

DEPARTMENT OF THE NAVY BUREAU OF MEDICINE AND SURGERY 7700 ARLINGTON BOULEVARD FALLS CHURCH, VA 22042

BUMEDINST 3500.6A BUMED-M3B7 15 Jun 2016

BUMED INSTRUCTION 3500.6A

From: Chief, Bureau of Medicine and Surgery

Subj: NAVY MEDICINE PANDEMIC INFLUENZA RESPONSE STOCKPILE LOGISTICAL GUIDANCE

Ref: (a) ASD(HA) Memorandum of 29 September 2006

(b) NAVMED P-5132, Equipment Management Manual

(c) Memorandum of Agreement between Naval Medical Logistics Command and the Department of Health and Human Services of 2 September 2014

Encl: (1) Pandemic Influenza H200 Assemblage (Minimal Allowance) List

(2) Acronyms

- 1. <u>Purpose</u>. To provide policy, procedural guidance, and establish responsibilities in support of the logistical components of the Navy Medicine (NAVMED) Pandemic Influenza (PI) Response Stockpile Program, per references (a) and (b). Enclosure (1) is the Pandemic Influenza H200 Assemblage (Minimal Allowance) List and enclosure (2) contains a list of acronyms.
- 2. Cancellation. BUMEDINST 3500.6.
- 3. <u>Scope and Applicability</u>. This instruction defines the responsibilities and authority of Chief, Bureau of Medicine and Surgery (BUMED), and the responsibilities of subordinate commands in managing the NAVMED PI Response Stockpile Program. This instruction applies to all BUMED medical treatment facilities (MTFs) that maintain PI response stockpile inventories.
- 4. <u>Background</u>. Influenza and other respiratory pathogens on a pandemic scale have the potential to significantly impact U.S. military forces across the spectrum of operations, both domestically and abroad. Per reference (a), the Assistant Secretary of Defense for Health Affairs (ASD(HA)) provided the initial funding to establish a response stockpile of essential materials, equipment, and pharmaceuticals to facilitate an expeditious Department of Defense (DoD) response to a PI event. Selected BUMED MTFs received these PI response stockpile items to ensure MTF mission effectiveness and continuity throughout a PI event.

5. Action

- a. BUMED Public Health, Emergency Preparedness & Response (BUMED-M3B7) must:
- (1) Develop and implement policy guidance for the NAVMED PI Response Stockpile Program. Oversee all aspects of this program, to include identification of items to be centrally

stored at a designated facility and locally stored at MTFs. (Note: Enclosure (1) enumerates the program stockpile requirements allocated per facility based on the most recent population at risk data. This enclosure does not differentiate specific amounts stored centrally vice locally.)

- (2) Coordinate with BUMED Logistics Policy (BUMED-M42), NAVMED East and West, and the Naval Medical Logistics Command (NAVMEDLOGCOM) in addressing PI response stockpile policy and logistics issues.
- (3) Coordinate with the Office of the ASD(HA) to develop the Navy Program Objective Memorandum financials for all NAVMED PI response stockpile program requirements.
 - (4) Establish the NAVMED PI Response Stockpile Program requirements.
- (5) Ensure the NAVMED PI Response Stockpile Program is executed effectively and efficiently.
- (6) Ensure the NAVMED East and West regional Emergency Management Officers (EMO) are notified of any changes or updates made to the H200 assemblage within 10 business days.

b. NAVMED East and West Regional Emergency Management Officers must:

- (1) Coordinate and manage in conjunction with NAVMEDLOGCOM, the procurement of NAVMED PI response stockpile materials, equipment, and pharmaceuticals for their regional MTFs.
- (2) Validate regional PI response stockpile statistics reported in the Defense Medical Logistics Standard Support-Assemblage Management (DMLSS-AM) utilizing the Joint Medical Asset Repository (JMAR). Ensure MTF semi-annual inventory reports created via the DMLSS-AM physical inventory module are consolidated and forwarded to BUMED-M3B7.

c. NAVMEDLOGCOM must:

- (1) Manage and update the PI required list of personal protective equipment, antivirals and antibiotics, as defined by BUMED-M3B7, in the DMLSS-AM module.
 - (2) Provide DMLSS-AM module training and support.
- (3) Per reference (b), provide additional guidance regarding PI response stockpile disposal and equipment management as required.
- (4) Provide shipping and delivery information for all MTF PI Response Stockpile Program transactions, to the respective NAVMED East or West regional EMO within 3 business days of the transaction, to facilitate proper receipt and tracking at the MTF.

- (5) Collaborate with the NAVMED regions to ensure the procurement and distribution of NAVMED PI response stockpile materials, equipment, and pharmaceuticals is standardized across the enterprise.
- (6) Per reference (c), NAVMEDLOGCOM will coordinate with the Department of Health and Human Services (DHHS) for the procurement, shipping, and centralized storage of pharmaceuticals, medical/surgical supplies, and related equipment to support the NAVMED PI Response Stockpile Program. NAVMEDLOGCOM will ensure the DHHS centrally stored pharmaceuticals, medical/surgical supplies, and related equipment are maintained in a temperature controlled room. NAVMEDLOGCOM will conduct annual inspections of DHHS centrally stored items to validate the inventory, database, and condition of the material. NAVMEDLOGCOM will audit centrally stored material configuration, inventory levels, and facility condition as required. NAVMEDLOGCOM will manage the NAVMED PI H200 Assemblage using the DMLSS-AM Physical Inventory module.

d. MTF Commanding Officers and Officers in Charge must:

- (1) Maintain operational control of PI materials, equipment, and pharmaceuticals stored at the MTF.
- (2) Ensure all PI response stockpile materials, equipment, and pharmaceuticals are accounted for in the DMLSS-AM.
- (3) Maintain continuous accountability for all PI Response Stockpile Program items and integrate their employment into the MTF and supported installation PI response plans.
- (4) Evaluate the command's PI Response Stockpile Program readiness and ensure an effective PI response capability is maintained.

e. MTF Emergency Managers (MEM) must:

- (1) Serve as the MTF program manager for the PI Response Stockpile Program.
- (2) Collaborate with the MTF Material Manager, Pharmacy Department, and Defense Medical Logistics Standard Support (DMLSS) Systems Administrator to ensure proper storage and assemblage management procedures are implemented, including the accurate reporting of PI response stockpile materials, equipment, and pharmaceuticals. All PI Response Stockpile Program materials will be stored in secure, environmentally-protected facilities to maintain a ready stockpile for immediate availability. PI response stockpile items may be stored off-site, but must remain readily accessible 24 hours per day, including during inclement weather. Additionally, the location of the material must be entered into the DMLSS-AM module.

- (3) Coordinate with the MTF Material Manager and Pharmacy Department to ensure the MTF maintains their minimum allowance levels for all PI response stockpile items. Ensure the respective NAVMED region is immediately notified whenever PI materials or pharmaceuticals become unserviceable, or fall below minimum allowance levels.
- (4) Conduct a 100 percent wall-to-wall inventory of all PI response stockpile items semi-annually during the months of April and October using the DMLSS-AM physical inventory module. Complete inventories will also be conducted whenever a significant change is made to the H200 PI assemblage, such as when an item is removed or replaced on the assemblage. Following each inventory, ensure the completed PI response stockpile material and equipment physical inventory data is updated in the DMLSS-AM module. Forward PI response stockpile inventory results to the respective NAVMED East or West regional EMO within 15 days.
- (5) Coordinate with the Pharmacy Department to ensure the pharmaceuticals listed in enclosure (1) of this instruction are entered into the Food and Drug Administration (FDA) Shelf Life Extension Program (SLEP) upon receipt at the MTF. Ensure the pharmaceutical expiration information is updated in the DMLSS-AM.

f. MTF Material Management Department must:

- (1) Gain and update PI response stockpile materials, equipment, and pharmaceuticals into the DMLSS-AM. The following information must be provided when gaining PI materials and pharmaceuticals into the DMLSS-AM record data module:
 - (a) Location
 - (b) Sub Location
 - (c) On-Hand Quantity
 - (d) "Strat" State
 - (e) Product Number
 - (f) Lot Number (if applicable)
 - (g) Manufacturer
 - (h) Manufacturer Date
 - (i) Expiration Date

- (2) Coordinate the rotation of PI response stockpile material as part of MTF normal operational use with the Pharmacy Department and the MEM. Implement reverse distribution programs for PI response stockpile items whenever possible to minimize the impact of expiration dates and reduce sustainment costs. Notify the MEM whenever PI materials or pharmaceuticals become unserviceable or fall below minimum allowance levels.
- (3) Maintain all PI pharmaceuticals in a secure, climate-controlled storage facility that meets the required temperature and security requirements. Paragraph 7 contains additional details.

g. MTF Pharmacy Department must:

- (1) Create a working stock rotation with PI response stockpile pharmaceuticals to minimize the impact of expiration dates and reduce sustainment costs.
- (2) Manage all PI response antibiotics and antivirals. PI response stockpile pharmaceutical levels are established at the minimum allowances and must not be reduced. Inform the MEM immediately whenever PI pharmaceuticals become unserviceable or the serviceable on-hand stock falls below the minimum allowance levels. Expired pharmaceuticals must be annotated as unserviceable in the DMLSS-AM module and cannot be discarded until they have been replaced with new serviceable stock.
- (3) Assist the MEM in ensuring the proper storage of PI pharmaceuticals per regulations, manufacturer's recommendations, and the requirements of paragraph 7.
- (4) Utilize the FDA SLEP to capture all relevant information for the on-hand allowance of the PI response stockpile antibiotics and antivirals listed in enclosure (1). The FDA SLEP facilitates deferring drug replacement costs for date-sensitive pre-positioned material. In the event of a product recall affecting a PI response stockpile pharmaceutical, the Pharmacy Department will notify the MEM and other responsible parties, providing the specific return instructions. In the event of a recall, do not return the PI response stockpile item(s) through the reverse distribution service provider until the FDA completes a product assessment/test, and concludes the product has no useful life.
- (5) Coordinate with the MEM in conducting a semi-annual inventory of PI response stockpile pharmaceuticals, ensuring the results are recorded into the FDA SLEP.
- 6. <u>Sustainment Management</u>. The proper implementation and sustainment of PI materials, equipment, and pharmaceuticals is a shared responsibility between the MTF, NAVMED regions, NAVMEDLOGCOM, and BUMED-M3B7. BUMED-M3B7 will coordinate with NAVMEDLOGCOM to establish a life-cycle phased replacement plan for all PI materials, equipment and pharmaceuticals, using the information reflected in JMAR. MEMs will coordinate with their Material Management and Pharmacy Departments to identify any

deficiencies or discrepancies in their PI response stockpile inventory, and with their respective regional EMO to prioritize the resource requirements for resolving any discrepancies and sustaining their PI response stockpile.

- 7. <u>Pharmaceutical Storage Requirements</u>. All antivirals and antibiotics listed in the H200 Assemblage should be stored per the following guidance:
- a. Stored between 68-77°F (20-25°C). Excursions between 59-86°F (15-30°C) are permitted if the mean temperature remains in the allowed range. Provided the mean temperature remains in the allowed range, transient spikes up to 40°C may be permitted as long as they do not exceed 24 hours in duration. If exposed above 104°F/40°C for longer than 24 hours, contact the pharmaceutical manufacturer for guidance and report the exposure to NAVMEDLOGCOM for evaluation of potency testing in the FDA SLEP program.
 - b. Protected from light.
 - c. Protected from freezing.
- d. Stored in a dry place that does not exceed 40 percent average relative humidity at a controlled room temperature of 68-77°F (20-25°C).
- 8. <u>Disposal of PI Response Stockpile Materials</u>, Equipment, and Pharmaceuticals
- a. All PI response stockpile material, equipment, and pharmaceuticals are considered to have an extended shelf-life and must not be discarded based on a manufacturer's recommended expiration date, or any other basis without approval from BUMED-M3B7.
- b. PI response stockpile material, equipment, and pharmaceuticals that have been formally removed from, or replaced on the authorized H200 Allowance List may be disposed of per reference (b). PI response stockpile items on-hand at levels above minimum allowances are not considered "excess" and shall not be discarded. With prior approval from BUMED-M3B7, regional EMOs can transfer PI response stockpile items held on-hand at levels above the minimum allowances between MTFs within their region, to maximize regional PI response stockpile readiness levels.

9. Logistics Management Information Systems

- a. <u>DMLSS</u>. The DMLSS-AM module is the mandatory tracking system for managing the NAVMED PI Response Stockpile Program.
- b. <u>JMAR</u>. Following data entry of PI material, equipment and pharmaceutical information into the DMLSS-AM, the inventory data is automatically uploaded into JMAR. JMAR is a viewable dashboard tool for Navy Medicine East and West regional commanders, BUMED, and ASD(HA).

- 10. <u>Records</u>. Records created as a result of this instruction, regardless of media and format, shall be managed per SECNAV M-5210.1 of January 2012.
- 11. <u>Reports</u>. The reports required in this instruction, are exempt from reports control per SECNAV M-5214.1 of December 2005, part IV, paragraph 7j.

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PANDEMIC INFLUENZA H200 ASSEMBLAGE (MINIMAL ALLOWANCE) LIST

Primary	Cefepime HCL 2g Intraveneous 20ml vial 10/pkg	Ceftriaxone Injection 1g Single-dose vial 25	Imipenem 500mg & Cilastin Sodium 500mg 25/pkg	Vancomycin HCL 1g 10/pkg	Doxycycline Hyclate 100mg 10/pkg	Doxycycline Hyclate 100mg 500 tablets/bottle	<u>Levofloxacin</u> <u>Solution</u> 750mg/30ml Single-dose vial	Levofloxacin Tablets 750mg tablets/bottle	Amoxicillin & Clavulanate Potassium 20 tablets/bottle	Amoxicillin & Clavulanate Potassium Oral Susp 400mg/5ml
	NDC: 51479005530	NDC: 63323034610	NDC: 00006351659	NDC: 00409653301	NDC: 63323013011	NDC: 00172362670	NDC: 00045006555	NDC: 00045153010	NDC: 00093227534	NDC: 00093227973
	31479003330	03323034010	00000331037	00407033301	03323013011	00172302070	00043000333	00043133010	00073221334	00093221913
NSN	6505014376228	6505015408738	6505013324794	6505012478801	6505015167604	6505011534335	6505015427929	6505014876727	6505014309740	6505015055928
Secondary (Primary: Secondary)	Piperacillin 4g & Tazobactam 0.5g Vials 10/pkg 6505015412276	Ceftriaxone Injection 1g 10ml Vial Single-dose vial 25 6505015544282	Meropenem				Ciprofloxacin Injection 400mg/40ml Single-dose vial 6505015766179	Moxifloxacin HCL 400mg 50 tablets/bottle 6505015163194 OR Levofloxacin 750mg 20 tablets/bottle 6505013618358		
FUGGLOVELL	222	82	127	665	222	9	2,376	24	222	475
FHCC LOVELL	348	88	199	1,044	348	14	3,727	37	348	745
NH BREMERTON NH CAMP LEJUENE	768	194	439	2,304	768	31	8,230	82	768	1,646
NH CAMP LEJUENE NH CAMP PENDLETON	879	221	502	2,636	879	35	9,414	94	879	1,883
USNH GUAM	113	28	64	338	113	5	1.209	12	113	242
USNH GUANTANAMO	11	3	6	32	11	1	116	1	11	23
NH JACKSONVILLE	524	132	300	1,572	524	21	5,616	56	524	1,123
USNH NAPLES	33	8	19	100	33	1	358	4	33	72
USNH OKINAWA	249	63	142	746	249	12	2,663	27	249	533
NH PENSACOLA	617	156	353	1,852	617	25	6,614	66	617	1,323
USNH ROTA	17	4	9	50	17	1	177	2	17	35
USNH YOKOSUKA	146	37	84	438	146	6	1,566	16	146	313
NHC CORPUS CHRISTI	339	85	194	1,017	339	14	3,631	36	339	726
NMC PORTSMOUTH	1,714	432	979	5,142	1,714	69	18,363	184	1,714	3,673
NMC SAN DIEGO	1,166	294	666	3,498	1,166	47	12,493	125	1,166	2,499

Notes:

⁽¹⁾ Due to product availability (costs or manufacturing), Assistant Secretary of the Defense (Health Affairs) via Defense Logistics Agency can select acceptable alternatives to augment or temporarily replace primary antibiotics until the product becomes available.

⁽²⁾ The minimal allowance levels required to be maintained for each antibiotic can be comprised of primary, secondary, or a combination of both primary and secondary antibiotics.

PANDEMIC INFLUENZA H200 ASSEMBLAGE (MINIMAL ALLOWANCE) LIST

<u>Facility</u>	Tamiflu 75 mg - 10 capsules per pkg	Relenza 5 mg - 5 disks per pkg		
National Stock Number	6505015280374	6505015355483		
FHCC LOVELL	4,488	6,800		
NH BEAUFORT	1,140	1,710		
NH BREMERTON	7,974	11,960		
NH CAMP LEJEUNE	15,677	23,515		
NH CAMP PENDLETON	17,931	26,896		
USNH GUAM	6907	3453		
USNH GUANTANAMO	1752	875		
NH LEMOORE	6,907	3.453		
NH JACKSONVILLE	10,697	16,045		
USNH NAPLES	2,044	1,022		
NH OAK HARBOR	2,640	3.960		
USNH OKINAWA	14,174	7,087		
NH PENSACOLA	12,598	18,897		
USNH ROTA	1010	505		
USNH SIGONELLA	1,781	890		
NH TWENTYNINE PALMS	3,152	4,727		
USNH YOKOSUKA	8,948	4,474		
NHC ANNAPOLIS	4,315	6,473		
NHC CHARLESTON	5,807	8,711		
NHC CHERRY POINT	2,697	4,045		
NHC CORPUS CHRISTI	6,917	10,375		
NHC NEW ENGLAND	6,666	9,999		
NHC QUANTICO	5,936	8,904		
NHC PATUXENT RIVER	5,771	8,656		
NHC HAWAII	14,338	7,169		
NMC PORTSMOUTH	34,978	52,467		
NMC SAN DIEGO	23,796	35,694		

Note: TAMIFLU quantities are 30 percent par for outside the continental United States MTFs and 10 percent par for continental United States MTFs based on 2013 par estimates. MTF Relenza quantities are 15 percent par for all MTFs based on 2013 par estimates.

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PANDEMIC INFLUENZA H200 ASSEMBLAGE (MINIMAL ALLOWANCE) LIST

<u>Facility</u>	<u>N-95s</u> (Large) Tan	<u>N-95s</u> (Medium) Blue	<u>N-95s</u> (Small) White	N-95s (Low Profile) Green	<u>N-95s</u> (Extra Small) Yellow
National Stock Number/Product#	4240014960918	4240014960916	4240014960850	1517-LP	1510-ES
FHCC LOVELL	28,955	72,388	28,955	7,239	7,239
NH BEAUFORT	24,353	60,883	24,353	6,088	6,088
NH BREMERTON	103,380	258,451	103,380	25,845	25,845
NH CAMP LEJEUNE	188,536	471,341	188,536	47,134	47,134
NH CAMP PENDLETON	237,243	593,107	237,243	59,311	59,311
USNH GUAM	73,544	183,859	73,544	18,386	18,386
USNH GUANTANAMO BAY	21,128	52,819	21,128	5,282	5,282
NH JACKSONVILLE	199,020	497,549	199,020	49,755	49,755
NH LEMOORE	48,868	122,170	48,868	12,217	12,217
USNH NAPLES	38,062	95,155	38,062	9,516	9,516
NH OAK HARBOR	39,514	98,784	39,514	9,878	9,878
USNH OKINAWA	149,668	374,170	149,668	37,417	37,417
NH PENSACOLA	164,667	411,667	164,667	41,167	41,167
USNH ROTA	33,385	83,463	33,385	8,346	8,346
USNH SIGONELLA	36,449	91,123	36,449	9,112	9,112
NH TWENTYNINE PALMS	55,480	138,701	55,480	13,870	13,870
USNH YOKOSUKA	68,060	170,151	68,060	17,015	17,015
NHC ANNAPOLIS	22,740	56,851	22,740	5,685	5,685
NHC CHARLESTON	23,224	58,061	23,224	5,806	5,806
NHC CHERRY POINT	27,740	69,351	27,740	6,935	6,935
NHC CORPUS CHRISTI	27,095	67,738	27,095	6,774	6,774
NHC NEW ENGLAND	69,028	172,570	69,028	17,257	17,257
NHC QUANTICO	30,643	76,608	30,643	7,661	7,661
NHC PATUXENT RIVER	24,031	60,078	24,031	6,008	6,008
NHC HAWAII	31,127	77,818	31,127	7,782	7,782
NMC PORTSMOUTH	557,061	1,392,653	557,061	139,265	139,265
NMC SAN DIEGO	530,934	1,327,335	530,934	132,733	132,733

NOTE: All N-95 respirators will be stored at a centralized warehouse by BUMED Public Health, Emergency Preparedness and Response (BUMED-M3B7) and will be shipped to MTFs prior to an event.

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PANDEMIC INFLUENZA H200 ASSEMBLAGE (MINIMAL ALLOWANCE) LIST

<u>Facility</u>	Exam Gloves (Medium)	Exam Gloves (Large)	Gowns	Surgical Masks	Goggles
NSN/PRODUCT#	6515015199172	6515015199161	6532011536517	6515014843880	4240000523776
FHCC LOVELL	31,620	7,905	144,775	19,763	1,724
NH BEAUFORT	3,831	958	15,221	2,394	181
NH BREMERTON	23,854	5,964	64,613	14,909	769
NH CAMP LEJEUNE	52,674	13,168	117,835	32,921	1,403
NH CAMP PENDLETON	60,248	15,062	148,277	37,655	1,765
USNH GUAM	7,735	1,934	45,965	4,835	547
USNH GUANTANAMO BAY	740	185	13,205	462	157
NH JACKSONVILLE	35,942	8,985	124,387	22,463	1,481
NH LEMOORE	11,404	2,851	30,542	7,128	364
USNH NAPLES	2,289	572	23,789	1,431	283
NH OAK HARBOR	8,870	2,217	24,696	5,544	294
USNH OKINAWA	15,875	3,969	93,542	9,922	1,114
NH PENSACOLA	42,330	10,582	102,917	26,456	1,225
USNH ROTA	1,132	283	20,866	707	248
USNH SIGONELLA	1,994	499	22,781	1,246	271
NH TWENTYNINE PALMS	10,590	2,647	34,675	6,618	413
USNH YOKOSUKA	10,022	2,506	42,538	6,264	506
NHC ANNAPOLIS	14,499	3,625	14,213	9,062	169
NHC CHARLESTON	19,511	4,878	14,515	12,195	173
NHC CHERRY POINT	9,060	2,265	17,338	5,663	206
NHC CORPUS CHRISTI	23,240	5,810	16,934	14,525	202
NHC NEW ENGLAND	22,398	5,600	43,142	13,999	514
NHC QUANTICO	19,945	4,986	19,152	12,465	228
NHC PATUXENT RIVER	19,390	4,848	15,019	12,119	179
NHC HAWAII	13,158	3,290	19,454	8,224	232
NMC PORTSMOUTH	117,526	29,382	348,163	73,454	4,145
NMC SAN DIEGO	79,955	19,989	331,834	49,972	3,950

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ACRONYMS

ASD(HA) Assistant Secretary of Defense (Health Affairs)

BUMED Bureau of Medicine and Surgery

DMLSS Defense Medical Logistics Standard Support

DMLSS-AM Defense Medical Logistics Standard Support-Assemblage

Management

EMO Emergency Management Officer
FDA Food and Drug Administration
JMAR Joint Medical Asset Repository
MEM MTF Emergency Manager
MTF Medical Treatment Facility

NAVMED Navy Medicine

NAVMEDLOGCOM Naval Medical Logistics Command

NDC
National Drug Code
NH
Naval Hospital
NHC
Naval Health Clinic
NMC
Naval Medical Center
NSN
National Stock Number
PAR
Population at Risk
PI
Pandemic Influenza

SLEP Shelf Life Extension Program USNH United States Naval Hospital