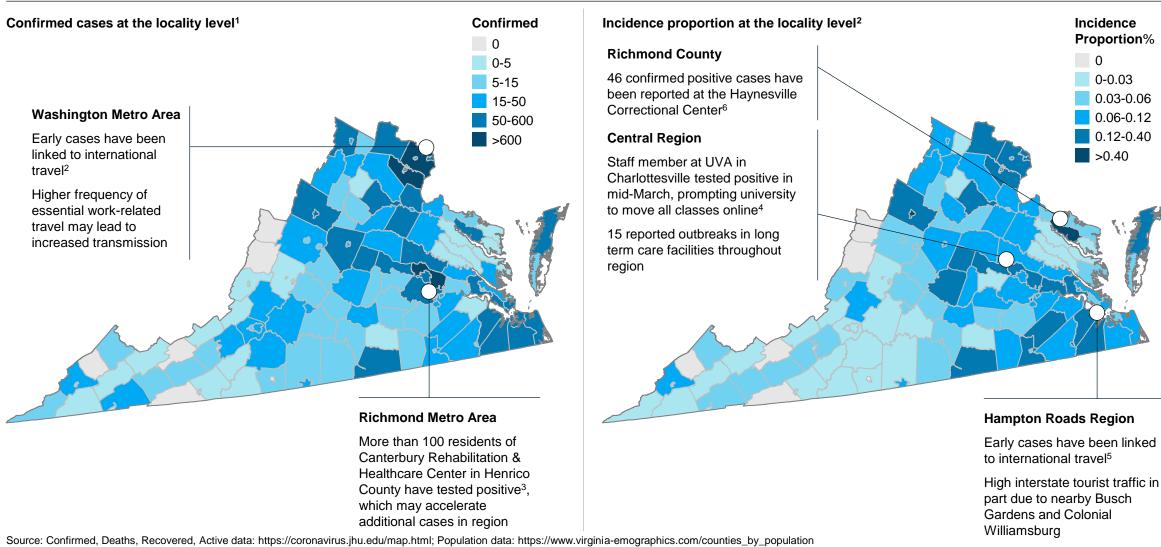
## Virginia is currently on a less aggressive trajectory than New York or New Jersey



### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- California: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

### Case volume is high in counties surrounding DC & Richmond, but incidence is particularly high in Central & Hampton Roads regions



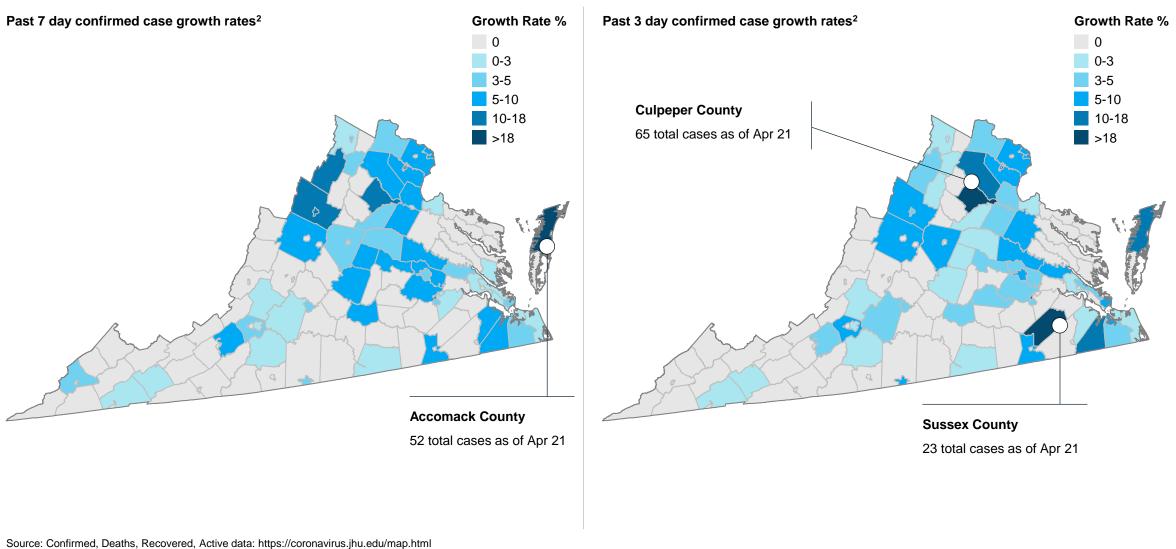
ttp://www.vdh.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/

https://www.wric.com/news/local-news/45-dead-in-coronavirus-outbreak-at-canterbury-rehabilitation-healthcare-center/

https://www.dailyprogress.com/news/local/uva-employee-tests-positive-for-covid/article 578b39be-77d6-5391-80dc-7fcf0277be69.html https://www.wric.com/health/coronavirus/coronavirus-update-46-confirmed-cases-of-covid-19-at-haynesville-correctional-center/

https://www.wtkr.com/iames-citv-county-continues-to-lead-region-in-number-of-cases

## Confirmed cases have grown particularly rapidly in the Eastern and Northern Regions over the past few days<sup>1</sup>



burce. Commined, Deaths, Recovered, Active data. https://coronavirus.jnd.edd/map.htm

<sup>.</sup> Outbreak has been recently reported in Fluvanna County long-term care facility (https://www.cbs19news.com/story/42017121/fluvanna-county-monitoring-outbreak-at-envoy-at-the-village)

10,000

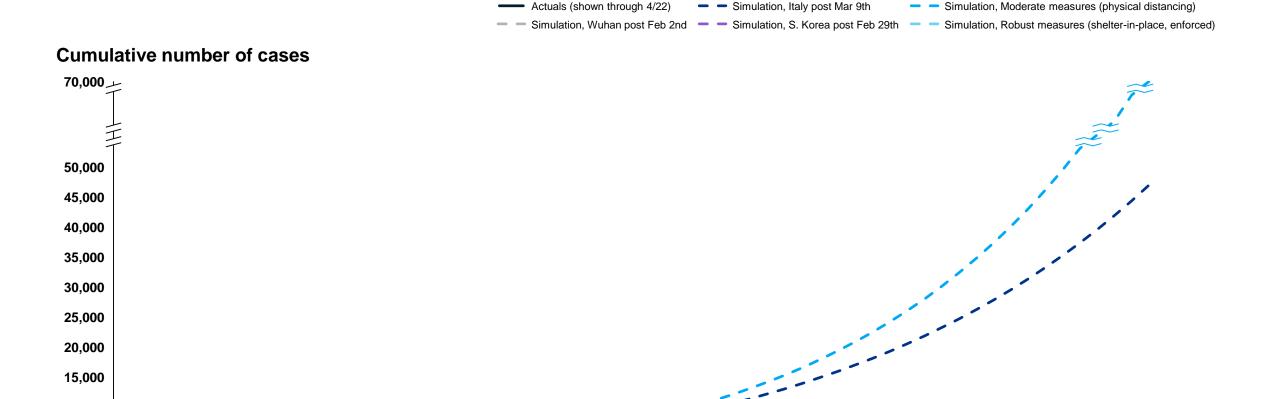
5,000

03/15

03/22

03/29

## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia



Date

04/19

04/26

05/03

04/12

04/05

05/10

05/17



## COMMONWEALTH OF VIRGINIA COVID-19 PPE RETOOLING PLAYBOOK



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 as a result of COVID-19. **This document is a tool; it is NOT an RFP or commitment that the Commonwealth government will purchase all PPE offers of assistance.** This document does not limit the government's policy on where and how to purchase PPE and/or 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**



### **Playbook contents**

 Share critical Personal Protective Equipment (PPE) needs with Virginia manufacturers

- 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

 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

Assist Virginia manufacturers with navigating the path to producing PPE in support of the Commonwealth

- Product information sheets for each type of PPE
- Suggested process maps and course of action for non-medical manufacturers to retool for PPE production
- Additional resources and assistance for each step of the way



### COVID-19 Virginia manufacturer's 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 greatest need of five types of medical-use PPE to support healthcare workers, first responders and public works

High 4

General level of FDA regulation

Low

Critical PPE needed	Definition	Quantity Commonwealth is procuring in next tranche (subset of total planned procurement)	
A B	<ul> <li>N95 respirators: A filtering facepiece respirator (FFR) offering protection from particulate materials</li> </ul>	• 5,000,000 units	
	<ul> <li>Surgical masks: A loose-fitting, disposable device that helps block large-particle droplets, splashes, sprays, or splatter</li> </ul>	• 5,000,000 units	
	<ul> <li>Exam gloves: A hand covering intended for medical use to prevent contamination</li> </ul>	<ul> <li>Vinyl exam gloves: 5,000,000 units</li> <li>Nitrile gloves: 4,000,000 units</li> <li>Latex gloves: 4,000,000 units</li> </ul>	
	<ul> <li>Gowns, non-surgical: A disposable or reusable product intended to protect the user from the transfer of materials in the wearer's environment</li> </ul>	<ul> <li>Isolation gowns: 5,000,000 units</li> <li>Hair caps: 5,000,000 units</li> <li>Boot covers: 2,000,000 units</li> <li>Medical coveralls: 900,000 units</li> </ul>	
3	<ul> <li>Eye protection: A device used to protect the user's eyes and / or face from bodily fluids, liquid splashes, or infectious materials</li> </ul>	<ul> <li>Medical goggles: 1,000,000 units</li> <li>Face shields: 1,000,000 units</li> </ul>	

# Who the PPE will help Hospitals and Healthcare workers



First responders



Public works

## Similarly, non-medical use PPE demand is increasing as the economy reopens – presenting an opportunity for retooling manufacturers

Non-medical use PPE needed

#### **Definition**



 Filtering facepiece respirators: A device that is a disposable half-face-piece intended for use to help reduce wearer to exposure to pathogenic biological airborne particulates



Face masks: A mask that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels

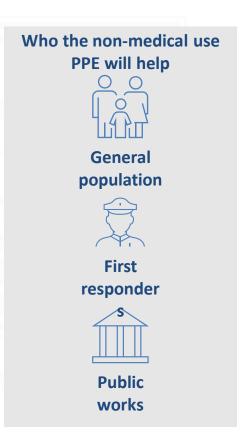


**Gloves**: A hand covering for the hand for protection against cold or dirt (e.g., nitrile industrial grade gloves)

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

### Indicators of increased demand

- The Southeast Asia PPE market size is expected to grow at a compound annual growth rate (CAGR) of 8.0% reaching \$2.1B by 2025<sup>1</sup>
- As of 20-April, 5 states require all residents to cover their faces when going in public during the COVID-19 pandemic (NY, CT, HI, MD, NJ)<sup>2</sup>
- Potential that face covers will be required for foreseeable future based on current expert opinions and press search





## 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

Not

**FDA** 

regulated

Medical

use

Non-

use

medical

**N95** respirators

**Surgical masks** 

**Exam gloves** 

Gowns, non-surgical

**Eve protection** 

**Filtering facepiece** respirators

Face masks

Gloves

Spun-bonded polypropylene

Polypropylene

• Nitrile, natural rubber, polychloroprene

Nonwovens (Spunlace, SMS, wet-laid)

Polycarbonate, polyethylene, PVC

Various

Various

• Nitrile, natural rubber, latex

### **Important distinctions**

- 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

### Message for manufacturers:

With appropriate labeling, manufacturers can start production immediately for the majority of PPE items needed

In certain cases (e.g., Class II/III medical devices), testing may be required – which can take 2 – 4 weeks for approval



### COVID-19 Virginia manufacturer's 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



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

### **Agency**

Food and Drug Administration (FDA)

### Mission

Protect public healthy by ensuring the safety, efficacy, and security of foods and drugs, including medical devices

### **Role relative to PPE**

Sets the regulations and specific performance standards for the majority of PPE

## **COVID-19 PPE manufacturer** resources available

Enforcement Policy for PPE during COVID-19: Immediately in Effect Guidance (6-Apr)

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 assure safe and healthful working conditions for employees may require 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

**Device** Less Regulatory requirements<sup>1</sup> PPE items in category<sup>2</sup> Class Exempt from 510(k) marketing Non-surgical gowns approval and design controls Exam gloves<sup>3</sup> General level of FDA regulation Class I Scrubs and coveralls Head and shoe covers 510(k) – required if marketing Surgical gloves a device for the first time. Surgical masks Class II Surgical gowns Surgical N95 respirators Premarket approval (PMA) – None

- The FDA has made exception under Emergency Use Authorizations 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)); must be labeled accordingly

the most stringent regulatory

category for medical devices

Class III

More

 $<sup>1.\</sup> https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing$ 

<sup>2.</sup> CDC PPE COVID19 guidance (23-Mar-2020)

<sup>3.</sup> 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	During normal conditions	During COVID-19 pandemic  Depends	
FDA marketing approval	<b>✓</b>		
Special labeling for non-medical and			
State approval for testing kits	X	I V HSD*	
Recall procedures in place	<b>✓</b>	X	
Diagnostic testing	<b>✓</b>	Depends	
Quality system procedures	<b>✓</b>	X	
Device listing	<b>✓</b>	X	
FDA facility registration	✓	X	



### 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<sup>1</sup>. Limited single-wearer re-use considered in contingency scenarios<sup>2</sup>

**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 Class 2, if surgical<sup>3</sup> – 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 in short supply

Design requirements<sup>2</sup>

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
- More difficult regulatory and compliance validation process

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

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



<sup>1.</sup> 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

### **(2)**

### Product information sheet: surgical masks



Product Information

**Product description:** Surgical masks (these are different from medical procedure 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<sup>2</sup>

Raw material availability: polypropylene, polystyrene, polycarbonate, polyethylene

Raw material shortages: High quality meltblown nonwoven in short supply

Design requirements<sup>1</sup>

	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 both surgical masks and face masks (non-medical use)

Standards: Surgical masks are regulated under 21 CFR 878.4040.

<sup>2.</sup> 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/respirator-use-faq.html; image courtesy of 3M; Image source: 3M.com



<sup>1.</sup> ASTM levels determined by ASTM F2100-11 standards, ASTM F1862, ASTM F2299

### 2

### Product information sheet: patient examination gloves

Product Information

**Demand** 

**Product description:** Patient examination gloves (21 CFR 880.6250)

**Product group:** Personal Protective Equipment

Usage guidance: Single use (do not re-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

Raw material shortages: None

### 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

Design requirements<sup>1</sup>

- 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<sup>2</sup>) 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



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

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

**ANSI/ AAMI Standard** barrier protection



Level 1 Level 2 Level 3 Level 4 Minimal Risk Moderate risk Low risk High risk Surgical gowns Surgical isolation gowns

Standard use

COVID-19 applicability standard isolation, unit

Blood draw, suturing, ICU, or

Routine potential

patient care

and current COVID

Arterial blood draw, inserting an IV, in the ER, or for trauma cases

intense procedures, surgery, infectious diseases suspected

Surgery, fluid

Surgical purposes and environments that will expose wearer to fluid

Non-surgical isolation gowns

Basic care, standard medical

Routine potential

patient care

and current COVID

pathology lab

**Environments that** will expose wearer

to fluid (e.g.,

intubations, vomiting patient,

etc.)

Healthcare professionals can use non-surgical isolation gowns when performing routine care for COVID-19 patients<sup>2</sup>

### Non-surgical gowns

- If gowns are running low, FDA<sup>2</sup> 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<sup>2</sup>

Minimum requirement for COVID

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



## Product information sheet: Non-surgical isolation gowns

**Product** Information **Product description:** Non-surgical isolation gowns (disposable)

**Product group:** Personal Protective Equipment

Demand<sup>1</sup>

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

**Current availability: Low** 

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

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

**Manufacturing** 

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 in short supply for converters

Design

- 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

requirements<sup>2</sup>

1 FDA Medical PPE for infection control Source: CDC: FDA

2 CDC PPE COVID-19 guidance (3/23/2020)

## 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** 

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

Degree of automation: Partially automated

Regulatory & compliance validation process difficulty: Low

Raw material availability: Available (polycarbonate, polyethylene, PVC)<sup>2</sup> Raw material shortages: None<sup>2</sup>

Manufacturing

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

### 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

FDA Classification: N/A1

Standards:

US: Meet specification of

ANSI Z87.1-20153 (D3

impact resistant rated)

splash marking, not

- 2. Derived from expert manufacturing interviews
- 3. 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



### COVID-19 Virginia manufacturer's 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



Action

WIP

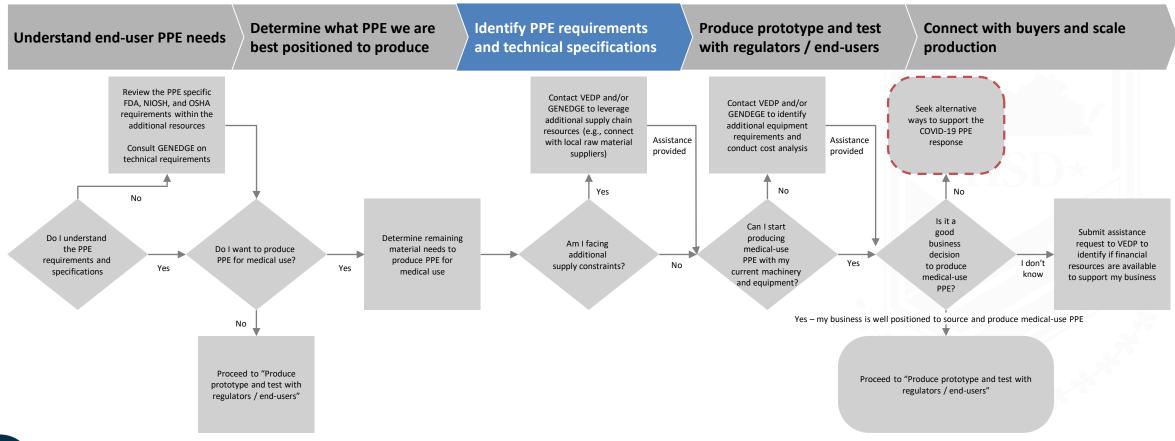
## Understanding end-user PPE needs and assessing internal capabilities will inform the decision to produce PPE

**Determine what PPE we are Identify PPE requirements** Produce prototype and test Connect with buyers and scale **Understand end-user PPE needs** best positioned to produce and technical specifications with regulators / end-users production Add: Would financial Find alternative ways to Call out distinction: assistance (e.g., Leverage GENEDGE and support COVID-19 PPE VMA resources and produce LT or ST? loan/grant) support supply efforts (e.g., Assistance provided manufacturing expertise donate PPE on-hand) your company in producing PPE? No No Do I have Do I have Are end-Assess current user PPE Am I interested in enough inaccess to Proceed to "Identify business model to Yes Yes Yes Yes helping produce needs house the Determine best type of PPE requirements determine if well-PPE for the COVIDexpertise necessary PPE to produce and technical enough positioned to produce 19 crisis? incentive to produce specifications" critical PPE to retool? PPE? materials? N95s/Masks - Textiles, Chemicals N95s/Masks/Gowns - Polypropylene **Gloves** - Commodity chemicals Gloves – Nitrile, natural rubber, chemicals Gowns - Textiles, Apparel Eve protection - Polycarbonate Eye protection - Plastics, apparel



Action

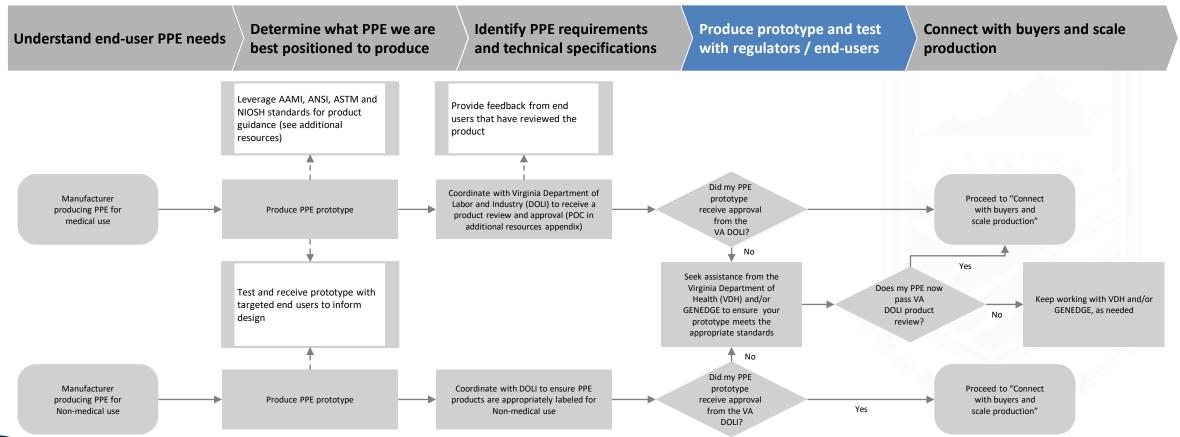
## Proper interpretation of specific manufacturing requirements will help to identify supply chain constraints ahead of time





Refine flowchart based on

## <sup>3</sup> Retooling manufacturers should incorporate targeted end-user food Mr. Paxton feedback and contact Virginia DOLI as early in the process as possible





Additional question that should be considered: Does my device normally require FDA approval?

### Sub-action

### SECRETARY OF PUBLIC SAFETY AND HOMELAND SECURITY

## 3 The Commonwealth and partnering organizations can assist manufacturers with connecting with PPE end-users

Connect with buyers and scale **Determine what PPE we are Identify PPE requirements** Produce prototype and test **Understand end-user PPE needs** best positioned to produce and technical specifications with regulators / end-users production Reference eVA to get an Seek guidance from Submit request for updated view of the VDH and additional assistance to VEDP to Connected to buyers Commonwealth's PPE assistance from learn more about GENEDGE to work demand signal Commonwealth through the approval business opportunities process I don't t No No know Have I received the Could I benefit from Continue producing PPE to Schedule delivery of PPE, Am I connected with Manufacturer producing PPE appropriate Identify potential and be prepared to scaling up meet demand from end a network for medical use FDA approval to buyers adjust design based on production to Yes of buyers? No begin distribution of End user feedback meet demand? Yes Review FDA requirements and Do I require additional approval process (references financial provided in Additional resources assistance? section Contact VEDP to determine if there are financial Yes Manufacturer producing PPE resources available to for non medical use support your production expansion



### COVID-19 Virginia manufacturer's 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



# 4 Commonwealth of Virginia resources to support retooling manufacturers

#### Resource

Virginia Department of Emergency Management

Virginia Department of Labor and Industry

Virginia Department of Health

Virginia Economic Development Partnership

Virginia's Manufacturing Extension Partnership (GENEDGE)

Virginia Manufacturer's Association

#### **Mission**

Coordinate broader COVID-19 response efforts, including management of PPE supplies and outreach to private sector Administer Virginia Occupational Safety and Health program, ensuring employers adhere to best practices in the workplace

Coordinate broader COVID-19 response WtPcs, including management of PPE supplies and outreach to private sector

Coordinate broader COVID-19 response efforts, including management of PPE supplies and outreach to private sector.

Provide tailored assistance to help manufacturers quickly develop and produce products, services, and equipment

Coordinate broader COVID-19 response WIPs, including management of PPE supplies and outreach to private sector

#### **Point of contact**

Private Sector Portal: https://bit.ly/VaPrivateSector
Email: private.sector@vdem.virginia.gov

and Mr. Justin Paxton
here Email: justin.Paxton@doli.viginia.gov

Private Sector Portal: https://bit.ly/VaPrivateSect

Private Sector Portal: https://bit.ly/VaPrivateSecto

Jeanne M. Grubbs, PHR Human Resources Manager Email: jgrubbs@genedge.org

Private Sector Portal: https://bit.ly/VaPrivateSecto Email: private.sector@vdem.virginia.gov

### **COVID-19 PPE manufacturer** resources available

Offers of assistance survey

eVA registration link

Occupational Safety and Health standards

**Job Hazard Analysis** 

TBD

TBD

<u>COVID-19 Resources for Virginia</u> Manufacturers

TBD



### 4 Additional information to support retooling manufacturers

## Another page: Additional information that could be helpful:

- 1. Information on all the EUAs
- 2. FDA/CDC guidance
- 3. PREP Act limiting liability



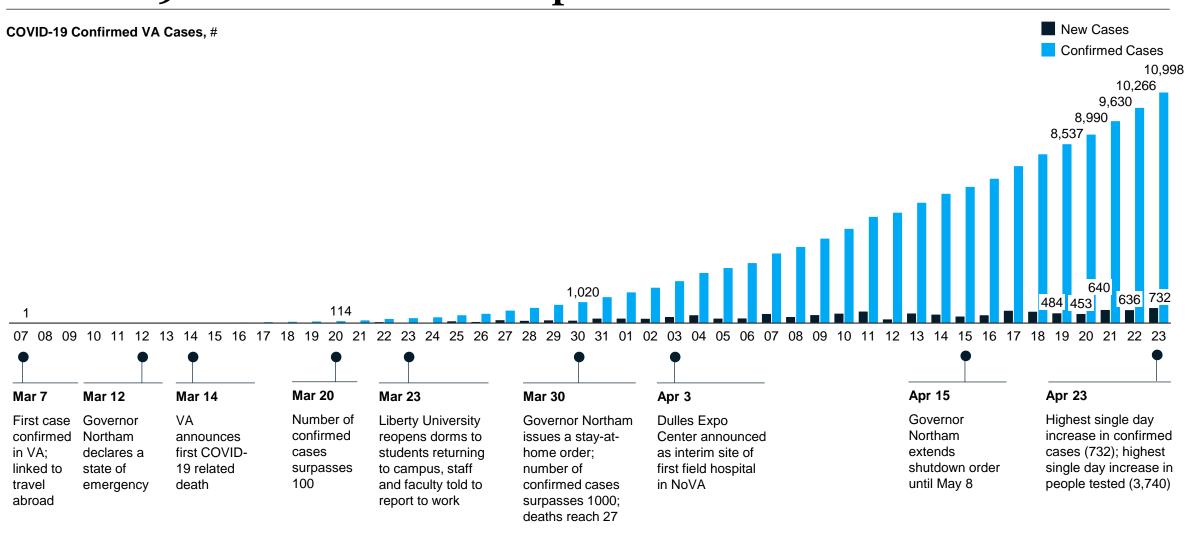
McKinsey & Company

## Commonwealth of Virginia COVID-19 Response

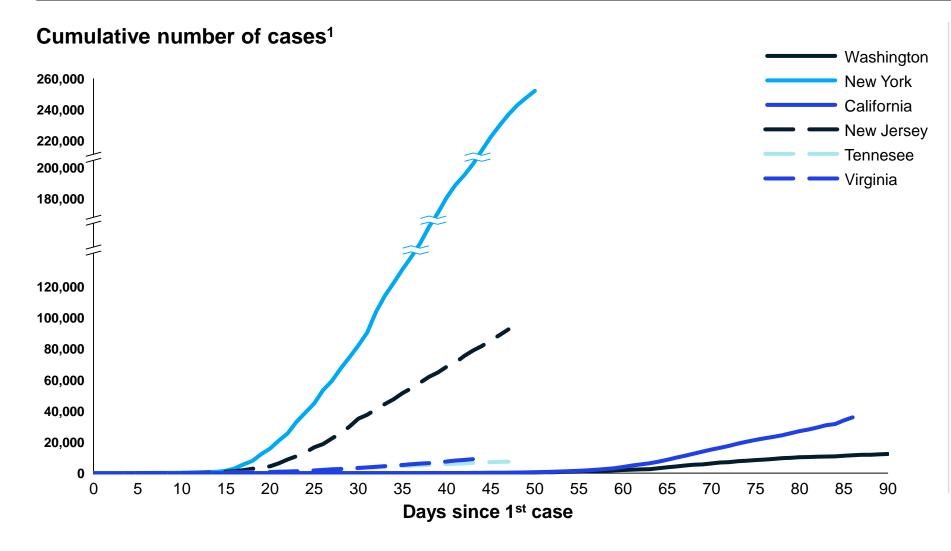
State of Play Fact Pack
23 April 2020



### **COVID-19** in VA: Timeline of Important Events



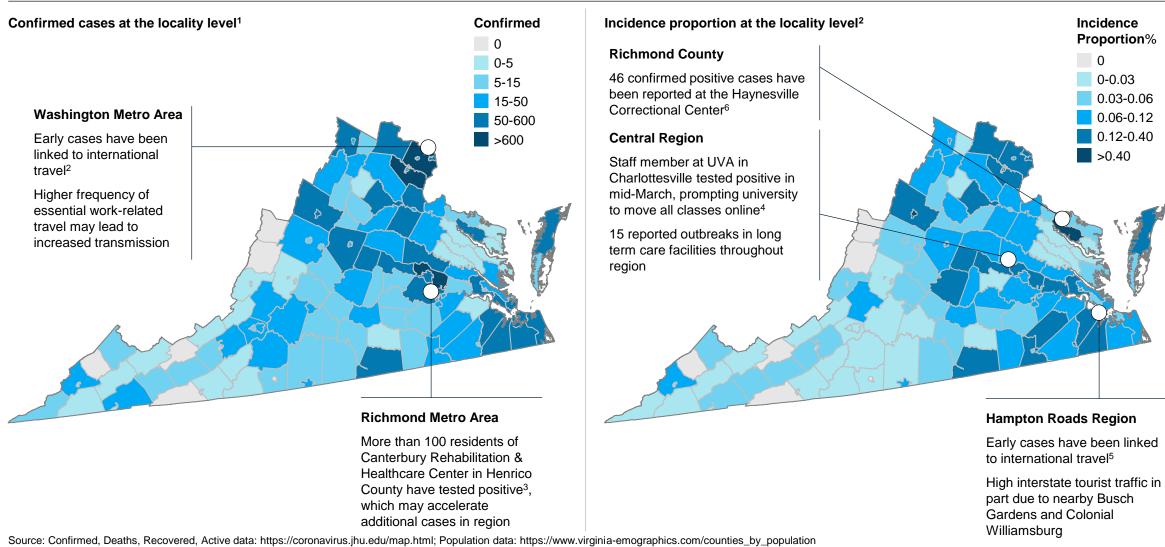
## Virginia is currently on a less aggressive trajectory than New York or New Jersey



#### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- California: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

# Case volume is high in counties surrounding DC & Richmond, but incidence is particularly high in Central & Hampton Roads regions



Incidence Proportion = Confirmed Cases / Estimated Population

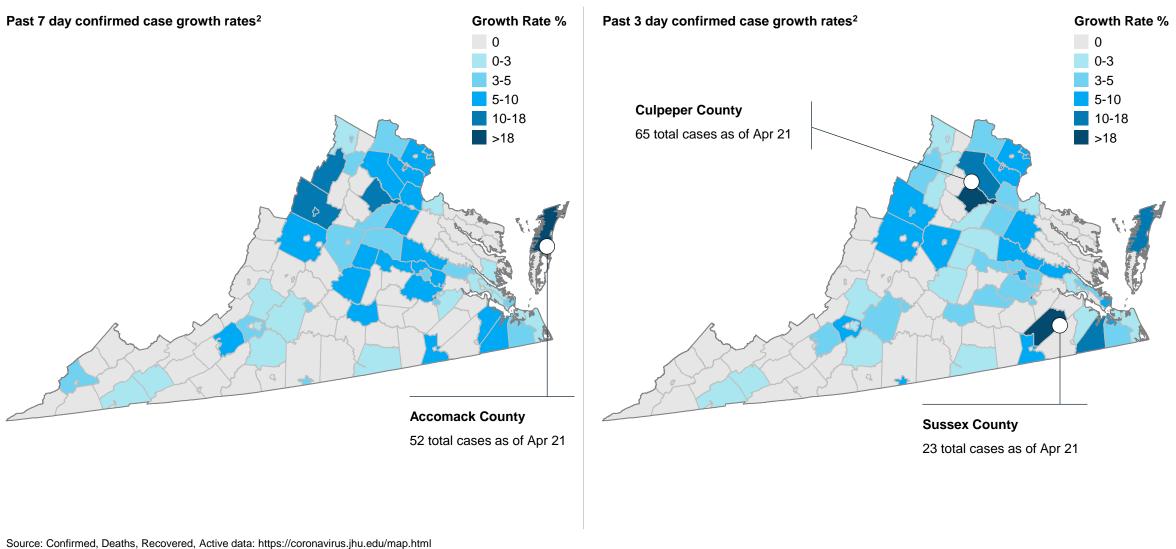
thtp://www.vdh.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/

https://www.wric.com/news/local-news/45-dead-in-coronavirus-outbreak-at-canterbury-rehabilitation-healthcare-center/

https://www.dailyprogress.com/news/local/uva-employee-tests-positive-for-covid/article\_578b39be-77d6-5391-80dc-7fcf0277be69.html

https://www.wtkr.com/james-city-county-continues-to-lead-region-in-number-of-cases
 https://www.wric.com/health/coronavirus/coronavirus-update-46-confirmed-cases-of-covid-19-at-haynesville-correctional-center/

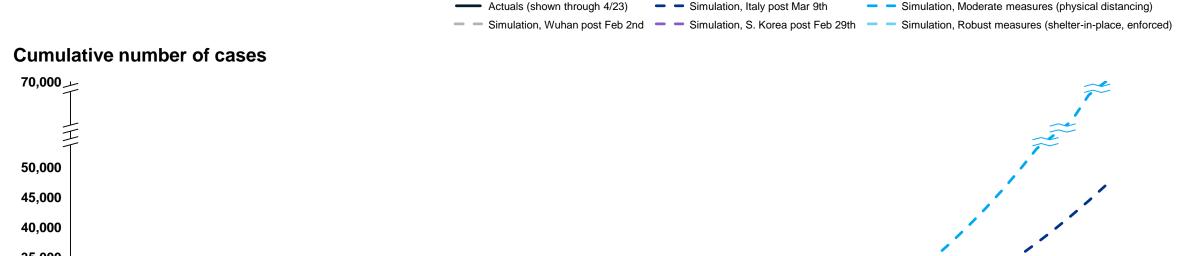
# Confirmed cases have grown particularly rapidly in the Eastern and Northern Regions over the past few days<sup>1</sup>

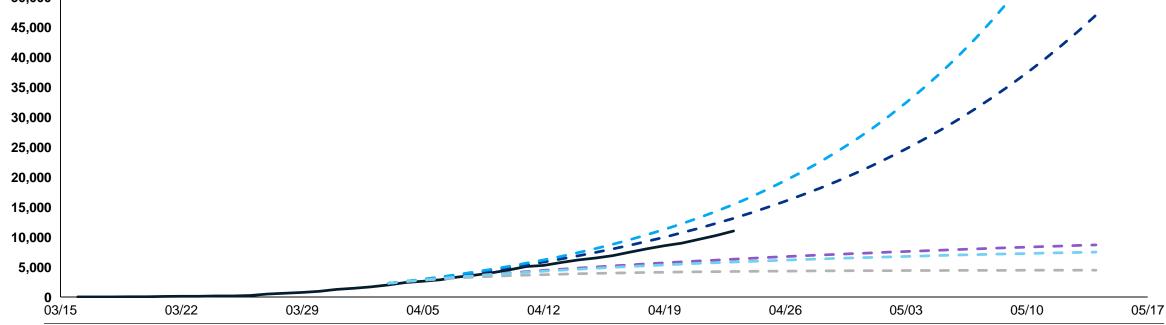


burce. Commined, Deaths, Recovered, Active data. https://coronavirus.jnd.edd/map.htm

Outbreak has been recently reported in Fluvanna County long-term care facility (https://www.cbs19news.com/story/42017121/fluvanna-county-monitoring-outbreak-at-envoy-at-the-village)

## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia





**Date** 

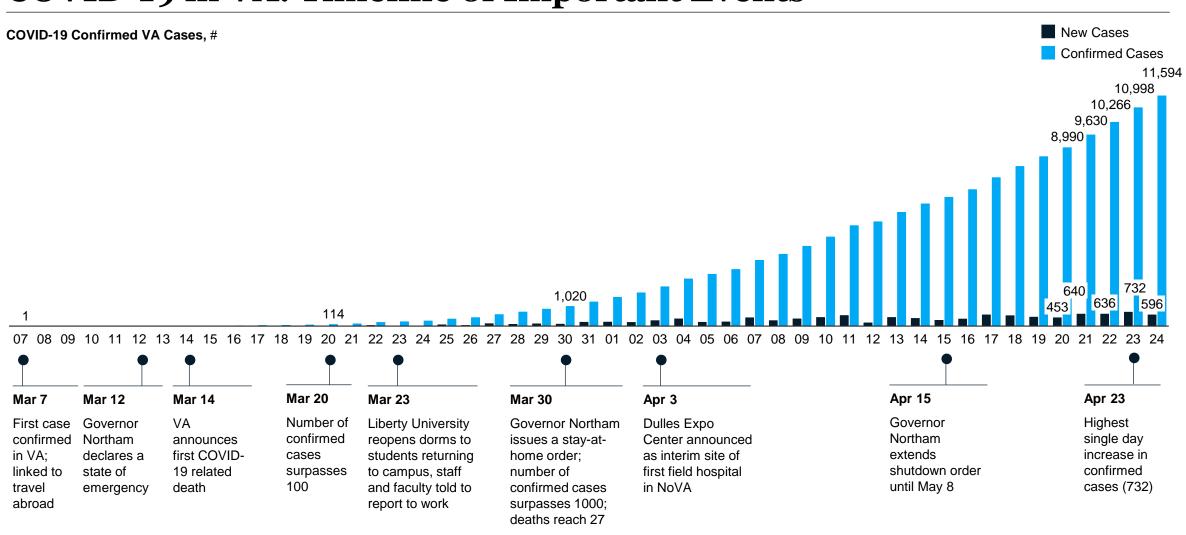
McKinsey & Company

## Commonwealth of Virginia COVID-19 Response

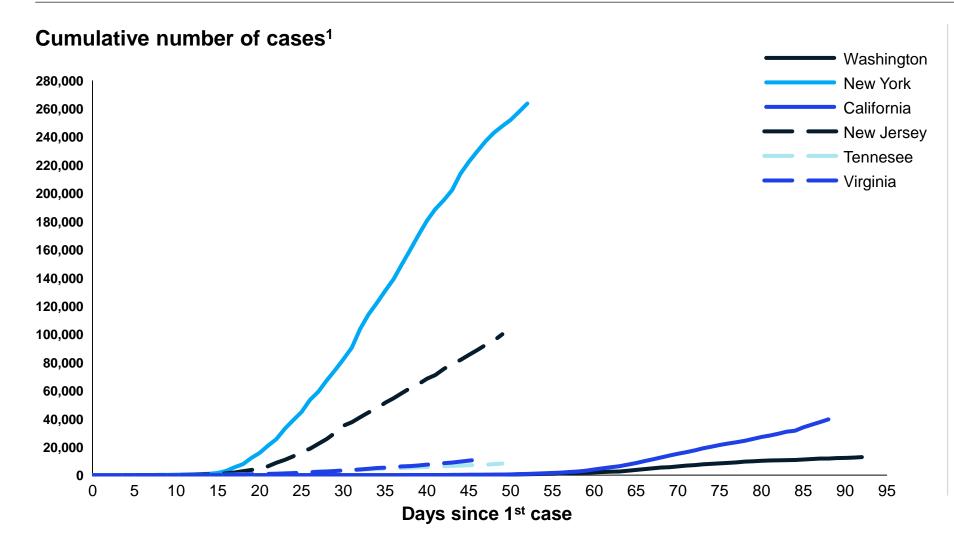
State of Play Fact Pack 24 April 2020



### **COVID-19** in VA: Timeline of Important Events



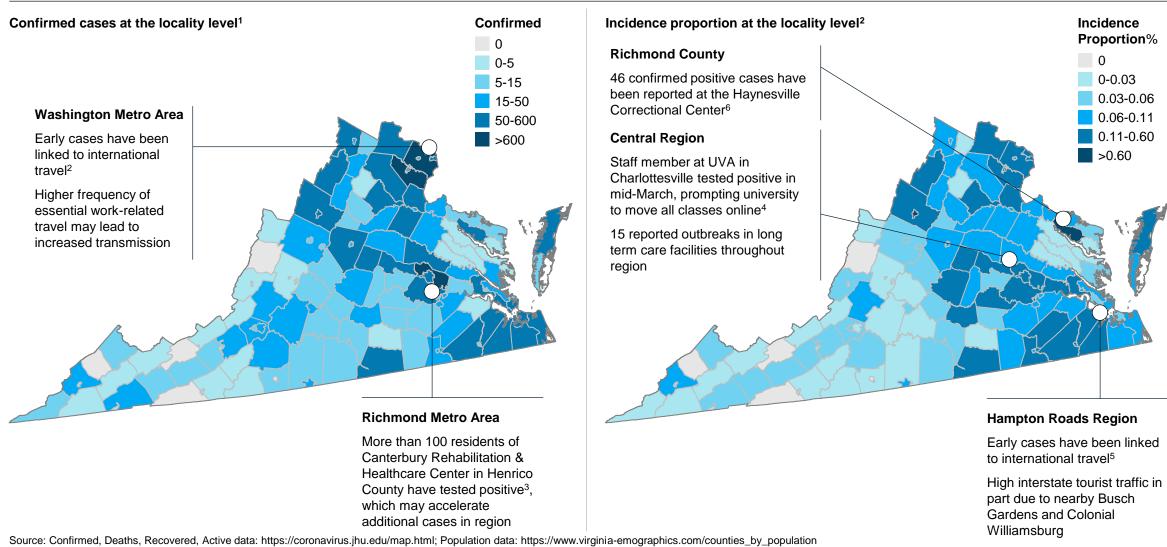
## Virginia is currently on a less aggressive trajectory than New York or New Jersey



#### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- california: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

### Case volume is high in counties surrounding DC & Richmond, but incidence is particularly high in Central & Hampton Roads regions



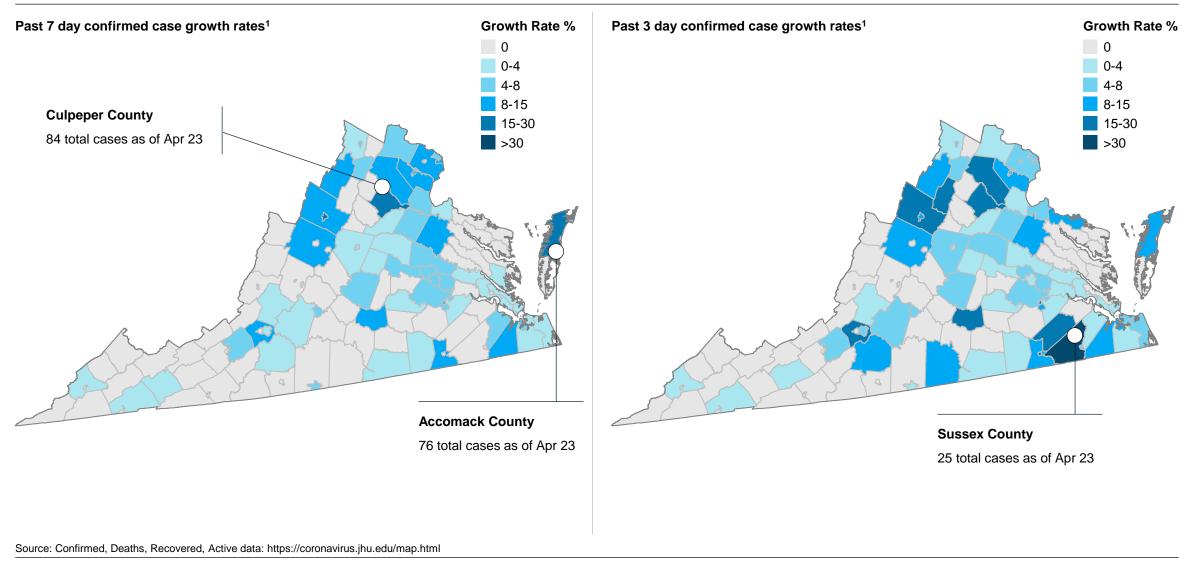
ttp://www.vdh.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/

https://www.wric.com/news/local-news/45-dead-in-coronavirus-outbreak-at-canterbury-rehabilitation-healthcare-center/

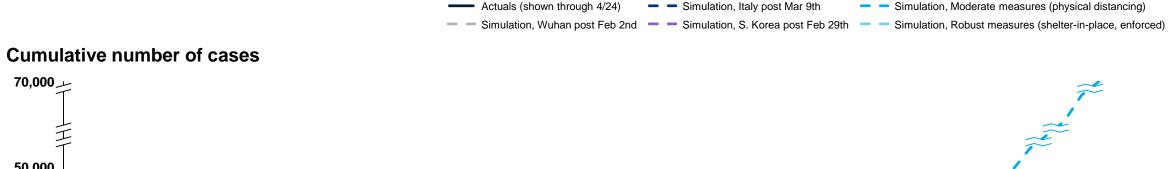
https://www.dailvprogress.com/news/local/uva-employee-tests-positive-for-covid/article 578b39be-77d6-5391-80dc-7fcf0277be69.html https://www.wric.com/health/coronavirus/coronavirus-update-46-confirmed-cases-of-covid-19-at-haynesville-correctional-center/

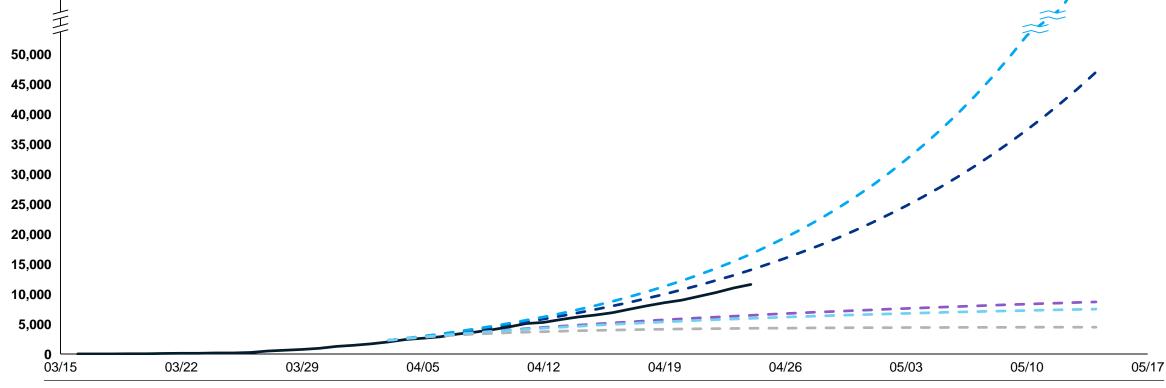
https://www.wtkr.com/iames-city-county-continues-to-lead-region-in-number-of-cases

## Confirmed cases have grown particularly rapidly in the Eastern and Northern Regions over the past few days



## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia





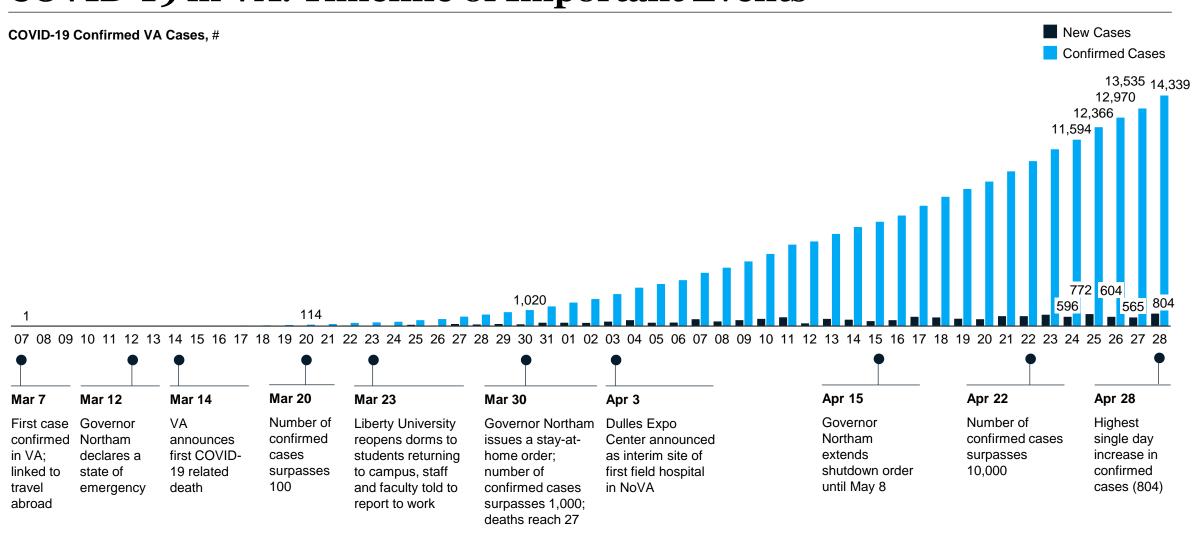
McKinsey & Company

## Commonwealth of Virginia COVID-19 Response

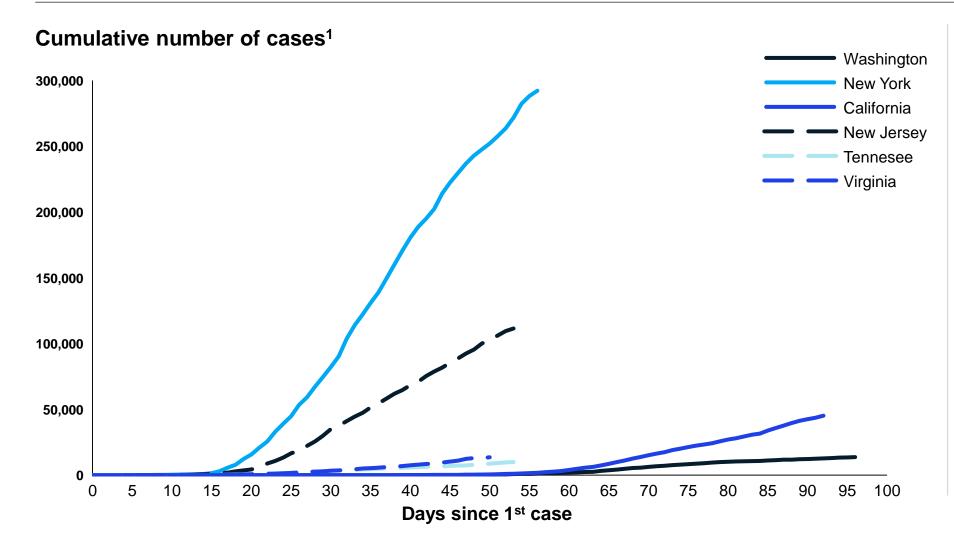
State of Play Fact Pack
28 April 2020



### **COVID-19** in VA: Timeline of Important Events



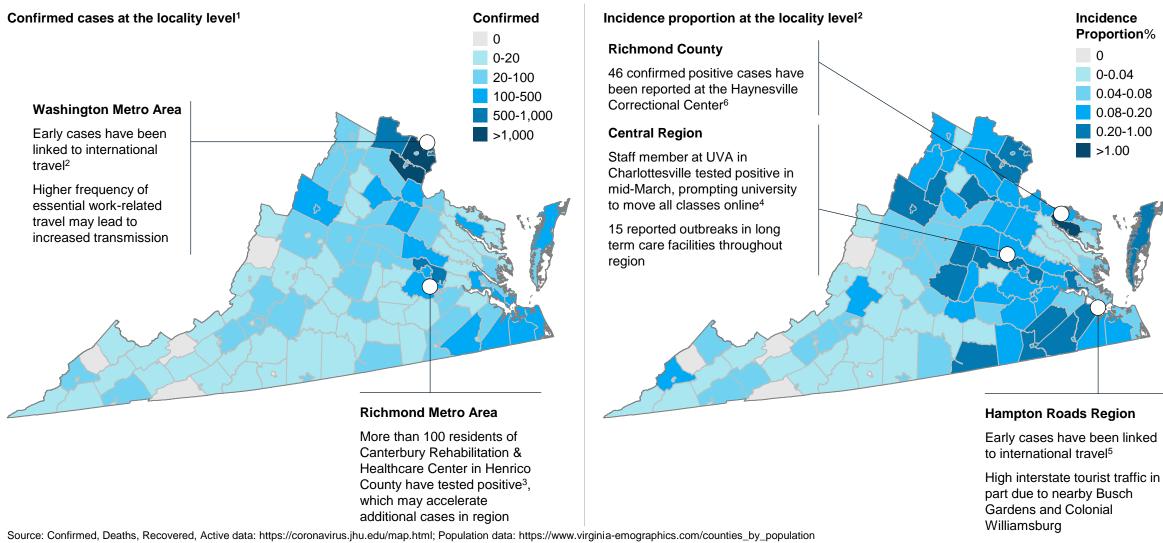
## Virginia is currently on a less aggressive trajectory than New York or New Jersey



#### Select state detail

- Virginia: Early containment measures enacted following the state's first case on Mar 7 may be effectively limiting transmission, but aggressive public health measures are still necessary to slow spread
- California: Several counties issued a state of emergency within ~2 weeks of the state's first case on Jan 26, but confirmed cases may begin to rise as testing capacity increases
- New York: Despite strict measures quickly enacted to limit travel and transmission following the state's first case on Mar 2, cases continue to rise rapidly

### Case volume is high in counties surrounding DC & Richmond, but incidence is particularly high in Central & Hampton Roads regions



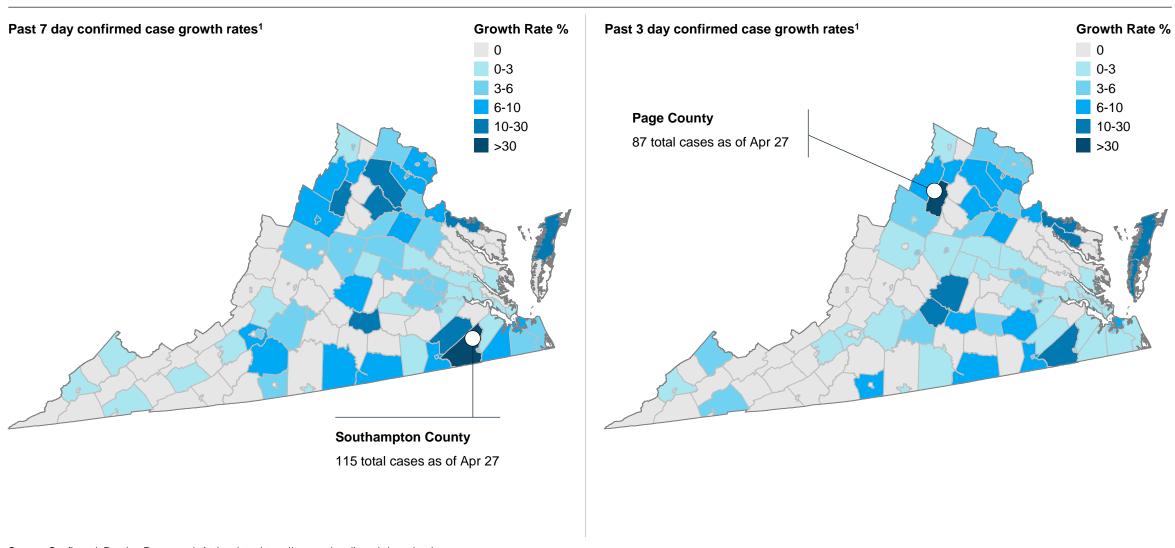
ttp://www.vdh.virginia.gov/blog/2020/03/09/virginia-department-of-health-confirms-third-presumptive-positive-case-of-coronavirus-disease-2019-covid-19-in-state/

https://www.wric.com/news/local-news/45-dead-in-coronavirus-outbreak-at-canterbury-rehabilitation-healthcare-center/

https://www.dailyprogress.com/news/local/uva-employee-tests-positive-for-covid/article 578b39be-77d6-5391-80dc-7fcf0277be69.html https://www.wric.com/health/coronavirus/coronavirus-update-46-confirmed-cases-of-covid-19-at-haynesville-correctional-center/

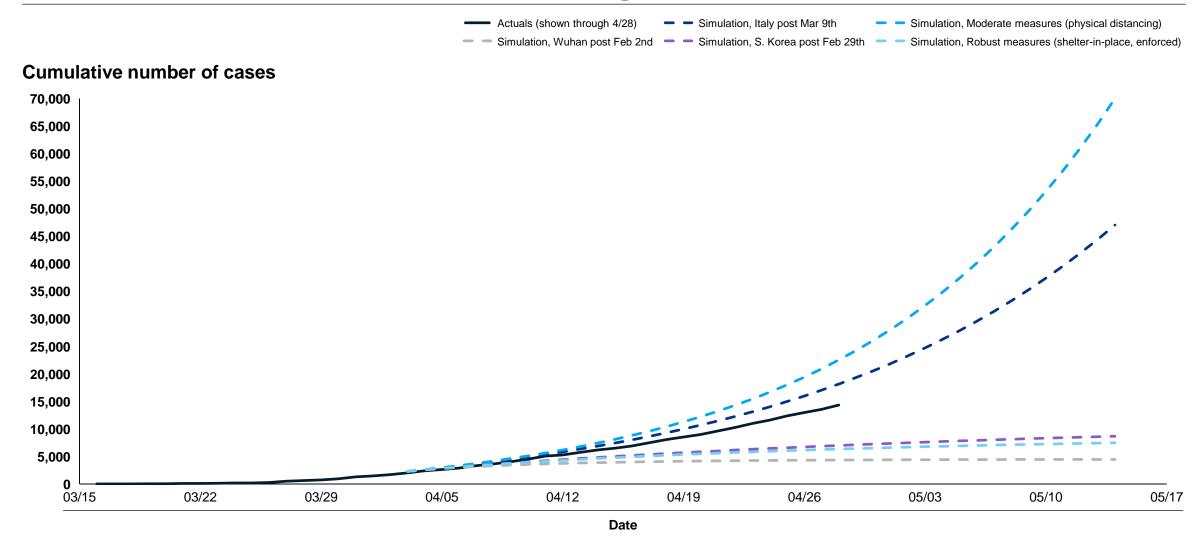
https://www.wtkr.com/iames-citv-county-continues-to-lead-region-in-number-of-cases

# Confirmed cases have grown particularly rapidly in the Eastern and Northern Regions over the past few days



Source: Confirmed, Deaths, Recovered, Active data: https://coronavirus.jhu.edu/map.html

## Data on how COVID-19 has progressed in other geographies informs different scenarios for Virginia



JEFFREY D. STERN, Ph.D. State Coordinator

CURTIS C. BROWN Chief Deputy State Coordinator/ Chief Diversity and Inclusion Officer



JOHN NORTHON Deputy State Coordinator – Disaster Services

ANDRES ALVAREZ
Deputy State Coordinator - Mission Support

### COMMONWEALTH OF VIRGINIA

Department of Emergency Management
9711 Farrar Court, Suite 200
North Chesterfield, Virginia 23236
TEL 804.267.7600 TDD 804 674.2417 FAX 804.272.2046

### CONTRACT NO.: VDEM-EM2020-0008

This is a Contract between McKinsey & Company, Inc. Washington, D.C. hereinafter called the "Contractor" and Commonwealth of Virginia, Virginia Department of Emergency Management called the "Purchasing Agency."

WITNESSETH that the Contractor and the Purchasing Agency, in consideration of the mutual covenants, promises and agreements herein contained, agree as follows:

SCOPE OF SERVICES: The Contractor shall provide the services - COVID-19 Response Assessment for PPE Availability -- to the Virginia Department of Emergency Management of the Commonwealth of Virginia as set forth in the Contract Documents.

PERIOD OF PERFORMANCE: From April 3, 2020 through April 24, 2020 (3 weeks).

The contract documents shall consist of:

- (1) This signed form;
- (2) The attached purchasing description, which consists of:
  - (a) The Scope of Work/Proposal and Budget
  - (b) McKinsey & Company, Inc. Consulting Agreement
  - (c) COV Agency Addendum To Contractor's Standard Form
  - (d) The General Terms and Conditions
  - (e) The Special Terms and Conditions
  - (f) The Federal Contract Provisions

IN WITNESS WHEREOF, the parties have caused this Contract to be duly executed intending to be bound thereby.

CONTRACTOR: McKinsey & Company, Inc. Washington, D.C.	PURCHASING AGENCY: Virginia Department of Emergency Management
By:gualTudesPay	By: Aleather I lane
Title: Partner	Title: Director of Prouvenat
Note: This public body does not discriminate again	nst faith-based organizations in accordance in the Color

Note: This public body does not discriminate against faith-based organizations in accordance with the Code of Virginia, § 2.2-4343.1 or against a bidder or offeror because of race, religion, color, sex, national origin, age, disability, sexual orientation, gender identity, political affiliation, or veteran status or any other basis prohibited by state law relating to discrimination in employment. Faith-based organizations may request that the issuing agency not include subparagraph 1.e in General Terms and Condition C. Such a request shall be in writing and explain why an exception should be made in that invitation to bid or request for proposal.

JEFFREY D. STERN, Ph.D. State Coordinator

CURTIS C. BROWN Chief Deputy State Coordinator/ Chief Diversity and Inclusion Officer



JOHN NORTHON Deputy State Coordinator - Disaster Services

ANDRES ALVAREZ Deputy State Coordinator - Mission Support

EIN: 56-2405213

### COMMONWEALTH OF VIRGINIA

Department of Emergency Management

9711 Farrar Court, Suite 200 North Chesterfield, Virginia 23236 TEL 804.267.7600 TDD 804.674.2417 FAX 804.272.2046

#### COMMONWEALTH OF VIRGINIA AGENCY ADDENDUM TO CONTRACTOR'S STANDARD FORM

AGENCY NAME: Virginia Department of Emergency Management ADDRESS: 9711 Farrar Court, Suite 200, North Chesterfield, VA 23836

CONTRACTOR NAME: McKinsey & Company, Inc. Washington, D.C.

ADDRESS: 1200 19th Street, NW, Suite 1000, Washington, DC 20036-2412

TITLE OF ATTACHED FORMS: McKinsey & Company, Inc. Washington, D.C. Proposal / Budget

The Commonwealth and the Contractor are this day entering into a contract, and for their mutual convenience, the parties are using the attached form agreement provided by the Contractor. Nevertheless, the parties agree that this Addendum is incorporated into and amends the form agreement, as provided below.

Notwithstanding anything in the attached form agreement, the payments to be made by the Commonwealth for all goods, services and other deliverables under this contract shall not exceed \$585,000.00; payments will be made only upon the Agency's receipt of a proper invoice detailing the goods/services provided. The total cumulative liability of the Commonwealth, its officers, employees and agents in connection with this contract or in connection with any goods, services, actions or omissions relating to the contract, shall not under any circumstance exceed payment of the above maximum purchase price plus liability for an additional amount equal to such maximum purchase price. All actions of the Contractor relating in any way to Agency shall be as an independent contractor, and not as an agent or

The Contractor's form agreement is, with the exceptions noted herein, acceptable to the Commonwealth. Nonetheless, because certain standard clauses that may appear in the Contractor's form agreement cannot be accepted by the Commonwealth, and in consideration of the convenience of using that form, and this form, without the necessity of specifically negotiating a separate contract document, the parties specifically agree that, notwithstanding any provisions appearing in the attached form agreement, none of the following shall have any effect or be enforceable against the Commonwealth:

- Requiring the Commonwealth to obtain or maintain any type of insurance; 1.
- Renewing or extending the agreement beyond the initial term or automatically continuing the contract period from term to term:
- Requiring or stating that the terms of the Contractor's form agreement shall prevail over this Addendum; 3.
- Requiring the Commonwealth to defend, indemnify or to hold the Contractor harmless for third party claims of 4. any kind:
- Imposing interest charges exceeding those permitted by Code of Virginia, § 2.2-4347 through 2.2-4354, Prompt

- Requiring the application of law other than Virginia law in interpreting or enforcing the contract, or requiring or permitting that any dispute under the contract be resolved in any court other than an appropriate state circuit court in Virginia;
- Requiring the Commonwealth to pay liquidated damages, or requiring the Commonwealth to make any payment for lost revenue or profits if the contract is terminated before its ordinary period;
- 8. Requiring that the contract be accepted or endorsed by the home office or by any other person subsequent to execution by the undersigned Agency representative before the contract is considered in effect, or otherwise delaying the formation or effective date of the contract to a time later than execution of the contract by the undersigned Agency representative;
- Requiring the Agency to agree to or be subject to any form of equitable relief not authorized by the Constitution
  or laws of Virginia;
- 10. Limiting or adding to the time period within which claims can be made or actions can be brought;
- 11. Limiting the liability of the Contractor for property damage or personal injury;
- 12. Permitting unilateral modification of this contract by the Contractor, or deeming the Commonwealth to agree to a modification by means other than affirmatively signing a modification agreement on paper:
- 13. Binding the Commonwealth to any arbitration process or decision;
- Obligating the Commonwealth to pay costs of collection or attorney's fees;
- 15. Granting the Contractor a security interest in property of the Commonwealth.
- 16. Granting any right or incurring any obligation that is beyond the legal authority of the undersigned Agency to empower its contract officers to grant or incur on behalf of the Commonwealth, or requiring the Commonwealth to violate any applicable law or regulation.

In addition, the parties agree that the contract between them shall be deemed to incorporate provisions that the Virginia Public Procurement Act requires to be included in Commonwealth contracts. These can be found in the following Sections of the *Code of Virginia*: § 2.2-4363 (procedure for filing claims); § 2.2-4354 (requirement to pay subcontractors); § 2.2-4311 (non-discrimination in contracts above \$10,000); § 2.2-4312 (drug-free workplace in contracts above \$10,000); § 2.2-4311.1 (compliance with federal immigration law); and § 2.2-4311.2 (authorization to transact business in Virginia, if legally required).

This contract, consisting of this Addendum and the attached form agreement, constitutes the entire agreement between the parties and may not be waived or modified except by written agreement between the parties.

IN WITNESS WHEREOF, the parties have caused this contract to be duly executed, intending thereby to be legally bound.

AGENCY by: Alatho Management	McKinsey & Company, Inc. Washington, D.C.
Title: Priestor of Grownant	Title: Partner
Date: 04/11/2020	Date: April 11, 2020

#### CONSULTING AGREEMENT

McKinsey & Company, Inc. Washington D.C. ("McKinsey") and the Commonwealth of Virginia, Virginia Department of Emergency Management (the "Client") hereby agree to the following terms in connection with consulting services that McKinsey will be providing to the Client as further described herein (the "Services").

1. SERVICES. The working arrangements, including scope of the Services, Deliverables (as defined below), team composition and workplan, are described in McKinsey's proposal attached hereto (the "Proposal"). These Services and Deliverables are being provided as covered countermeasures to the COVID-19 epidemic pursuant to the U.S. Department of Health and Human Services' February 4, 2020 Declaration pursuant to the Public Readiness and Emergency Preparedness Act, and are to be used as authorized by any public agency to which they ultimately may be provided. The Services and Deliverables are an extension of and supplement to the government functions performed by the receiving public agency. The Services shall include the evaluation or discussion of potential services and McKinsey's preparation of the Proposal. The parties may meet at mutually agreed times to discuss the progress of the Services and to exchange feedback. In order to be able to complete the Services within the agreed timeframe and budget and to fulfill its responsibilities on a timely basis. McKinsey will rely on the Client's timely cooperation, including the Client making available relevant data, information and personnel, performing any tasks or responsibilities assigned to the Client and notifying McKinsey of any issues or concerns the Client may have relating to the Services. During the course of the Services, priorities may shift or unexpected events may occur which may necessitate changes to the Services. In this event, the parties will jointly discuss the anticipated impact on the Services and agree on any appropriate adjustments, including to the scope of work, timeframe and budget. McKinsey will not provide advice, opinions or recommendations on policy or political matters nor will it be involved in, or support, any advocacy, policy, or lobbying efforts.

The Client acknowledges and agrees that the situation around COVID-19 is highly dynamic, evolving rapidly, subject to significant uncertainty, a lack of reliable information and other events completely beyond the parties' control. McKinsey cannot and will not give medical, regulatory, public health or legal advice. The Client must consider this context and secure appropriate legal, medical and other relevant advice prior to making any decisions in connection with the Services. McKinsey's Services are being provided on an expedited basis and may not have the benefit of certain detailed analyses in performing the Services. The Client will review and approve or concur in McKinsey's work, including its methodologies and approaches and the Deliverables, in carrying out the Services.

2. COMPENSATION. The Client shall compensate McKinsey for its professional fees and expenses in connection with the Services, as set forth in the applicable Proposal. The Client agrees that it will not, without McKinsey's prior written permission, disclose the terms of this agreement or any Proposal (including McKinsey's fees, expenses and other commercial terms) to any third parties (including the Client's external procurement and other service providers). McKinsey will invoice the Client for professional fees and expenses in connection with the Services monthly or as otherwise set forth in the service.

3. <u>CONFIDENTIALITY</u>. McKinsey will keep confidential any confidential information, including any personal data (as defined below), furnished by the Client to McKinsey in connection with the Services ("Confidential Information"). McKinsey will disclose Confidential Information only to its employees, agents and contractors who have a need to know and are bound to keep it confidential, will use Confidential Information only for purposes of performing the Services, including preparing Proposals and evaluating potential Services, or as otherwise requested or authorized by the Client, and will protect Confidential Information in accordance with the McKinsey Data Protection Protocols available at <a href="https://solutions.mckinsey.com/msd/data-protocols.pdf">https://solutions.mckinsey.com/msd/data-protocols.pdf</a> (the "Protocols"). Subject to its confidentiality

obligations, where the agreed upon Services include benchmarking services McKinsey may also incorporate Confidential Information into its benchmarking databases for use in reporting on sanitized or aggregate trends and metrics without attribution to the Client. To bring the best of McKinsey's global resources to serve the Client, the Client agrees that McKinsey may transfer Confidential Information to geographics other than those in which it was collected or received, including to McKinsey affiliates and sub-processors that comprise or support McKinsey's infrastructure and maintenance functions as set forth in the Protocols, to facilitate any activities authorized by the Client, provided that at all times Confidential Information will be treated as confidential and protected in accordance with the terms of this agreement. Confidential Information shall not include information that is or becomes publicly available, already known to McKinsey, independently acquired or developed by McKinsey or legally required to be disclosed. McKinsey will reasonably cooperate with the Client, at Client's expense, in responding to any legally required disclosure. In performing the Services, McKinsey will use and rely primarily on information and data available from public sources and information and data provided by or on behalf of the Client, including the Confidential Information. Client acknowledges and agrees that, with respect to such information and data: (a) it shall comply with all applicable laws and regulations in gathering and providing the same to McKinsey, and has obtained the necessary consents of individual data subjects with respect to any personal data; (b) it has and will have full and sufficient right to assign or grant the rights and/or licenses in and to such information and data for McKinsey's use as authorized pursuant to this agreement; (c) McKinsey has no obligation to independently verify any such information or data; and (d) it shall promptly notify McKinsey if it becomes aware that the Client is in breach of any of the foregoing representations and warranties. At the Client's election and notification to McKinsey, McKinsey shall promptly return or destroy any Confidential Information, including any personal data, in its possession or control when the same is no longer necessary for the provision of the Services, provided that McKinsey may retain such Confidential Information only as required by applicable law, regulation or documented professional archival policy or as otherwise authorized or instructed by the Client. Any Confidential Information so retained shall at all times remain subject to the terms and conditions of this agreement, including with respect to confidentiality, security and non-disclosure.

- 4. DATA SECURITY. Without limiting the foregoing, if McKinsey processes data as part of the Services and on behalf of the Client which relates to an identified or identifiable person ("personal data"), McKinsey shall (i) only process such personal data, including with respect to McKinsey's use of subcontractors or sub-processors, as set forth in this agreement and the Protocols, as otherwise authorized in writing by the Client, or as required by applicable law, (ii) implement appropriate technical and organizational measures to protect such personal data as set forth in the Protocols, (iii) promptly notify the Client of any incident in which the confidentiality, integrity or security of the personal data has been compromised, and (iv) collaborate with the Client as required by applicable law or the Client's request to document the personal data, data subjects and processing activities related to the Services, including as part of an applicable Proposal. McKinsey will comply with the Client's reasonable requests to furnish information regarding McKinsey's processing activities as is reasonably necessary to enable the Client to verify that McKinsey is complying with its obligations under this agreement, including by making its Director of IT Security or person of comparable knowledge and position available to provide information about the Protocols and McKinsey's processing in connection with the Services, and the foregoing shall apply in full satisfaction of any Client audit or inspection rights of McKinsey, but shall not limit or restrict the ability of any legal or regulatory authority to conduct such audit or inspection pursuant to applicable law.
- 5. INTELLECTUAL PROPERTY. Upon McKinsey's completion of the Services and provision to the Client the final Deliverables, and Client's final payment for the Services and Deliverables, the Client will own all reports and other deliverables prepared for and furnished to the Client by McKinsey in connection with the Services (the "Deliverables") provided that McKinsey is free to copy, use, share, and disclose the Deliverables. McKinsey further retains ownership of all concepts, know-how, tools, questionnaires and assessments, modules, courses, frameworks, software, algorithms, databases, content, models, and industry perspectives developed or enhanced outside of or in connection with the Services (the "McKinsey Tools"), it being understood that none of the McKinsey Tools will contain the Client's Confidential Information. To the extent

the Deliverables include any embedded McKinsey Tools, McKinsey hereby grants the Client a non-exclusive, non-transferable, non-sublicenseable, worldwide, royalty-free license to use and copy the McKinsey Tools solely as part of the Deliverables and subject to the limitations herein on disclosure of McKinsey materials and publicity. The Client agrees that, without McKinsey's prior written permission, it will not, or permit any third party to (a) access, copy or reverse engineer any McKinsey Tool or Deliverable, or (b) remove or circumvent security or technological safeguards, including notices, digital protection mechanisms, metadata, watermarks, or disclaimers provided with any McKinsey Tool or Deliverable.

- 6. DISCLOSURE OF McKINSEY MATERIALS: PUBLICITY. McKinsey's work for the Client is confidential and for the Client's internal use only. The Client will not disclose any materials or information that McKinsey furnishes to the Client, including the Deliverables, to any third parties without McKinsey's prior written permission, except as required by law. The Client further agrees not to use McKinsey's name or trademarks in any communication with any third party without McKinsey's prior written permission. McKinsey may disclose that we have been retained by the Client and a general description of the Services. McKinsey recognizes that the Client may need to partner with Virginia state and local government agencies in connection with countermeasures to COVID-19 epidemic, and McKinsey agrees that Client may share the Deliverables to Virginia State and local government agencies for purposes of furthering such countermeasures, provided that no attribution or reference is made to McKinsey in connection with such disclosure. McKinsey further acknowledges that the Client may request McKinsey to participate directly in meetings or other interactions with government officials from federal, Virginia state, and local government agencies in connection with the Services and Deliverables as described in the Proposal, and in such event, McKinsey and the Client shall align on the scope and role of McKinsey prior to such participation.
- 7. SERVING COMPETITORS. It is McKinsey's long-standing policy to serve competing clients and clients with potentially conflicting interests as well as counter-parties in merger, acquisition and alliance opportunities, and to do so without compromising McKinsey's professional responsibility to maintain the confidentiality of client information. Consistent with such practice and McKinsey's confidentiality obligations to its other clients, McKinsey is not able to advise or consult with the Client about McKinsey's serving the Client's competitors or other parties. Nothing in this section shall operate to limit or reduce McKinsey's obligations with respect to the Client's Confidential Information, including the confidentiality and non-disclosure obligations with respect thereto.
- 8. LIMITATION OF LIABILITY. The Services are not (and will not be interpreted as) medical, investment, legal, tax, accounting or other regulated advice, and do not constitute policy advice. McKinsey's Services do not supplant the Client's management, policy-making, or decision-making functions and do not guarantee results. The Client remains solely responsible for its decisions (including policy decisions), actions, use of the Deliverables and any other materials received pursuant to this agreement, and compliance with applicable laws, rules and regulations. The Client agrees to hold harmless and not pursue claims or suits against McKinsey for any losses, damages, costs or expenses arising out of the provision of these Services. Should third party suits be filed against McKinsey arising out of the provision of these Services, the parties hereto agree to cooperate with each other during such litigation, including the timely provision of documents and witnesses to each other as well as the filing of supportive documents and briefs in such litigation. The Client agrees to pay for any costs, including attorney fees, McKinsey incurs as a result of its participation as a non-party in any legal, regulatory, administrative or other proceeding relating to the Services. Neither party will be liable for any lost profits or other indirect, consequential, incidental, punitive or special damages.

Subject to the availability of appropriated funds under this consulting agreement, McKinsey shall be reimbursed by Client for liabilities (and expenses incidental to such liabilities, such as defense costs and expert fees), to third parties, including business entities, without regard to and as an exception to any limitation of cost or limitation of funds. These reimbursable liabilities must arise out of the performance of this engagement, whether or not caused by the negligence or the gross negligence of McKinsey or of McKinsey's agents or employees and must be represented by final judgments or settlements approved in writing by Client. These reimbursable liabilities are for: i--the loss of or damage to property, (other than property owned, occupied or

used by McKinsey, rented or in the care, custody or control of McKinsey); ii--third party business interruption or economic loss claims; and iii--third party death and injury.

- 9. CONTINGENCIES: ADVERSE EVENTS. If an event, circumstance, regulation, restriction, development or a combination thereof (an "Adverse Event"), whether or not foreseeable or preventable through the exercise of reasonable diligence, occurs, is implemented or becomes effective during the term of this agreement and makes it unsafe (or gives rise to a health risk), impracticable, onerous, uneconomic or burdensome for McKinsey to proceed with or continue the performance of the Services or any part thereof (including, without limitation, the occurrence of any Adverse Event having the characteristics of force majeure such as natural disaster, act of God, act of government, war and other hostilities, terrorism, protest, external disruptions, pandemic, or others), McKinsey may, upon notice in writing to the Client, suspend the Services indefinitely until such time as the Adverse Event has subsided and the parties mutually deem it practicable for the Services to resume. If the suspension exceeds 60 days, either party may terminate this agreement upon notice in writing to the other party. Suspension hereunder shall be without liability and without payment of any amount by way of penalty, damages or other compensation.
- 10. TERM AND TERMINATION. This agreement takes effect on the date the Services commenced and shall continue until terminated in accordance with its terms. Except as otherwise provided in the applicable Proposal, either party may terminate the Services at any time effective upon written notice to the other.
- management and business judgement only and will not contain, nor are the Deliverables provided for the purpose of constituting or informing, policy judgments or advice. McKinsey emphasizes that statements of expectation, forecasts and projections relate to future events and are based on assumptions that may not remain valid for the whole of the relevant period. Consequently, they cannot be relied upon, and McKinsey expresses no opinion as to how closely the actual results achieved will correspond to any statements of expectation, forecasts or projections. McKinsey makes no representation or warranty of any kind, express or implied, regarding the accuracy, adequacy, validity, reliability, availability or completeness of any information in the Deliverables.
- 12. MISCELLANEOUS. This agreement and the Proposal constitute the entire agreement between the parties, and there are no prior or contemporaneous oral or written representations, understandings or agreements relating to this subject matter that are not fully expressed herein or therein. The terms of this agreement may only be amended or modified in writing signed by both parties. This agreement and the Proposals shall be governed by and construed in accordance with the laws of the State of [INSERT] without regard to conflicts of law principles and shall inure to the benefit of and be binding on the successors and assigns of the Client and McKinsey. The following Sections shall survive the completion or any termination of the Services: 3 (Confidentiality), 4 (Data Security), 5 (Intellectual Property), 6 (Disclosure of McKinsey Materials; Publicity), 7 (Serving Competitors), 8 (Limitation of Liability), 9 (Contingencies; Adverse Events), 10 (Term and Termination). 11 (Warranty) and 12 (Miscellaneous) and any other provision which by law or by its nature should survive. Neither party may assign its rights or obligations under this agreement to any person or entity without the written consent of the other party, not to be unreasonably withheld, provided, however, that either party may assign its rights and obligations under this agreement to its affiliates upon reasonable written notice to the other party but without the written consent of the other party. Assignment shall not relieve either party of its obligations hereunder. McKinsey is an independent contractor and not the Client's agent or fiduciary. Notwithstanding any course of dealings of the parties at any time or any statement to the contrary contained therein, no purchase order, invoice or other similar document issued by a party shall be construed to modify the terms of this agreement. Rights and remedies provided in this agreement are cumulative and not exclusive of any right or remedy provided at law or in equity.

The Client's audit rights under this Agreement, except as provided under Section 4, are solely limited to McKinsey providing the Client any invoices and final Deliverables arising out of this Agreement. McKinsey

agrees that to the best of its knowledge, no actual conflicts of interest exist between the McKinsey key personnel assigned to provide services under the Agreement and the Client.

Virginia Department of Emergency Management

McKinsey & Company, Inc. Washington

D.C.

Name: Sarah Tucker-Ray

Title: Partner Date: April 11, 2020

### **GENERAL TERMS AND CONDITIONS:**

- A. <u>VENDORS MANUAL</u>: This solicitation is subject to the provisions of the Commonwealth of Virginia Vendors Manual and any changes or revisions thereto, which are hereby incorporated into this contract in their entirety. The procedure for filing contractual claims is in section 7.19 of the Vendors Manual. A copy of the manual is normally available for review at the purchasing office and is accessible on the Internet at <a href="https://www.eva.virginia.gov">www.eva.virginia.gov</a> under "Vendors Manual" on the vendors tab.
- B. APPLICABLE LAWS AND COURTS: This solicitation and any resulting contract shall be governed in all respects by the laws of the Commonwealth of Virginia, without regard to its choice of law provisions, and any litigation with respect thereto shall be brought in the circuit courts of the Commonwealth. The agency and the contractor are encouraged to resolve any issues in controversy arising from the award of the contract or any contractual dispute using Alternative Dispute Resolution (ADR) procedures (Code of Virginia, § 2.2-4366). ADR procedures are described in Chapter 9 of the Vendors Manual. The contractor shall comply with all applicable federal, state and local laws, rules and regulations.
- C. ANTI-DISCRIMINATION: By submitting their (bids/proposals), (bidders/offerors) certify to the Commonwealth that they will conform to the provisions of the Federal Civil Rights Act of 1964, as amended, as well as the Virginia Fair Employment Contracting Act of 1975, as amended, where applicable, the Virginians With Disabilities Act, the Americans With Disabilities Act and § 2.2-4311 of the Virginia Public Procurement Act (VPPA). If the award is made to a faith-based organization, the organization shall not discriminate against any recipient of goods, services, or disbursements made pursuant to the contract on the basis of the recipient's religion, religious belief, refusal to participate in a religious practice, or on the basis of race, age, color, gender or national origin and shall be subject to the same rules as other organizations that contract with public bodies to account for the use of the funds provided; however, if the faith-based organization segregates public funds into separate accounts, only the accounts and programs funded with public funds shall be subject to audit by the public body. (Code of Virginia, § 2.2-4343.1E).

In every contract over \$10,000 the provisions in 1. and 2. below apply:

- During the performance of this contract, the contractor agrees as follows:
  - a. The contractor will not discriminate against any employee or applicant for employment because of race, religion, color, sex, national origin, age, disability, or any other basis prohibited by state law relating to discrimination in employment, except where there is a bona fide occupational qualification reasonably necessary to the normal operation of the contractor. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices setting forth the provisions of this nondiscrimination clause.
  - b. The contractor, in all solicitations or advertisements for employees placed by or on behalf of the contractor, will state that such contractor is an equal opportunity employer.
  - c. Notices, advertisements and solicitations placed in accordance with federal law, rule or regulation shall be deemed sufficient for the purpose of meeting the requirements of this section.

- d. The requirements of these provisions 1. and 2. are a material part of the contract. If the Contractor violates one of these provisions, the Commonwealth may terminate the affected part of this contract for breach, or at its option, the whole contract. Violation of one of these provisions may also result in debarment from State contracting regardless of whether the specific contract is terminated.
- e. In accordance with Executive Order 61 (2017), a prohibition on discrimination by the contractor, in its employment practices, subcontracting practices, and delivery of goods or services, on the basis of race, sex, color, national origin, religion, sexual orientation, gender identity, age, political affiliation, disability, or veteran status, is hereby incorporated in this contract.
- The contractor will include the provisions of 1. above in every subcontract or purchase order over \$10,000, so that the provisions will be binding upon each subcontractor or vendor.
- D. <u>ETHICS IN PUBLIC CONTRACTING</u>: By submitting their (bids/proposals), (bidders/offerors) certify that their (bids/proposals) are made without collusion or fraud and that they have not offered or received any kickbacks or inducements from any other (bidder/offeror), supplier, manufacturer or subcontractor in connection with their (bid/proposal), and that they have not conferred on any public employee having official responsibility for this procurement transaction any payment, loan, subscription, advance, deposit of money, services or anything of more than nominal value, present or promised, unless consideration of substantially equal or greater value was exchanged.
- E. <u>IMMIGRATION REFORM AND CONTROL ACT OF 1986</u>: Applicable for all contracts over \$10,000: By entering into a written contract with the Commonwealth of Virginia, the Contractor certifies that the Contractor does not, and shall not during the performance of the contract for goods and services in the Commonwealth, knowingly employ an unauthorized alien as defined in the federal immigration Reform and Control Act of 1986.
- F. <u>DEBARMENT STATUS</u>: By participating in this procurement, the vendor certifies that they are not currently debarred by the Commonwealth of Virginia from submitting a response for the type of goods and/or services covered by this solicitation. Vendor further certifies that they are not debarred from filling any order or accepting any resulting order, or that they are an agent of any person or entity that is currently debarred by the Commonwealth of Virginia.
  - If a vendor is created or used for the purpose of circumventing a debarment decision against another vendor, the non-debarred vendor will be debarred for the same time period as the debarred vendor.
- G. <u>ANTITRUST</u>: By entering into a contract, the contractor conveys, sells, assigns, and transfers to the Commonwealth of Virginia all rights, title and interest in and to all causes of action it may now have or hereafter acquire under the antitrust laws of the United States and the Commonwealth of Virginia, relating to the particular goods or services purchased or acquired by the Commonwealth of Virginia under said contract.
- H. MANDATORY USE OF STATE FORM AND TERMS AND CONDITIONS FOR IFBs AND RFPs (Insert wording below appropriate to the solicitation type as indicated):
  - (For Invitation For Bids): Failure to submit a bid on the official state form provided for that
    purpose shall be a cause for rejection of the bid. Modification of or additions to any portion of
    the Invitation for Bids may be cause for rejection of the bid; however, the Commonwealth

reserves the right to decide, on a case by case basis, in its sole discretion, whether to reject such a bid as nonresponsive. As a precondition to its acceptance, the Commonwealth may, in its sole discretion, request that the bidder withdraw or modify nonresponsive portions of a bid which do not affect quality, quantity, price, or delivery. No modification of or addition to the provisions of the contract shall be effective unless reduced to writing and signed by the parties.

- (For Request For Proposals): Failure to submit a proposal on the official state form provided for that purpose may be a cause for rejection of the proposal. Modification of or additions to the General Terms and Conditions of the solicitation may be cause for rejection of the proposal; however, the Commonwealth reserves the right to decide, on a case by case basis, in its sole discretion, whether to reject such a proposal.
- CLARIFICATION OF TERMS: If any prospective (bidder/offeror) has questions about the specifications
  or other solicitation documents, the prospective (bidder/offeror) should contact the buyer whose
  name appears on the face of the solicitation no later than five working days before the due date. Any
  revisions to the solicitation will be made only by addendum issued by the buyer.

#### J. PAYMENT:

#### 1. To Prime Contractor:

- a. Invoices for items ordered, delivered and accepted shall be submitted by the contractor directly to the payment address shown on the purchase order/contract. All invoices shall show the state contract number and/or purchase order number; social security number (for individual contractors) or the federal employer identification number (for proprietorships, partnerships, and corporations).
- b. Any payment terms requiring payment in less than 30 days will be regarded as requiring payment 30 days after invoice or delivery, whichever occurs last. This shall not affect offers of discounts for payment in less than 30 days, however.
- c. All goods or services provided under this contract or purchase order, that are to be paid for with public funds, shall be billed by the contractor at the contract price, regardless of which public agency is being billed.
- d. The following shall be deemed to be the date of payment: the date of postmark in all cases where payment is made by mail, or when offset proceedings have been instituted as authorized under the Virginia Debt Collection Act.
- e. Unreasonable Charges. Under certain emergency procurements and for most time and material purchases, final job costs cannot be accurately determined at the time orders are placed. In such cases, contractors should be put on notice that final payment in full is contingent on a determination of reasonableness with respect to all invoiced charges. Charges which appear to be unreasonable will be resolved in accordance with Code of Virginia, § 2.2-4363 and -4364. Upon determining that invoiced charges are not reasonable, the Commonwealth shall notify the contractor of defects or improprieties in invoices within fifteen (15) days as required in Code of Virginia, § 2.2-4351., The provisions of this section do not relieve an agency of its prompt payment obligations with respect to those charges which are not in dispute (Code of Virginia, § 2.2-4363).

#### To Subcontractors:

- a. Within seven (7) days of the contractor's receipt of payment from the Commonwealth, a contractor awarded a contract under this solicitation is hereby obligated:
  - To pay the subcontractor(s) for the proportionate share of the payment received for work performed by the subcontractor(s) under the contract; or
  - (2) To notify the agency and the subcontractor(s), in writing, of the contractor's intention to withhold payment and the reason.
- b. The contractor is obligated to pay the subcontractor(s) interest at the rate of one percent per month (unless otherwise provided under the terms of the contract) on all amounts owed by the contractor that remain unpaid seven (7) days following receipt of payment from the Commonwealth, except for amounts withheld as stated in (2) above. The date of mailing of any payment by U. S. Mail is deemed to be payment to the addressee. These provisions apply to each sub-tier contractor performing under the primary contract. A contractor's obligation to pay an interest charge to a subcontractor may not be construed to be an obligation of the Commonwealth.
- 3. Each prime contractor who wins an award in which provision of a SWaM procurement plan is a condition to the award, shall deliver to the contracting agency or institution, on or before request for final payment, evidence and certification of compliance (subject only to insubstantial shortfalls and to shortfalls arising from subcontractor default) with the SWaM procurement plan. Final payment under the contract in question may be withheld until such certification is delivered and, if necessary, confirmed by the agency or institution, or other appropriate penalties may be assessed in lieu of withholding such payment.
- The Commonwealth of Virginia encourages contractors and subcontractors to accept electronic and credit card payments.
- K. PRECEDENCE OF TERMS: The following General Terms and Conditions VENDORS MANUAL, APPLICABLE LAWS AND COURTS, ANTI-DISCRIMINATION, ETHICS IN PUBLIC CONTRACTING, IMMIGRATION REFORM AND CONTROL ACT OF 1986, DEBARMENT STATUS, ANTITRUST, MANDATORY USE OF STATE FORM AND TERMS AND CONDITIONS, CLARIFICATION OF TERMS, PAYMENT shall apply in all instances. In the event there is a conflict between any of the other General Terms and Conditions and any Special Terms and Conditions in this solicitation, the Special Terms and Conditions shall apply.
- L. QUALIFICATIONS OF (BIDDERS/OFFERORS): The Commonwealth may make such reasonable investigations as deemed proper and necessary to determine the ability of the (bidder/offeror) to perform the services/furnish the goods and the (bidder/offeror) shall furnish to the Commonwealth all such information and data for this purpose as may be requested. The Commonwealth reserves the right to inspect (bidder's/offeror's) physical facilities prior to award to satisfy questions regarding the (bidder's/offeror's) capabilities. The Commonwealth further reserves the right to reject any (bid/proposal) if the evidence submitted by, or investigations of, such (bidder/offeror) fails to satisfy the Commonwealth that such (bidder/offeror) is properly qualified to carry out the obligations of the contract and to provide the services and/or furnish the goods contemplated therein.

- M. <u>TESTING AND INSPECTION</u>: The Commonwealth reserves the right to conduct any test/inspection it may deem advisable to assure goods and services conform to the specifications.
- N. <u>ASSIGNMENT OF CONTRACT</u>: A contract shall not be assignable by the contractor in whole or in part without the written consent of the Commonwealth.
- O. CHANGES TO THE CONTRACT: Changes can be made to the contract in any of the following ways:
  - 1. The parties may agree in writing to modify the terms, conditions, or scope of the contract. Any additional goods or services to be provided shall be of a sort that is ancillary to the contract goods or services, or within the same broad product or service categories as were included in the contract award. Any increase or decrease in the price of the contract resulting from such modification shall be agreed to by the parties as a part of their written agreement to modify the scope of the contract.
  - 2. The Purchasing Agency may order changes within the general scope of the contract at any time by written notice to the contractor. Changes within the scope of the contract include, but are not limited to, things such as services to be performed, the method of packing or shipment, and the place of delivery or installation. The contractor shall comply with the notice upon receipt, unless the contractor intends to claim an adjustment to compensation, schedule, or other contractual impact that would be caused by complying with such notice, in which case the contractor shall, in writing, promptly notify the Purchasing Agency of the adjustment to be sought, and before proceeding to comply with the notice, shall await the Purchasing Agency's written decision affirming, modifying, or revoking the prior written notice. If the Purchasing Agency decides to issue a notice that requires an adjustment to compensation, the contractor shall be compensated for any additional costs incurred as the result of such order and shall give the Purchasing Agency a credit for any savings. Said compensation shall be determined by one of the following methods:
    - a. By mutual agreement between the parties in writing; or
    - b. By agreeing upon a unit price or using a unit price set forth in the contract, if the work to be done can be expressed in units, and the contractor accounts for the number of units of work performed, subject to the Purchasing Agency's right to audit the contractor's records and/or to determine the correct number of units independently; or
    - c. By ordering the contractor to proceed with the work and keep a record of all costs incurred and savings realized. A markup for overhead and profit may be allowed if provided by the contract. The same markup shall be used for determining a decrease in price as the result of savings realized. The contractor shall present the Purchasing Agency with all vouchers and records of expenses incurred and savings realized. The Purchasing Agency shall have the right to audit the records of the contractor as it deems necessary to determine costs or savings. Any claim for an adjustment in price under this provision must be asserted by written notice to the Purchasing Agency within thirty (30) days from the date of receipt of the written order from the Purchasing Agency. If the parties fail to agree on an amount of adjustment, the question of an increase or decrease in the contract price or time for performance shall be resolved in accordance with the procedures for resolving disputes provided by the Disputes Clause of this contract or, if there is none, in accordance with the disputes provisions of the Commonwealth of Virginia Vendors Manual. Neither the existence of a claim nor a dispute resolution process, litigation or any other provision of

this contract shall excuse the contractor from promptly complying with the changes ordered by the Purchasing Agency or with the performance of the contract generally.

- P. <u>DEFAULT</u>: In case of failure to deliver goods or services in accordance with the contract terms and conditions, the Commonwealth, after due oral or written notice, may procure them from other sources and hold the contractor responsible for any resulting additional purchase and administrative costs. This remedy shall be in addition to any other remedies which the Commonwealth may have.
- Q. <u>TAXES</u>: Sales to the Commonwealth of Virginia are normally exempt from State sales tax. State sales and use tax certificates of exemption, Form ST-12, will be issued upon request. Deliveries against this contract shall usually be free of Federal excise and transportation taxes. The Commonwealth's excise tax exemption registration number is 54-73-0076K.

If sales or deliveries against the contract are not exempt, the contractor shall be responsible for the payment of such taxes unless the tax law specifically imposes the tax upon the buying entity and prohibits the contractor from offering a tax-included price.

(NOT NORMALLY REQUIRED FOR SERVICE CONTRACTS)

- R. <u>USE OF BRAND NAMES</u>: Unless otherwise provided in this solicitation, the name of a certain brand, make or manufacturer does not restrict (bidders/offerors) to the specific brand, make or manufacturer named, but conveys the general style, type, character, and quality of the article desired. Any article which the public body, in its sole discretion, determines to be the equivalent of that specified, considering quality, workmanship, economy of operation, and suitability for the purpose intended, shall be accepted. The (bidder/offeror) is responsible to clearly and specifically identify the product being offered and to provide sufficient descriptive literature, catalog cuts and technical detail to enable the Commonwealth to determine if the product offered meets the requirements of the solicitation. This is required even if offering the exact brand, make or manufacturer specified. Normally in competitive sealed bidding only the information furnished with the bid will be considered in the evaluation. Failure to furnish adequate data for evaluation purposes may result in declaring a bid nonresponsive. Unless the (bidder/offeror) clearly indicates in its (bid/proposal) that the product offered is an equivalent product, such (bid/proposal) will be considered to offer the brand name product referenced in the solicitation. (NOT NORMALLY REQUIRED FOR SERVICE CONTRACTS)
- S. TRANSPORTATION AND PACKAGING: By submitting their (bids/proposals), all (bidders/offerors) certify and warrant that the price offered for FOB destination includes only the actual freight rate costs at the lowest and best rate and is based upon the actual weight of the goods to be shipped. Except as otherwise specified herein, standard commercial packaging, packing and shipping containers shall be used. All shipping containers shall be legibly marked or labeled on the outside with purchase order number, commodity description, and quantity.

  (NOT NORMALLY REQUIRED FOR SERVICE CONTRACTS)
- T. INSURANCE: OMITTED
- U. <u>ANNOUNCEMENT OF AWARD</u>: Upon the award or the announcement of the decision to award a contract as a result of this solicitation, the purchasing agency will publicly post such notice on the DGS/DPS eVA VBO (<u>www.eva.virginia.gov</u>) for a minimum of 10 days.

V. DRUG-FREE WORKPLACE: Applicable for all contracts over \$10,000:

During the performance of this contract, the contractor agrees to (i) provide a drug-free workplace for the contractor's employees; (ii) post in conspicuous places, available to employees and applicants for employment, a statement notifying employees that the unlawful manufacture, sale, distribution, dispensation, possession, or use of a controlled substance or marijuana is prohibited in the contractor's workplace and specifying the actions that will be taken against employees for violations of such prohibition; (iii) state in all solicitations or advertisements for employees placed by or on behalf of the contractor that the contractor maintains a drug-free workplace; and (iv) include the provisions of the foregoing clauses in every subcontract or purchase order of over \$10,000, so that the provisions will be binding upon each subcontractor or vendor.

For the purposes of this section, "drug-free workplace" means a site for the performance of work done in connection with a specific contract awarded to a contractor, the employees of whom are prohibited from engaging in the unlawful manufacture, sale, distribution, dispensation, possession or use of any controlled substance or marijuana during the performance of the contract.

- W. NONDISCRIMINATION OF CONTRACTORS: A bidder, offeror, or contractor shall not be discriminated against in the solicitation or award of this contract because of race, religion, color, sex, national origin, age, disability, faith-based organizational status, any other basis prohibited by state law relating to discrimination in employment or because the bidder or offeror employs ex-offenders unless the state agency, department or institution has made a written determination that employing ex-offenders on the specific contract is not in its best interest. If the award of this contract is made to a faith-based organization and an individual, who applies for or receives goods, services, or disbursements provided pursuant to this contract objects to the religious character of the faith-based organization from which the individual receives or would receive the goods, services, or disbursements, the public body shall offer the individual, within a reasonable period of time after the date of his objection, access to equivalent goods, services, or disbursements from an alternative provider.
- Internet electronic procurement solution, web site portal <a href="www.eVA.virginia.gov">www.eVA.virginia.gov</a>, streamlines and automates government purchasing activities in the Commonwealth. The eVA portal is the gateway for vendors to conduct business with state agencies and public bodies. All vendors desiring to provide goods and/or services to the Commonwealth shall participate in the eVA Internet e-procurement solution by completing the free eVA Vendor Registration. All bidders or offerors must register in eVA and pay the Vendor Transaction Fees specified below; failure to register will result in the bid/proposal being rejected.

Vendor transaction fees are determined by the date the original purchase order is issued and the current fees are as follows:

For orders issued July 1, 2014, and after, the Vendor Transaction Fee is:

(i) DSBSD-certified Small Businesses: 1%, capped at \$500 per order.

- (ii) Businesses that are not DSBSD-certified Small Businesses: 1%, capped at \$1,500 per order.
- b. Refer to Special Term and Condition "eVA Orders and Contracts" to identify the number of purchase orders that will be issued as a result of this solicitation/contract with the eVA transaction fee specified above assessed for each order.

For orders issued prior to July 1, 2014, the vendor transaction fees can be found at <a href="https://www.eVA.virginia.gov">www.eVA.virginia.gov</a>.

The specified vendor transaction fee will be invoiced, by the Commonwealth of Virginia Department of General Services, typically within 60 days of the order issue date. Any adjustments (increases/decreases) will be handled through purchase order changes.

- Y. <u>AVAILABILITY OF FUNDS</u>: It is understood and agreed between the parties herein that the agency shall be bound hereunder only to the extent that the legislature has appropriated funds that are legally available or may hereafter become legally available for the purpose of this agreement.
- Z. SET-ASIDES IN ACCORDANCE WITH THE SMALL BUSINESS ENHANCEMENT AWARD PRIORITY: This solicitation is set-aside for award priority to DSBSD-certified micro businesses or small businesses when designated as "Micro Business Set-Aside Award Priority" or "Small Business Set-Aside Award Priority" accordingly in the solicitation. DSBSD-certified micro businesses or small businesses also includes DSBSD-certified women-owned and minority-owned businesses when they have received the DSBSD small business certification. For purposes of award, bidders/offerors shall be deemed micro businesses or small businesses if and only if they are certified as such by DSBSD on the due date for receipt of bids/proposals.
- AA. <u>BID PRICE CURRENCY</u>: Unless stated otherwise in the solicitation, bidders/offerors shall state bid/offer prices in US dollars.
- BB. AUTHORIZATION TO CONDUCT BUSINESS IN THE COMMONWEALTH: A contractor organized as a stock or nonstock corporation, limited liability company, business trust, or limited partnership or registered as a registered limited liability partnership shall be authorized to transact business in the Commonwealth as a domestic or foreign business entity if so required by Title 13.1 or Title 50 of the Code of Virginia or as otherwise required by law. Any business entity described above that enters into a contract with a public body pursuant to the Virginia Public Procurement Act shall not allow its existence to lapse or its certificate of authority or registration to transact business in the Commonwealth, if so required under Title 13.1 or Title 50, to be revoked or cancelled at any time during the term of the contract. A public body may void any contract with a business entity if the business entity fails to remain in compliance with the provisions of this section.

# **SPECIAL TERMS AND CONDITIONS:**

- 1. CANCELLATION OF CONTRACT: The purchasing agency reserves the right to cancel and terminate any resulting contract, in part or in whole, without penalty, upon (7) days written notice to the contractor. Any contract cancellation notice shall not relieve the contractor of the obligation to deliver and/or perform on all outstanding orders issued prior to the effective date of cancellation.
- 2. eVA ORDERS AND CONTRACTS: The contract will result in (one) purchase order.
- EXTRA CHARGES NOT ALLOWED: Extra charges will not be allowed, unless approved in advance by the Purchasing Agency.
- 4. STATE CORPORATION COMMISSION IDENTIFICATION NUMBER: Pursuant to Code of Virginia, §2.2-4311.2 subsection B, a bidder or offeror organized or authorized to transact business in the Commonwealth pursuant to Title 13.1 or Title 50 is required to include in its bid or proposal the identification number issued to it by the State Corporation Commission (SCC). Any bidder or offeror that is not required to be authorized to transact business in the Commonwealth as a foreign business entity under Title 13.1 or Title 50 or as otherwise required by law is required to include in its bid or proposal a statement describing why the bidder or offeror is not required to be so authorized. Indicate the above information on the SCC Form provided. Contractor agrees that the process by which compliance with Titles 13.1 and 50 is checked during the solicitation stage (including without limitation the SCC Form provided) is streamlined and not definitive, and the Commonwealth's use and acceptance of such form, or its acceptance of Contractor's statement describing why the bidder or offeror was not legally required to be authorized to transact business in the Commonwealth, shall not be conclusive of the issue and shall not be relied upon by the Contractor as demonstrating compliance.

# Federal Contract Provisions

#### 1. REMEDIES

- a. <u>Standard</u>. Contracts for more than the simplified acquisition threshold, currently set at \$250,000, must address administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as appropriate. See 2 C.F.R. Part 200, Appendix II(A).
- Applicability. This requirement applies to all FEMA grant and cooperative agreement programs.

# 2. TERMINATION FOR CAUSE AND CONVENIENCE

- a. <u>Standard</u>. All contracts in excess of \$10,000 must address termination for cause and for convenience by the non-Federal entity, including the manner by which it will be effected and the basis for settlement. <u>See</u> 2 C.F.R. Part 200, Appendix II(B).
- Applicability. This requirement applies to all FEMA grant and cooperative agreement programs.

# 3. EQUAL EMPLOYMENT OPPORTUNITY

If applicable, exact language below in subsection 3.d is required.

a. <u>Standard</u>. Except as otherwise provided under 41 C.F.R. Part 60, all contracts that meet the definition of "federally assisted construction contract" in 41 C.F.R.

§ 60-1.3 must include the equal opportunity clause provided under 41 C.F.R. § 60- 1.4(b), in accordance with Executive Order 11246, Equal Employment Opportunity (30 Fed. Reg. 12319, 12935, 3 C.F.R. Part, 1964-1965 Comp., p.

339), as amended by Executive Order 11375, Amending Executive Order 11246 Relating to Equal Employment Opportunity, and implementing regulations at

C.F.R. Part 60 (Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor). <u>See</u> 2 C.F.R. Part 200, Appendix II(C).

#### b. Key Definitions.

- i. Federally Assisted Construction Contract. The regulation at 41 C.F.R. § 60- 1.3 defines a "federally assisted construction contract" as any agreement or modification thereof between any applicant and a person for construction work which is paid for in whole or in part with funds obtained from the Government or borrowed on the credit of the Government pursuant to any Federal program involving a grant, contract, loan, insurance, or guarantee, or undertaken pursuant to any Federal program involving such grant, contract, loan, insurance, or guarantee, or any application or modification thereof approved by the Government for a grant, contract, loan, insurance, or guarantee under which the applicant itself participates in the construction work.
- ii. Construction Work. The regulation at 41 C.F.R. § 60-1.3 defines "construction work" as the construction, rehabilitation, alteration, conversion, extension, demolition or repair of buildings, highways, or other changes or improvements to real property, including facilities providing utility services. The term also includes the supervision, inspection, and other onsite functions incidental to the actual construction.
- c. <u>Applicability</u>. This requirement applies to all FEMA grant and cooperative agreement programs.
- d. Required Language. The regulation at 41 C.F.R. Part 60-1.4(b) requires the insertion of the following contract clause.

# During the performance of this contract, the contractor agrees as follows:

(1) The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, sexual orientation, gender identity, or national origin. The contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment without regard to their race, color, religion, sex, sexual orientation, gender identity, or national origin. Such action shall include, but not be limited to the following:

Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided setting forth the provisions of this nondiscrimination clause.

- (2) The contractor will, in all solicitations or advertisements for employees placed by or on behalf of the contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, or national origin.
- discriminate against any employee or applicant for employment because such employee or applicant has inquired about, discussed, or disclosed the compensation of the employee or applicant or another employee or applicant. This provision shall not apply to instances in which an employee who has access to the compensation information of other employees or applicants as a part of such employee's essential job functions discloses the compensation of such other employees or applicants to individuals who do not otherwise have access to such information, unless such disclosure is in response to a formal complaint or charge, in furtherance of an investigation, proceeding, hearing, or action, including an investigation conducted by the employer, or is consistent with the contractor's legal duty to furnish information.
- (4) The contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice to be provided advising the said labor union or workers' representatives of the contractor's commitments under this section, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.
- (5) The contractor will comply with all provisions of Executive Order 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.
- (6) The contractor will furnish all information and reports required by Executive Order 11246 of September 24, 1965, and by rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and

accounts by the administering agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

- (7) In the event of the contractor's noncompliance with the nondiscrimination clauses of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended in whole or in part and the contractor may be declared ineligible for further Government contracts or federally assisted construction contracts in accordance with procedures authorized in Executive Order 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.
- (8) The contractor will include the portion of the sentence immediately preceding paragraph (1) and the provisions of paragraphs (1) through (8) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the administering agency may direct as a means of enforcing such provisions, including sanctions for noncompliance:

Provided, however, that in the event a contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the administering agency, the contractor may request the United States to enter into such litigation to protect the interests of the United States.

The applicant further agrees that it will be bound by the above equal opportunity clause with respect to its own employment practices when it participates in federally assisted construction work: *Provided*, That if the applicant so participating is a State or local government, the above equal opportunity clause is not applicable to any agency, instrumentality or subdivision of such government which does not participate in work on or under the contract.

The applicant agrees that it will assist and cooperate actively with the administering agency and the Secretary of Labor in obtaining the compliance of contractors and subcontractors with the equal opportunity clause and the rules, regulations, and relevant orders of the Secretary of Labor, that it will furnish the administering agency and the Secretary of Labor such information as they may require for the supervision of such compliance, and that it will otherwise assist the administering agency in the discharge of the agency's primary responsibility for securing compliance.

The applicant further agrees that it will refrain from entering into any contract or contract modification subject to Executive Order 11246 of September 24, 1965, with a contractor debarred from, or who has not demonstrated eligibility for, Government contracts and federally assisted construction contracts pursuant to the Executive Order and will carry out such sanctions and penalties for violation of the equal opportunity clause as may be imposed upon contractors and subcontractors by the administering agency or the Secretary of Labor pursuant to Part II, Subpart D of the Executive Order. In addition, the applicant agrees that if it fails or refuses to comply with these undertakings, the administering agency may take any or all of the following actions: Cancel, terminate, or suspend in whole or in part this grant (contract, loan, insurance, guarantee); refrain from extending any further assistance to the applicant under the program with respect to which the failure or refund occurred until satisfactory assurance of future compliance has been received from such applicant; and refer the case to the Department of Justice for appropriate legal proceedings.

#### 4. DAVIS-BACON ACT

- a. Standard. All prime construction contracts in excess of \$2,000 awarded by non-Federal entities must include a provision for compliance with the Davis-Bacon Act (40 U.S.C. §§ 3141-3144 and 3146-3148) as supplemented by Department of Labor regulations at 29 C.F.R. Part 5 (Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction). See 2 C.F.R. Part 200, Appendix II(D). In accordance with the statute, contractors must be required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor. In addition, contractors must be required to pay wages not less than once a week.
- b. <u>Applicability</u>. The Davis-Bacon Act only applies to the Emergency Management Preparedness Grant Program, Homeland Security Grant Program, Nonprofit Security Grant Program, Tribal Homeland Security Grant Program, Port Security Grant Program, and Transit Security Grant Program. It DOES NOT apply to other FEMA grant and cooperative agreement programs, including the Public Assistance Program.

- c. Requirements. If applicable, the non-federal entity must do the following:
  - i. The non-Federal entity must place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation. The decision to award a contract or subcontract must be conditioned upon the acceptance of the wage determination. The non-Federal entity must report all suspected or reported violations to the Federal awarding agency.
  - ii. Additionally, pursuant 2 C.F.R. Part 200, Appendix II(D), contracts subject to the Davis-Bacon Act, must also include a provision for compliance with

the Copeland "Anti-Kickback" Act (40 U.S.C. § 3145), as supplemented by Department of Labor regulations at 29 C.F.R. Part 3 (Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States). The Copeland Anti-Kickback Act provides that each contractor or subrecipient must be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he or she is otherwise entitled. The non-Federal entity must report all suspected or reported violations to FEMA.

iii. Include a provision for compliance with the Davis-Bacon Act (40 U.S.C. 3141-3144, and 3146-3148) as supplemented by Department of Labor regulations (29 CFR Part 5, "Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction").

Suggested Language. The following provides a sample contract clause:

# Compliance with the Davis-Bacon Act.

- a. All transactions regarding this contract shall be done in compliance with the Davis-Bacon Act (40 U.S.C. 3141-3144, and 3146-3148) and the requirements of 29 C.F.R. pt. 5 as may be applicable. The contractor shall comply with 40 U.S.C. 3141-3144, and 3146-3148 and the requirements of 29 C.F.R. pt. 5 as applicable.
- b. Contractors are required to pay wages to laborers and mechanics at a rate not less than the prevailing wages specified in a wage determination made by the Secretary of Labor.

c. Additionally, contractors are required to pay wages not less than once a week

## 5. COPELAND ANTI-KICKBACK ACT

- a. <u>Standard</u>. Recipient and subrecipient contracts must include a provision for compliance with the Copeland "Anti-Kickback" Act (40 U.S.C. 3145), as supplemented by Department of Labor regulations (29 CFR Part 3, "Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States").
- b. <u>Applicability</u>. This requirement applies to all contracts for construction or repair work above \$2,000 in situations where the Davis-Bacon Act also applies. It DOES NOT apply to the FEMA Public Assistance Program.
- c. Requirements. If applicable, the non-federal entity must include a provision for compliance with the Copeland "Anti-Kickback" Act (40 U.S.C. § 3145), as supplemented by Department of Labor regulations at 29 C.F.R. Part 3 (Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States). Each contractor or subrecipient must be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he or she is otherwise entitled. The non-Federal entity must report all suspected or reported violations to FEMA. Additionally, in accordance with the regulation, each contractor and subcontractor must furnish each week a statement with respect to the wages paid each of its employees engaged in work covered by the Copeland Anti-Kickback Act and the Davis Bacon Act during the preceding weekly payroll period. The report shall be delivered by the contractor or subcontractor, within seven days after the regular payment date of the payroll period, to a representative of a Federal or State agency in charge at the site of the building or work.

Sample Language. The following provides a sample contract clause:

# Compliance with the Copeland "Anti-Kickback" Act.

- a. Contractor. The contractor shall comply with 18 U.S.C. § 874, 40 U.S.C. § 3145, and the requirements of 29 C.F.R. pt. 3 as may be applicable, which are incorporated by reference into this contract.
- Subcontracts. The contractor or subcontractor shall insert in any subcontracts the clause above and such other clauses as

FEMA may by appropriate instructions require, and also a clause requiring the subcontractors to include these clauses in any lower tier subcontracts. The prime contractor shall be responsible for the compliance by any subcontractor or lower tier subcontractor with all of these contract clauses.

 Breach. A breach of the contract clauses above may be grounds for termination of the contract, and for debarment

as a contractor and subcontractor as provided in 29 C.F.R. § 5.12."

# 6. CONTRACT WORK HOURS AND SAFETY STANDARDS ACT

- a. Standard. Where applicable (see 40 U.S.C. §§ 3701-3708), all contracts awarded by the non-Federal entity in excess of \$100,000 that involve the employment of mechanics or laborers must include a provision for compliance with 40 U.S.C. §§ 3702 and 3704, as supplemented by Department of Labor regulations at 29 C.F.R. Part 5. See 2 C.F.R. Part 200, Appendix II(E). Under 40 U.S.C. § 3702, each contractor must be required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than one and a half times the basic rate of pay for all hours worked in excess of 40 hours in the work week. Further, no laborer or mechanic must be required to work in surroundings or under working conditions which are unsanitary, hazardous, or dangerous.
- b. Applicability. This requirement applies to all FEMA contracts awarded by the nonfederal entity in excess of \$100,000 under grant and cooperative agreement programs that involve the employment of mechanics or laborers. It is applicable to construction work. These requirements do not apply to the purchase of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.
- c. <u>Suggested Language</u>. The regulation at 29 C.F.R. § 5.5(b) provides contract clause language concerning compliance with the Contract Work Hours and Safety Standards Act. FEMA suggests including the following contract clause:

# Compliance with the Contract Work Hours and Safety Standards Act.

(1) Overtime requirements. No contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of

laborers or mechanics shall require or permit any such laborer or mechanic in any workweek in which he or she is employed on such work to work in excess of forty hours in such workweek unless such laborer or mechanic receives compensation at a rate not less than one and one-half times the basic rate of pay for all hours worked in excess of forty hours in such workweek.

- (2) Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the clause set forth in paragraph (b)(1) of this section the contractor and any subcontractor responsible therefor shall be liable for the unpaid wages. In addition, such contractor and subcontractor shall be liable to the United States (in the case of work done under contract for the District of Columbia or a territory, to such District or to such territory), for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic, including watchmen and guards, employed in violation of the clause set forth in paragraph (b)(1) of this section, in the sum of \$27 for each calendar day on which such individual was required or permitted to work in excess of the standard workweek of forty hours without payment of the overtime wages required by the clause set forth in paragraph (b)(1) of this section.
- (3) Withholding for unpaid wages and liquidated damages. The (write in the name of the Federal agency or the loan or grant recipient) shall upon its own action or upon written request of an authorized representative of the Department of Labor withhold or cause to be withheld, from any moneys payable on account of work performed by the contractor or subcontractor under any such contract or any other Federal contract with the same prime contractor, or any other federally-assisted contract subject to the Contract Work Hours and Safety Standards Act, which is held by the same prime contractor, such sums as may be determined to be necessary to satisfy any liabilities of such contractor or subcontractor for unpaid wages and liquidated damages as provided in the clause set forth in paragraph (b)(2) of this section.
- (4) Subcontracts. The contractor or subcontractor shall insert in any subcontracts the clauses set forth in paragraph (b)(1) through (4) of this section and also a clause requiring the subcontractors to include these clauses in any lower tier subcontracts. The prime contractor shall be responsible for compliance by any subcontractor or lower tier subcontractor with the clauses set forth in paragraphs (b)(1) through (4) of this section.

# 7. RIGHTS TO INVENTIONS MADE UNDER A CONTRACT OR AGREEMENT

- a. Standard. If the FEMA award meets the definition of "funding agreement" under 37C.F.R. § 401.2(a) and the non-Federal entity wishes to enter into a contract with a small business firm or nonprofit organization regarding the substitution of parties, assignment or performance of experimental, developmental, or research work under that "funding agreement," the non-Federal entity must comply with the requirements of 37 C.F.R. Part 401 (Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements), and any implementing regulations issued by FEMA. See 2 C.F.R. Part 200, Appendix II(F).
- b. Applicability. This requirement applies to "funding agreements," but it DOES NOT apply to the Public Assistance, Hazard Mitigation Grant Program, Fire Management Assistance Grant Program, Crisis Counseling Assistance and Training Grant Program, Disaster Case Management Grant Program, and Federal Assistance to Individuals and Households – Other Needs Assistance Grant Program, as FEMA awards under these programs do not meet the definition of "funding agreement."
- c. Funding Agreements Definition. The regulation at 37 C.F.R. § 401.2(a) defines "funding agreement" as any contract, grant, or cooperative agreement entered into between any Federal agency, other than the Tennessee Valley Authority, and any contractor for the performance of experimental, developmental, or research work funded in whole or in part by the Federal government. This term also includes any assignment, substitution of parties, or subcontract of any type entered into for the performance of experimental, developmental, or research work under a funding agreement as defined in the first sentence of this paragraph.

## 8. CLEAN AIR ACT AND THE FEDERAL WATER POLLUTION CONTROL ACT

a. <u>Standard</u>. If applicable, contracts must contain a provision that requires the contractor to agree to comply with all applicable standards, orders, or regulations issued pursuant to the Clean Air Act (42 U.S.C. §§ 7401-7671q.) and the Federal Water Pollution Control Act as amended (33 U.S.C. §§ 1251-1387). Violations must be reported to FEMA and the Regional Office of the Environmental Protection Agency. <u>See</u> 2 C.F.R. Part 200, Appendix II(G).

- b. <u>Applicability</u>. This requirement applies to contracts awarded by a non-federal entity of amounts in excess of \$150,000 under a federal grant.
- c. Suggested Language. The following provides a sample contract clause.

#### Clean Air Act

- The contractor agrees to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act, as amended, 42 U.S.C. § 7401 et seq.
- The contractor agrees to report each violation to the (name of applicant entering into the contract) and understands and agrees that the (name of the applicant entering into the contract) will, in turn, report each violation as required to assure notification to the Federal Emergency Management Agency, and the appropriate Environmental Protection Agency Regional Office.
- The contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

## Federal Water Pollution Control Act

- The contractor agrees to comply with all applicable standards, orders, or regulations issued pursuant to the Federal Water Pollution Control Act, as amended, 33 U.S.C. 1251 et seq.
- The contractor agrees to report each violation to the (name of the applicant entering into the contract) and understands and agrees that the (name of the applicant entering into the contract) will, in turn, report each violation as required to assure notification to the Federal Emergency Management Agency, and the appropriate Environmental Protection Agency Regional Office.
- The contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

## 9. DEBARMENT AND SUSPENSION

- a. <u>Standard</u>. Non-Federal entities and contractors are subject to the debarment and suspension regulations implementing Executive Order 12549, *Debarment and Suspension* (1986) and Executive Order 12689, *Debarment and Suspension* (1989) at 2 C.F.R. Part 180 and the Department of Homeland Security's regulations at 2 C.F.R. Part 3000 (Nonprocurement Debarment and Suspension).
- Applicability. This requirement applies to all FEMA grant and cooperative agreement programs.

#### c. Requirements.

- i. These regulations restrict awards, subawards, and contracts with certain parties that are debarred, suspended, or otherwise excluded from or ineligible for participation in Federal assistance programs and activities. See 2 C.F.R. Part 200, Appendix II(H); and 2 C.F.R. § 200.213. A contract award must not be made to parties listed in the SAM Exclusions. SAM Exclusions is the list maintained by the General Services Administration that contains the names of parties debarred, suspended, or otherwise excluded by agencies, as well as parties declared ineligible under , statutory or regulatory authority other than Executive Order 12549. SAM exclusions can be accessed at <a href="https://www.sam.gov.">www.sam.gov.</a>. See 2 C.F.R. § 180.530.
- ii. In general, an "excluded" party cannot receive a Federal grant award or a contract within the meaning of a "covered transaction," to include subawards and subcontracts. This includes parties that receive Federal funding indirectly, such as contractors to recipients and subrecipients. The key to the exclusion is whether there is a "covered transaction," which is any nonprocurement transaction (unless excepted) at either a "primary" or "secondary" tier. Although "covered transactions" do not include contracts awarded by the Federal Government for purposes of the nonprocurement common rule and DHS's implementing regulations, it does include some contracts awarded by recipients and subrecipients.
- iii. Specifically, a covered transaction includes the following contracts for goods or services:
  - The contract is awarded by a recipient or subrecipient in the amount of at least \$25,000.
  - 2. The contract requires the approval of FEMA, regardless of amount.

- 3. The contract is for federally-required audit services.
- A subcontract is also a covered transaction if it is awarded by the contractor of a recipient or subrecipient and requires either the approval of FEMA or is in excess of \$25,000.
- d. <u>Suggested Language</u>. The following provides a debarment and suspension clause. It incorporates an optional method of verifying that contractors are not excluded or disqualified.

## Suspension and Debarment

- (1) This contract is a covered transaction for purposes of 2 C.F.R. pt. 180 and 2 C.F.R. pt. 3000. As such, the contractor is required to verify that none of the contractor's principals (defined at 2 C.F.R. § 180.995) or its affiliates (defined at 2 C.F.R. § 180.905) are excluded (defined at 2 C.F.R. § 180.940) or disqualified (defined at 2 C.F.R. § 180.935).
- (2) The contractor must comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, and must include a requirement to comply with these regulations in any lower tier covered transaction it enters into.
- (3) This certification is a material representation of fact relied upon by (insert name of recipient/subrecipient/applicant). If it is later determined that the contractor did not comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, in addition to remedies available to (insert name of recipient/subrecipient/applicant), the Federal Government may pursue available remedies, including but not limited to suspension and/or debarment.
- (4) The bidder or proposer agrees to comply with the requirements of 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C while this offer is valid and throughout the period of any contract that may arise from this offer. The bidder or proposer further agrees to include a provision requiring such compliance in its lower tier covered transactions.

## 10. PROCUREMENT OF RECOVERED MATERIALS

a. <u>Standard</u>. A non-Federal entity that is a state agency or agency of a political subdivision of a state and its contractors must comply with Section 6002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act. <u>See</u> 2 C.F.R. Part 200, Appendix II(J); and 2 C.F.R. § 200.322.

- Applicability. This requirement applies to all contracts awarded by a nonfederal entity under FEMA grant and cooperative agreement programs.
- c. Requirements. The requirements of Section 6002 include procuring only items designated in guidelines of the EPA at 40 C.F.R. Part 247 that contain the highest percentage of recovered materials practicable, consistent with maintaining a satisfactory level of competition, where the purchase price of the item exceeds \$10,000 or the value of the quantity acquired by the preceding fiscal year exceeded \$10,000; procuring solid waste management services in a manner that maximizes energy and resource recovery; and establishing an affirmative procurement program for procurement of recovered materials identified in the EPA guidelines.

## d. Suggested Language.

- In the performance of this contract, the Contractor shall make maximum use of products containing recovered materials that are EPA-designated items unless the product cannot be acquired—
  - Competitively within a timeframe providing for compliance with the contract performance schedule;
     Meeting contract performance requirements; or
     At a reasonable price.
- ii. Information about this requirement, along with the list of EPAdesignated items, is available at EPA's Comprehensive Procurement Guidelines web site, <a href="https://www.epa.gov/smm/comprehensive-procurement-guideline-cpg-program">https://www.epa.gov/smm/comprehensive-procurement-guideline-cpg-program</a>.
- iii. The Contractor also agrees to comply with all other applicable requirements of Section 6002 of the Solid Waste Disposal Act."

The Contractor, McKinsey & Company, Inc. Washington, D.C., certifies or affirms the truthfulness and accuracy of each statement of its certification and disclosure, if any.

garal Tucker Pay	
Signature of Contractor'	s Authorized Official
Sarah Tucker-Ray, Partner	
Name and Title of Contra	actor's Authorized Official
April 11, 2020	
Date	

# 11. BYRD ANTI-LOBBYING AMENDMENT

a. Standard. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, officer or employee of Congress, or an employee of a Member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. § 1352. FEMA's regulation at 44 C.F.R. Part 18 implements the requirements of 31 U.S.C. § 1352 and provides, in Appendix A to Part 18, a copy of the certification that is required to be completed by each entity as described in 31 U.S.C. § 1352. Each tier must also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any

Federal award. Such disclosures are forwarded from tier to tier up to the Federal awarding agency.

b. <u>Applicability</u>. This requirement applies to all FEMA grant and cooperative agreement programs. Contractors that apply or bid for a contract of \$100,000 or more under a federal grant must file the required certification. <u>See</u> 2 C.F.R. Part 200, Appendix II(I); 31 U.S.C. § 1352; and 44 C.F.R. Part 18.

## c. Suggested Language.

# Byrd Anti-Lobbying Amendment, 31 U.S.C. § 1352 (as amended)

Contractors who apply or bid for an award of \$100,000 or more shall file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, officer or employee of Congress, or an employee of a Member of Congress in connection with obtaining any Federal contract, grant, or any other award covered by 31 U.S.C. § 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient who in turn will forward the certification(s) to the awarding agency.

d. Required Certification. If applicable, contractors must sign and submit to the non-federal entity the following certification.

# APPENDIX A, 44 C.F.R. PART 18 - CERTIFICATION REGARDING LOBBYING

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

- 1. No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
- 2. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

The Contractor, McKinsey & Company, Inc. Washington, D.C., certifies or affirms the truthfulness and accuracy of each statement of its certification and disclosure, if any. In addition, the Contractor understands and agrees that the provisions of 31 U.S.C. Chap. 38, Administrative Remedies for False Claims and Statements, apply to this certification and disclosure, if any.

Signature of Contractor's Authorized Official

Sarah Tucker-Ray, Partner

garal Viker Fay

Name and Title of Contractor's Authorized Official

April 11, 2020

Date

# Supporting response to the COVID-19 crisis for the Commonwealth of Virginia

#### **OUR UNDERSTANDING OF THE SITUATION**

COVID-19 is a humanitarian challenge that has affected communities across multiple continents, with significant loss of life around the world. Solving the humanitarian challenge is the top priority, and much remains to be done globally to prepare, respond, and recover, from protecting populations at risk, to supporting affected communities, to developing a vaccine.

The Commonwealth of Virginia (the Commonwealth) is already facing statewide challenges, both in terms of mitigating short-term harm and planning for longer-term recovery, across health, economy, state finances, and social services, among many other dimensions.

As part of its broader crisis response effort, the Commonwealth is seeking to rapidly develop and implement a plan to address the risk of critical shortages in health system capacity, specifically personal protective equipment (PPE). Likely shortages of PPE are nationwide and global problems, the result of disrupted global supply chains, surges in demand from countries that experienced the virus early, increasing COVID-19 caseloads in the US, and many other factors.

States and cities that are best managing their health system capacity are pursuing a concerted effort to do all actions possible to manage demand, increase supply, predict likely capacity shortages, provide transparency through data across the supply chain, and coordinate stakeholders.

This memorandum summarizes our proposed approach for the Commonwealth to mobilize rapidly to do all possible to maximize supply and manage demand of PPE across three weeks.

Acknowledging that conditions are rapidly changing, we will work with Commonwealth leaders to adjust course and maintain flexible in our approach during the three-week period to ensure impact.

#### **OUR APPROACH**

Based on our discussions and understanding of the situation, we outline an approach across three weeks to help Virginia pursue all action possible to close supply and demand gaps for PPE:

- Estimate current health system capacity gaps, grounded in current data and scenarios for progression of the virus in Virginia:
  - Model scenarios of progression. Help the State understand scenarios of progression of the virus using epidemiological models and real-time

data on cases identified. Example output shown below. Estimate share of cases in need of different tiers of treatment.

Analysis as of 3/28/2020





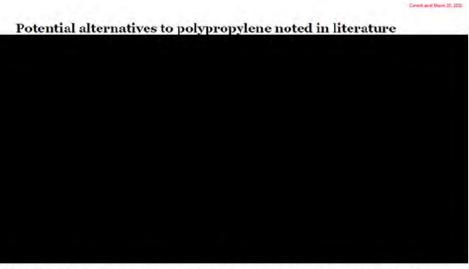
- Gather data on the current capacity of the health system. Build a
  perspective grounded in multiple data sources on the existing supply of
  PPE but also beds, health care workers, and other equipment across
  Virginia, down to the county level.
- Estimate likely capacity gaps. Translate epidemiological scenarios and expected disease burden to necessary inpatient bed capacity, and corresponding demands for workforce, supplies, (PPE, ventilators, etc.), and other assets over the time horizon of the pandemic. Identify gaps state-wide and at the county level, in the short term, but also taking into account the possibility of a resurgence in a global location, and a second peak in Virginia in later 2020.
- Identify approaches to increase PPE capacity across supply and demand:
  - Define the full suite of supply and demand levers that can best increase PPE capacity. Examples include:
    - Conserve and Preserve: communication of clear guidelines and engagement with primary users, e.g., reuse, care team guidelines on critical staff needed, sanitization process (all would need to be tested and validated with local and federal regulations). Other demand-side levers include breaking down the activities for which PPE is required, including testing, and considering alternatives. Estimate of impact for overall US demand by implementing strict conservation and preservation methods is shown below, compared to demand for N95 respirator masks.

Significant gap exists between estimated supply and demand in key supplies used to treat COVID-19 patients, including N-95 respirators

- Un-stick and unleash existing manufacturing base (and ability for goods to reach frontline workers): define existing manufacturing base for Virginia and assess potential to increase production, explore potential to increase speed-to-market, collaborate with sites to take necessary action. Identify key risks (e.g., financial, COVID exposure) and support them in mitigating actions;
- Expand the manufacturing base (and ability for goods to reach frontline workers) within Virginia but also to explore other international sources of production: identify potential candidates for production, understand challenges, assess logistics options (e.g., air freight vs. container ship), support expansion. Engage with Virginia local businesses where possible to explore expansion opportunities in line with broader economic recovery goals for the State. This includes
- Re-route goods stuck within existing supply chains at non-healthcare end customers, toward healthcare frontline workers: identify primary non-health care users and estimate size of stock. A catalog that tracks the of gloves, face shields, surgical masks, N95 masks, eye protection, gowns, scrubs across non-health care industries can help to prioritize this outreach (industries included as primary consumers of PPE include). Example from such a catalog is shown below.



Develop alternate specifications and designs. Develop alternate specs and designs using current or alternate material that meets performance and regulatory requirements. An example of alternatives to a main respirator component are shown below, gathered from publiclyavailable sources (note that each of these would need to be tested and validated by scientific professionals);



- Estimate the potential capacity unlocked from each lever. Build an integrated perspective on the highest-value unlocks for Virginia to help prioritize activity.
- Rigorously manage execution of an integrated program to capture the opportunity to meet capacity:
  - Build and operate a "project management function" to track capacity unlocked by lever and coordinate across government.
     Activities include daily stand-up meetings to track progress, coordination across agencies to ensure follow through, and use of management

dashboards to monitor data. Provide leadership coordination, project management support, and engagement with government agency partners.

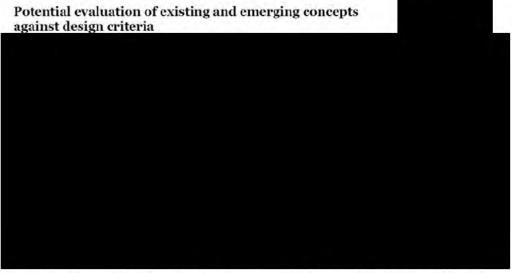
Define potential actions the State can take itself. Example actions include:

;
·
Communications to health system providers, e.g.,
Example of a clinical workflow adjustment and effect on PPE usage is shown below.

Current as of March 27, 202

If determined appropriate, transitioning IV poles outside of patient rooms could lead to reductions in daily patient interactions and use of PPE

- Funding, e.g., challenge grants, direct support for PPE sanitization process to be deployed to provider sites (through UV or heat decontamination or Ethylene Oxide sterilization), investment into new designs and materials;
- Visibility into near-real time supply and demand to allow for the market to shift resources to "hot spots";
- a A supply from non-health care end customers;
- Open-source sharing of alternate designs, e.g., 3D printing. See below for example emerging concept evaluation for masks;



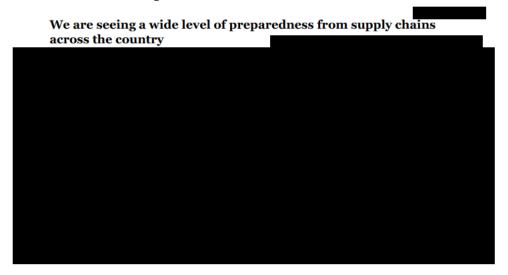
- Identification of foreign stock and pursuit of expedited international shipping;
- Support for logistics to match supply and demand.
- Build an approach to coordinate with stakeholders in the public, private, and nonprofit sectors to increase supply and manage demand. Identify approach to engage with Virginia businesses, especially those affected by COVID-19, and how they could support capacity unlocks.

## Provide supply chain and logistics insights and best practices:

Monitor traditional supply chain for Virginia health system and for US
health system and provide insights into availability over time. For
example, experts are tracking availability of critical supplies, of which PPE
is one category – see exhibit below.



 Engage supply chain participants to monitor sentiment and gather latest information. Engage with logistics companies to understand conditions in the market. Examples from research conducted to date are below.



■ An optional phase two could include support to identify Virginiabased firms positioned in the mid- and long-term to become part of the PPE supply chain, and defining the actions needed to activate those firms.

#### POTENTIAL IMPACT FROM THIS APPROACH

If the Commonwealth were to pursue an approach as outlined above, potential impact could include: the identification and coordination of new supply sources; reductions in demand that meaningfully conserve PPE for the most urgent uses; new actions taken by the State that unlock alternative sources, alternative materials, or other innovations; a clear coordination and stakeholder engagement approach to make sure the State benefits from private sector offers to help, e.g., via PPE donations; and a project management function inside of government able to continue to monitor and improve capacity of PPE.

Our experience working with other states, the federal government, and health systems in managing shortages in health system capacity generally and in PPE in particular show impact is possible, e.g., in one state, our work helped

. In one state, we helped

. We have also helped implement workflow changes in health care delivery systems that reduce demand and have helped other states ensure distribution of PPE to the highest areas of need. While the details of our work for each client is confidential, we are happy to discuss additional examples of impact.

#### **OUR CAPABILITIES**

As a partner to public, private, and social sector organizations across the globe, McKinsey & Company (McKinsey) has quickly mobilized teams now serving several US states, US federal government and international governments, hospital systems, nonprofits, and leading private sector organizations on their responses to the COVID-19 crisis. McKinsey's global experience supporting organizations through past pandemics, including SARS and MERS, as well as supporting state and local governments in response to past natural disasters provide us with expertise in supporting governments during crises. We have supported logistics activities in the wake of the 2010 Haiti earthquake, state governments in mitigating the impact of Hurricane Sandy in 2012, national governments during the Ebola outbreak in 2016, including health system capacity modeling, and supply chain and logistics support.

and a dedicated, full-time team made up of and and a dedicated.

Our core team would be made up of

Our team will be
. We have identified experts in
to support the
Commonwealth. We will also draw on our team for
the US Public Sector and a team, plus numerous
colleagues who are experts in elements of the health system response to COVID-
19, including
. We are a global firm and bring learnings from our colleagues'
experience in countries that experienced the crisis earlier. We also have dedicated
COVID-19 response teams by sector (e.g.,
), who offer insight into
$\cdot$
Finally, our team also brings the Commonwealth proprietary knowledge
and tools that help our clients solve problems more
support for new solutions and that it is a research team that
to answer clients' questions about issues such as
; and a Team.
For any additional or any entional scene, we will review the scene of the
For any additional or any optional scope, we will review the scope of the expected services and work in good faith to agree on an applicable price for
the additional services.

#### **TEAM TRAVEL CONSIDERATIONS GIVEN COVID-19**

During the COVID-19 pandemic, McKinsey is focused on keeping our clients and our teams safe, while continuing to offer the high quality of service and support our clients have come to know and expect. In order to do this, we have suspended all but essential travel for our teams and have asked teams to work remotely. Our teams are following local guidelines and are expected to adhere to restrictions imposed in home areas. We bring a full suite of digital collaboration and communication tools we can use in conjunction with the Commonwealth's own systems and norms. We can discuss potential exceptions to this approach if there is critical need.

#### **DISCLAIMER**

The information included in this white paper will not contain, nor are they for the purpose of constituting, policy advice. We emphasize that statements of expectation, forecasts, and projections relate to future events and are based on assumptions that may not remain valid for the whole of the relevant period. Consequently, they cannot be relied upon, and we express no opinion as to how closely the actual results achieved will correspond to any statements of expectation, forecasts or projections.

JEFFREY D. STERN, Ph.D. State Coordinator

CURTIS C. BROWN Chief Deputy State Coordinator/ Chief Diversity and Inclusion Officer



JOHN NORTHON
Deputy State Coordinator – Disaster Services

ANDRES ALVAREZ
Deputy State Coordinator – Mission Support

## **COMMONWEALTH OF VIRGINIA**

## Department of Emergency Management

9711 Farrar Court, Suite 200 North Chesterfield, Virginia 23236 TEL 804.267.7600 TDD 804.674.2417 FAX 804.272.2046

#### CONTRACT MODIFICATION AGREEMENT

Date:

April 24, 2020

Contract #:

VDEM-EM2020-0008

Modification #:

1

Issued By:

Commonwealth of Virginia

Virginia Department of Emergency Management

9711 Farrar Court, Suite 200 North Chesterfield, VA 23236

Contractor:

McKinsey & Company, Inc. Washington, D.C.

1200 19<sup>th</sup> Street, N.W. Suite 1000 Washington, D.C. 20036-2412

Commodity:

91800 - Consulting Services

This Supplemental Agreement is entered into pursuant to the provision of the basic contract.

This modification is to modify the current contract to extend the current period of performance beginning April 25, 2020 – May 1, 2020.

This modification includes additional services per section 2.0 Week 4 Scope of Work provided in the McKinsey & Company, Inc. Washington D.C. proposal dated April 24, 2020.

Except for the changes provided herein, all other terms and conditions of this contract remain unchanged and in full force and effect.

CONTRACTOR: McKinsey &

Company, Inc. Washington D.C.

By: Sarah Voker for

Sarah Tucker-Ray, Partner

April 24, 2020

Name and Title (Type or Print)

Date Signed

AGENCY: VIRGINIA DEPARTMENT OF

**EMERGENCY MANAGEMENT** 

Name and Title (Type or Print)

Date Signed

JEFFREY D. STERN, Ph.D. State Coordinator

CURTIS C. BROWN
Chief Deputy State Coordinator/
Chief Diversity and Inclusion Officer



JOHN NORTHON
Deputy State Coordinator – Disaster Services

ANDRES ALVAREZ Deputy State Coordinator – Mission Support

# **COMMONWEALTH OF VIRGINIA**

Department of Emergency Management

9711 Farrar Court, Suite 200 North Chesterfield, Virginia 23236 TEL 804.267.7600 TDD 804.674.2417 FAX 804.272.2046

This page is intentionally left blank

McKinsey & Company

Commonwealth of Virginia,

Virginia Department of Emergency Management

COVID-19

REVISED Proposal to VDEM-EM2020-0008 Contract Submitted: April 24, 2020

Proposed By:

McKinsey & Company, Inc. Washington D.C.

Sarah Tucker-Ray, Partner

1200 19th Street NW, Suite 1000

Washington, DC 20036

Submitted to:

Heather T. Payne, VCM, VCO, VCA

Director of Procurement - Mission Support Bureau

Virginia Department of Emergency Management

9711 Farrar Court, Suite 200 North Chesterfield, VA 23236



April 24, 2020

Table of Conte	nts
----------------	-----

1.0	MCKINSEY'S COVID-19 PRICING APPROACH	. 1
2.0	WEEK 4 SCOPE - VDEM-EM2020-0008 CONTRACT	. 1
3.0	COVID-SPECIFIC TEAM-BASED CLIENT SERVICE MODEL	. 2
4.0	PRICE QUOTE	4
5.0	ASSUMPTIONS	. 5
	Table of Exhibits	
Exhibi	it 1: McKinsey's COVID-19 Client Service Model	. 2
Exhibi	it 2: McKinsey's Basis of Estimate and Price Quote	4

April 24, 2020

#### 1.0 MCKINSEY'S COVID-19 PRICING APPROACH

These are extraordinary, unprecedented times across the world and we recognize that governments, citizens, and businesses are all in uncharted territory. Government organizations and agencies are being asked to respond quickly and efficiently to multiple topics (e.g., healthcare, supply chain management, service operations, economic stability/recovery, and employment). We view Government organizations and agencies as critical drivers and central stabilizers to society's ability to respond and recover.

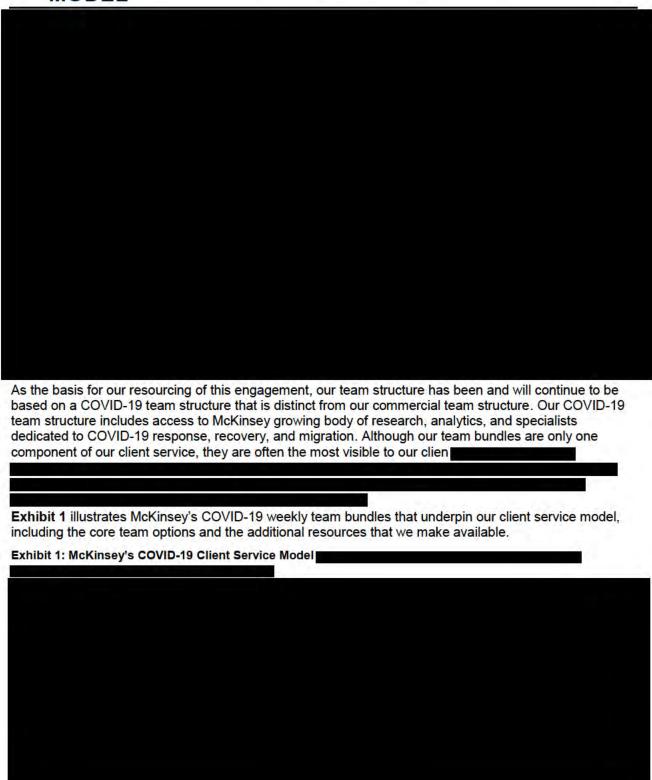
In recognition of this critical time, we have developed new philanthropic prices for all U.S. public sector work directly related to the response to, and recovery from, COVID. This applies only to COVID-specific work and is not applicable for scopes of work that do not directly relate to COVID. For this engagement, we are submitting this revised proposal to offer the Commonwealth of Virginia, Virginia Department of Emergency Management (VDEM) our COVID-only team bundle structure retroactively under VDEM-EM2020-0008 Contract, which includes focused research, analytics, and content specialists dedicated to the COVID response, recovery, and mitigation. Additionally, at VDEM's request, McKinsey will be providing an additional week of support – extending the period of performance of the VDEM-EM2020-0008 Contract from three to four weeks. The scope of work to be performed in the final week four of VDEM-EM2020-0008 Contract is outlined in below in Section 2.0.

## 2.0 WEEK 4 SCOPE - VDEM-EM2020-0008 CONTRACT

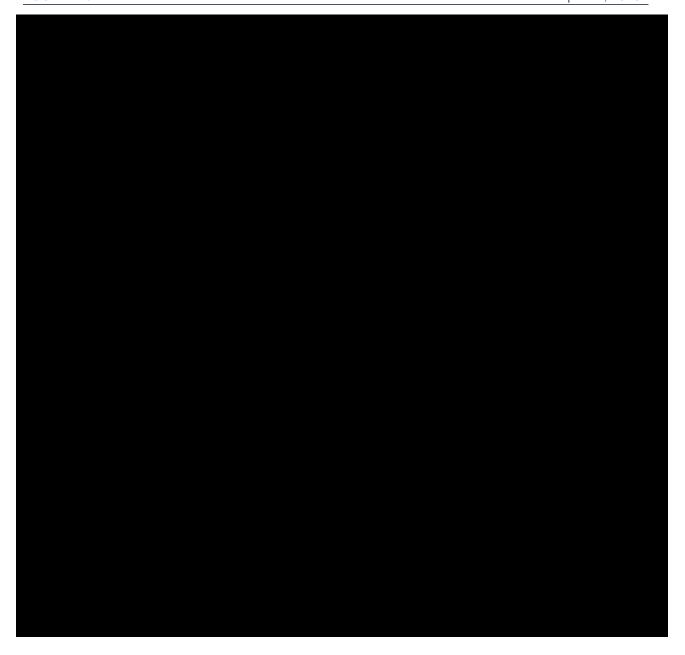
In addition to the previously confirmed scope on VDEM-EM2020-0008 Contract, VDEM has requested that the McKinsey team undertake the following activities as part of the Firm's investment to support State Government's on COVID topics through a reduction in our standard pricing applied retroactively on our initial price proposal. The additional scope of work to be completed are as follows:

•	Provide additional support to operationalize additional interventions to unlock PPE supplies. Specifically, (i) PPE retooling playbook; (ii) support VEDP/Genedge with (iii) handover suppliers database prioritization methodology
•	<b>Develop a methodology for, and size state-wide PPE requirements</b> (beyond public health system requirements) under a reopen scenario, and options on the role of the state to ensure availability
	Design and build analytical dashboards for future decision-making. (i) Leading economic dashboard – includes indicators at a state and county-level to triangulate and and as a way to track progress over time

# 3.0 COVID-SPECIFIC TEAM-BASED CLIENT SERVICE MODEL



COVID-19 April 24, 2020



COVID-19 April 24, 2020

### 4.0 PRICE QUOTE

McKinsey recognizes the gravity of the COVID-19 pandemic and is submitting this revised proposal to update the total price in McKinsey's VDEM-EM2020-0008 Contract to reflect our COVID-specific pricing. The proposed price of \$573,680 covers the current scope of work within the VDEM-EM2020-0008 Contract and that which is proposed in Section 2.0 of this proposal.

Our COVID-19 specific pricing demonstrates McKinsey's commitment with supporting public sector leaders using the full weight of our global resources. This revised price is offered on a Firm-Fixed-Price basis and is inclusive of all costs, including but not limited to wages, overhead, general and administrative expenses, and materials.

Exhibit 2: McKinsey's Basis of Estimate and Price Quote.

	TOTAL FFP	\$573,680
		· ' /

April 24, 2020

## 5.0 ASSUMPTIONS

McKinsey's approach to providing the services in VDEM-EM2020-0008 Contract and those proposed hereunder (the "Services") and the updated corresponding price are based on the following assumptions:

