

**Attachment D**  
**Federal Fiscal Year 2012**  
**9<sup>th</sup> Year Grant - ASPR**  
**Department of Health and Human Services**  
**HHS Guidelines on Federal and State Stockpiles**  
**of Critical Medical Supplies for an Influenza Pandemic**

The following recommendations were developed by HHS in the *HHS Guidelines on Federal and State Stockpiles of Critical Medical Supplies for an Influenza Pandemic* and are divided into three sections: Ventilator and Ancillary Supply List, PPE and Infection Control Supplies for healthcare delivery sites and general work sites, and PPE and Infection Control Supplies for mortuary services. The ventilator section establishes qualitative criteria that are critical, and includes beneficial options. The list of ventilator characteristics does not include oxygen sources. The availability and necessity of supplemental oxygen should be considered in planning efforts. There are no quantitative recommendations for ventilator units in the recommendations. The supply section does include recommendations on supply types and quantities. Hospitals should also address plans for storage, maintenance and distribution of these resources.

Articles that are intended for use in the prevention, treatment, mitigation, or cure of disease, including the ventilators and personal protective equipment and infection control supplies described below, are subject to regulation under the Federal Food, Drug, and Cosmetic Act (FFDCA). We recommend that hospitals procure products that have met applicable FDA pre-market review requirements (e.g., approval or clearance). Distribution of devices or drugs that are not FDA-cleared or –approved, or are FDA-cleared or approved for a different use or population, requires obtaining an Emergency Use Authorization (EUA) or other action to comply with the FFDCA.

## I. Ventilator and Ancillary Supply List

VENTILATOR CRITERIA	IDEAL CHARACTERISTICS	BENEFICIAL, OPTIONAL CHARACTERISTICS	COMMENTS
<b>Operating Characteristics</b>			
1. Power source	1. AC with battery back-up and ability to run w/o gas source 2. Battery duration should be at least 4 hours duration	Pneumatic-operable (must also have a sustained battery option)	<ul style="list-style-type: none"> <li>▪ Must define standard operating settings for battery time</li> <li>▪ Ventilator with only Pneumatic-operability does not have sufficient power source, must also have battery option</li> </ul>
2. FDA-cleared or approved for use in pediatric populations	10 kg	5 kg	Availability of ventilators that would be used on neonate/infant population needs to be assessed on the local level
3. Modes of ventilation	Volume control (assist/control and SIMV)	Pressure control (only in addition to volume control) CPAP (for weaning)	Simplicity is key
4. Control of settings	Respiratory Rate PEEP V <sub>T</sub> Flow or Inspiratory:Expiratory ratio FiO <sub>2</sub> (on 50-55 PSI source O <sub>2</sub> )	Trigger sensitivity and mode of ventilation (if available)  Flow waveform	
5. Maximum flow	Minimum of $\leq$ 10 L/min  Upper limit $\geq$ 70 L/min		

6. Positive End Expiratory Pressure (PEEP)	Internal PEEP PEEP compensation	PEEP upper limit $\geq 20$ cm H <sub>2</sub> O	
7. Oxygen titration	Room air to FiO <sub>2</sub> 1.0 on 50-55psi oxygen source		
8. Operate w/o 50-55 psi oxygen source	Yes	FiO <sub>2</sub> $\geq 0.7$ on low flow oxygen and V <sub>E</sub>	<ul style="list-style-type: none"> <li>▪ Must be able to operate on oxygen concentrator or low flow compressed oxygen source</li> <li>▪ Standard settings for testing oxygen delivery on low flow oxygen source</li> </ul>
9. Measurements	Measure and display inspiratory V <sub>T</sub>	<ol style="list-style-type: none"> <li>1. Inspiratory plateau pressure</li> <li>2. Auto PEEP</li> <li>3. Expired V<sub>T</sub></li> </ol>	
<b>Performance</b>			
1. Ease to set up/set ventilation settings/trouble shoot	<ol style="list-style-type: none"> <li>1. Ability to read screen at a distance</li> <li>2. Clear, easily understood, in plain language instructions in both hard copy and electronically (internet and stored within ventilator) is recommended. Expert users may not be available in sufficient numbers. Novice users will need to be able to work with the ventilators without additional help.</li> </ol>	<ol style="list-style-type: none"> <li>1. Color coding of connections</li> <li>2. Unique connections for equipment with specific functions</li> <li>3. Laminated quick reference/troubleshooting guide</li> </ol>	Must develop standard criteria for evaluating ease to read screen

2. Oxygen consumption		Minimization of oxygen consumption for standard settings	2 standard ventilator settings to empty a full E-cylinder
3. Sustained use	Reference contacts for $\geq 3$ clinical settings where equipment used $\geq 2$ weeks continuously	Reference contacts for $\geq 3$ clinical settings where equipment used $\geq 4$ weeks continuously	
<b>Safety</b>			
1. Alarms	Audible and visible alarms -disconnect, apnea, high pressure, low source gas pressure	1. Remote alarm interface 2. Visible alarm remains lit until reset by operator	Visual alarm must be easily visible at defined-distance and ambient lighting conditions
<b>Stockpiling Issues</b>			
1. Ventilator has FDA clearance (510(k)) or approval for use in desired population	1. Fluid spill resistance 2. Mechanical shock (similar to 4 foot drop, military standard) 3. Mechanical vibration 4. EMC and electrical safety testing 5. Storage temperature and humidity: • -20 C to 60 C, 0 - 95% RH 6. Operating temperature and humidity: • 5 C to 40 C, 0 - 95% RH		

2. Vendor & support contract	<ol style="list-style-type: none"> <li>1. Company will continue to produce ventilator model until at least 2012</li> <li>2. Ability to produce all ordered vents within 6 months from order. If unable to meet this criterion, estimated time frame for delivery must be stated.</li> <li>3. 24 hours/7 days a week direct phone access to senior-level technician <ul style="list-style-type: none"> <li>▪ Vendor responsible for maintaining call coverage</li> </ul> </li> <li>4. Warranty</li> <li>5. Provide any storage life data if available</li> </ol>	<ol style="list-style-type: none"> <li>1. Warranty period starts at first beneficial contact with patient</li> <li>2. Components for additional purchased vents available in the United States at all times</li> </ol>	
3. Maintenance	$\geq 1$ year for battery and all equipment interval maintenance also include battery replacement if needed	<ol style="list-style-type: none"> <li>1. All usual maintenance activities can be performed with ventilator in kit</li> <li>2. All usual maintenance activities can be performed with kits in stockpiled configuration</li> </ol>	
4. Purchasing costs	$\leq$ \$10,000		Cost must include all necessary equipment to ventilate one patient on both 50-55 psi and low flow oxygen
5. End-user training program	<ol style="list-style-type: none"> <li>1. Internet based training</li> <li>2. DVD/CD</li> </ol>	Interactive training via internet or DVD	Must demonstrate educational format at time of RFI submission

VENTILATOR ANCILLARY EQUIPMENT	RECOMMENDED QUANTITIES	BENEFICIAL, OPTIONAL CHARACTERISTICS	COMMENTS
<b>Airway</b>			
Endotracheal tubes	None		Stockpile needs at the local level need to be assessed. Sufficient quantities may already be available
Manual ventilator	None		Stockpile needs at the local level need to be assessed. Sufficient quantities may already be available
Non-invasive ventilation patient interfaces (masks)	None		Non-invasive interfaces may have role in mass casualty respiratory failure, but recommend endotracheal intubation/tracheotomy for most patients
<b>Circuit-Related</b>			
Ventilator circuits	1 adult and pediatric circuit per <u>kitted</u> ventilator  Additional equipment for re-supply kits to be held in inventory: 4 adult circuits per ventilator 2 pediatric circuits per ventilator		1 Re-supply kit per 10 ventilator kits  Incorporate consideration for replacement parts when damage or contaminated.
Closed circuit suction catheters	1 per ventilator circuit		Adult 14Fr Pediatrics 8Fr & 12Fr

VENTILATOR ANCILLARY EQUIPMENT	RECOMMENDED QUANTITIES	BENEFICIAL, OPTIONAL CHARACTERISTICS	COMMENTS
			May want to consider a higher ratio of catheters to ventilators if funding is available to address potential catheter malfunction etc
Humidification and filtration	HMEF: 3 per adult circuit 3 per pediatric circuit  Re-supply: 3 per circuit (adult and pediatric)		<ul style="list-style-type: none"> <li>▪ Recommend: Absolute humidity <math>\geq 30</math> mg/L at tidal volume of 500mL. dead space &lt; 75 mL</li> <li>▪ Dead space for peds &lt;20mL</li> <li>▪ Wanted inspiratory limb HME and expiratory filter, but concern may be incorrectly put in circuit, so recommend HMEF</li> <li>▪ Filtration recommended for staff safety but acknowledge no convincing effectiveness demonstrated</li> <li>▪ Active humidification may be necessary for some patients but will not be stockpiled. May impact duration of filter use.</li> </ul>
Medication delivery	MDI adapter, 1 per circuit  Re-supply: 1 per circuit		

VENTILATOR ANCILLARY EQUIPMENT	RECOMMENDED QUANTITIES	BENEFICIAL, OPTIONAL CHARACTERISTICS	COMMENTS
<b>Kits</b>			
Kit	Rigid case  Weight of kit with ventilator and all equipment to ventilate one pt ≤ 30 lbs	Weight ranges: Under 15 lbs Under 20 lbs Under 25 lbs  Wheels provided on kit	Lower ventilator weight facilitates portability in the event patient transport is needed.
<b>Oxygen</b>			
Oxygen: Concentrators	No	No	Oxygen supply is crucial issue, but concentrators are limited solution due to expense and would significantly reduce ventilator quantity States/local need alternative oxygen solution
<b>Respiratory Monitoring</b>			
End tidal CO <sub>2</sub>			Not essential except for calorimetric devices already in SNS for endotracheal tube anatomical confirmation
Point of care blood gas analysis			Not essential
Pulse Oximetry	1. All patient with at least one disposable probe; one probe per ventilator circuit 2. One portable oximeter for at most 6 patients	Inclusion within mechanical ventilator housing	Goal is continuous oxygen saturation monitoring

## Abbreviations

SIMV Synchronized Intermittent Mandatory Ventilation(S)

CPAP Continuous Positive Airway Pressure

O<sub>2</sub> Oxygen

PEEP Positive End Expiratory Pressure

V<sub>T</sub> Tidal Volume

PSI Pounds per Square Inch

FiO<sub>2</sub> Fraction of Inspired Oxygen

H<sub>2</sub>O Water

V<sub>E</sub> Minute Ventilation

RH Relative Humidity

RFI Request For Information

HMEF Heat and Moisture Exchangers with Filter

HME Heat and Moisture Exchangers

MDI Meter Dose Inhaler

CO<sub>2</sub> Carbon Dioxide

## II. Personal Protective Equipment and Infection Control Supplies for Healthcare Delivery and General Sites

PRODUCT	QUANTITIES	COMMENTS
Healthcare Delivery Sites		

PRODUCT	QUANTITIES	COMMENTS
Alcohol hand hygiene gel	Calculate ~10ml per patient interaction.	<p>Quantities should be sufficient for all personnel engaged in healthcare delivery and for all individuals (e.g., patients, accompanying family members – consider children accompanied by parents) to use while receiving care. This is why the total amount per patient interaction is 10 ml, rather than 2 ml for just a single healthcare provider.</p> <p>Signage in appropriate languages directing personnel and patients to follow hand and respiratory hygiene practices, laminated hardcopies plus PDF files for reproduction on site should be considered.</p>
Disposable or reusable full-face shields for splash protection	Calculate for use by ~10% of clinical care staff who may perform splash-generating procedures.	
Surgical masks	Calculate for all patients with confirmed or suspected pandemic influenza to wear during patient care, if needed, plus 5/day for all personnel not engaged in face-to-face care of the above specified patients.	<p>Please refer to the CDC's Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Healthcare Settings during an Influenza Pandemic (<a href="http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html">http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html</a>) for specific guidance regarding the use of surgical masks and respirators by healthcare workers.</p>

PRODUCT	QUANTITIES	COMMENTS
Filtering face-piece respirators (N-95 or equivalent respirators)	Calculate for 5/day* for all personnel engaged in face-to-face care of patients with confirmed or suspected pandemic influenza.	<p>It is recommended that face-piece respirators be FDA-cleared and NIOSH certified. Some products that meet NIOSH certification are not legally marketed for use as devices under the Federal Food, Drug, and Cosmetic Act (FFDCA) and thus, their distribution may require clearance or an Emergency Use Authorization (EUA) .</p> <p>*With respect to the estimation of quantities, consider that a healthcare worker will not be able to discard a respirator after each patient. Instead a "single use" will encompass a series of patient interactions, e.g., 3 or 4 patients evaluated while in the patient care area. Respirators should only be reused by a "single wearer."</p> <p>At least 3 or 4 different makes in a reasonable distribution of sizes should be procured to increase probability of providing an acceptable fit for most personnel. Respirators with high-quality elastic components and construction should be identified and selected.</p>
Non-sterile latex-free examination gloves, distributed among small, medium and large sizes	Calculate quantities to allow one pair to be used and discarded for each patient interaction, if needed.	Choice of size distribution should reflect local care provider needs, e.g., proportion of male or female staff members.
Surgical gowns	Calculate quantities to allow one pair to be used and discarded for each patient interaction, if needed.	<p>Gowns may be reasonable for pediatric care but likely not necessary for adult patient care. (Children are less likely to adhere to recommended infection control measures. Such patients, when held by care providers, are likely to smear potentially infectious substances on the care provider. In contrast, adults are rarely held when receiving care.)</p> <p>In addition to surgical gowns, FDA-cleared devices labeled as "patient isolation gowns" are available, some of which are also fluid-resistant. (Check labeling).</p>

PRODUCT	QUANTITIES	COMMENTS
Powered air-purifying respirators (battery packs, filters, and disposable headpieces)	Calculate battery packs and filters for ~5% of clinical care staff who are unable to wear a face-piece respirator; and disposable headpieces/shrouds to allow 2/day for those personnel.	See use instructions as listed in Infection Control Guidance for Healthcare Personnel. ( <a href="http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html">http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html</a> )
<b>Ancillary Supplies</b>		
Waste bags, normal and biological waste	Dependent on number of facilities stockpiles are supporting.	In calculating the quantity of biohazardous waste containers, it is suggested that the facilities consider not only what their stockpile is supporting but also take into consideration state regulations that govern biohazardous waste. Leak-resistant biohazard bags are usually adequate for containment of regulated medical wastes provided the bag is sturdy and the waste can be discarded without contaminating the bag's exterior.
Disinfectants, bleach		<p>It is suggested that disinfectants for patient care facilities be included in the stockpile. It is recommended that only EPA hospital grade disinfectants be made available. EPA registered disinfectants are available in many dispensing sizes and containers, and have shelf life information included in the labeling. Bleach is a well accepted alternative for some spill clean-ups; however, long term storage of bleach may be difficult.</p> <p>It is also recommended that Material Safety Data Sheets (MSDS) be stored with the disinfectants as these will be needed for safety purposes, e.g., in cases of undue exposure or contamination to persons using, mixing or handling these products.</p>

PRODUCT	QUANTITIES	COMMENTS
<b>General Work Sites</b>		
Cleaning equipment (mops, buckets, heavy cleaning gloves, boots, vinyl aprons or coveralls)	Dependent on work stations.	
25-50 gallon barrels or similar reservoirs for storing water and disinfectants at temporary work sites	Dependent on work stations.	
Spray bottles and paper towels	Quantities to allow frequent (4x/hour) disinfection of work surfaces in clinical care sites; one bottle for each table/desk/room.	

### **III. Personal Protective Equipment and Infection Control Supplies for Mortuary Services**

PRODUCT	QUANTITIES	COMMENTS
<b>Mortuary Supplies</b>		
Disposable or reusable full-face shields for splash protection	Calculate for use by all mortuary staff.	
Protective covering (i.e., aprons, gowns)		Aprons (e.g., heavy vinyl) would be more appropriate than gowns for handling human remains.

Gloves		Heavy re-useable gloves should be considered in this particular context if local Disaster Mortuary Team (DMORT) colleagues indicate it is necessary. The numbers to stockpile should also reflect DMORT input.
Leak-proof body bags with additional sealing tape, labeling materials.	Calculate based on expected local readiness to handle as much as 0.6% of the regional population, per the current federal planning assumptions.	
Stretchers/Litters for carrying remains	Calculate based on expected local readiness to handle as much as 0.6% of the regional population, per the current federal planning assumptions.	
Tents for storing remains when other options are exhausted	Dependent on local facility capacity.	The primary option that needs to be considered should include some form of refrigerated storage (i.e., refrigerated trucks). As many communities may request these assets, alternative options should be considered.
Transparent containers for personal effects	Calculate based on expected local readiness to handle as much as 0.6% of the regional population, per the current federal planning assumptions.	Containers or bags should facilitate easy identification of any materials placed inside and also be easily labeled.

<p>Disinfectants, (e.g., any household disinfectant such as lysol or pinesol) or bleach for cleaning mortuary surfaces</p>	<p>Dependent on local facility capacity.</p>	<p>It is suggested that disinfectants for patient care facilities be included in the stockpile. It is recommended that only EPA hospital grade disinfectants be made available. EPA registered disinfectants are available in many dispensing sizes and containers, and have shelf life information included in the labeling. Bleach is a well accepted alternative for some spill clean-ups; however, long term storage of bleach may be difficult.</p> <p>It is also recommended that Material Safety Data Sheets (MSDS) be stored with the disinfectants as these will be needed for safety purposes, e.g., in cases of undue exposure or contamination to persons using, mixing or handling these products.</p>
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