



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

AUG 10 2015

Dear Mr. Chairman:

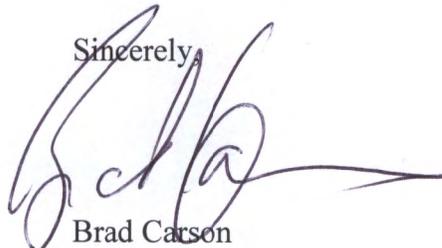
The enclosed report is in response to section 727 of the Carl Levin and Howard P. “Buck” McKeon National Defense Authorization Act for Fiscal Year 2015 (Public Law 113-291) which requires the Secretary of Defense to carry out an antimicrobial stewardship program at medical facilities of the Department of Defense (DoD) and to submit a plan for carrying out the program. The report includes the plan of DoD actions being taken to carry out the antimicrobial stewardship program at medical facilities of the DoD.

Executive Order 13676, “Combating Antibiotic Resistant Bacteria (CARB),” and a National Action Plan, chart the government’s efforts to address this important issue. Under the National Action Plan, the DoD agrees to work with the Department of Health and Human Services (HHS) and the Department of Veterans Affairs (VA) to optimize standardization of stewardship programs and activities, including monitoring and reporting criteria within one year (December 2015). DoD and VA have launched a collaborative work group focused on data exchange in support of the antimicrobial stewardship program. The focus of DoD work with HHS Centers for Disease Control and Prevention is the reporting of military treatment facility laboratory data and antibiotic drug use by October 2015.

DoD strongly supports the CARB and the National Action Plan, and continues to drive toward optimization and standardization. A multidisciplinary group, under the purview of the Assistant Secretary of Defense for Health Affairs, is being chartered to support and coordinate stewardship activities across the DoD.

Thank you for your interest in the health and well-being of our Service members, Veterans, and their families. A similar letter is being sent to the House Armed Services Committee.

Sincerely,



Brad Carson
Acting

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

AUG 10 2015

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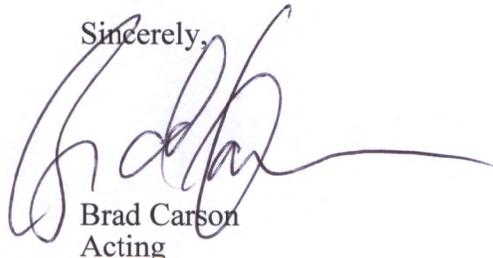
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Sincerely,



Brad Carson
Acting

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

**Section 727 of the Carl Levin and Howard P. “Buck” McKeon
National Defense Authorization Act for Fiscal Year 2015
Public Law 113-291**

**Antimicrobial Stewardship Program Plan
Medical Facilities
Department of Defense**



Office of the Secretary of Defense

June 2015

The estimated cost of this report or study for the Department of Defense is approximately \$700 in Fiscal Years 2014 - 2015. This includes \$0 in expenses and \$700 in DoD labor.

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Executive Summary

Section 727 of the Carl Levin and Howard P. “Buck” McKeon National Defense Authorization Act for Fiscal Year (FY) 2015 (Public Law 113-291) requires the Department of Defense (DoD) to create an antimicrobial stewardship program at medical facilities of the DoD within one year of enactment of the Act. In carrying out the antimicrobial stewardship program (ASP), the Secretary is required to develop a consistent manner in which to collect and analyze data on antibiotic usage, health issues related to antibiotic usage, and antimicrobial resistance trends in the Department. This report is submitted in response to the requirement in section 727 for a plan for implementing an ASP at DoD medical facilities to the Committees on Armed Services of the House of Representatives and the Senate. The plan developed in response to section 727 aligns with the actions being taken by the department in response to the President issued Executive Order (EO) 13676, “Combating Antibiotic Resistant Bacteria (CARB),” and National Action Plan.

The DoD is committed to supporting the establishment of this program under the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) with task force representation and *ex officio* membership on the President’s Advisory Council on Combating Antibiotic-Resistant Bacteria. The plan guiding the ASP development is designed to address the structures, systems and processes needed to implement the program.

1.0 Introduction

Antibiotic resistant bacteria are recognized globally as one of the greatest threats to human health worldwide. It has been estimated that there are more than two million infected persons and over 23,000 deaths per annum within the United States alone as a result of this drug resistance. Cost estimates exceed \$35 billion annually (World Health Organization (WHO) 2014, Centers for Disease Control and Prevention (CDC) 2013). Detecting, preventing, and controlling antibiotic resistance requires a multi-pronged approach and sustained effort.

In September, 2014, the President issued EO 13676, “Combating Antibiotic Resistant Bacteria (CARB),” to address the growing crisis of resistant bacteria and related morbidity and mortality. Within this EO, a task force, co-chaired by the Secretaries of Defense, Agriculture, and Health and Human Services, is established and charged with the creation and implementation of a National Strategy and 5-year National Action Plan to identify specific actions taken on behalf of the United States Government to prevent, detect, and control illness and death related to infections caused by antibiotic resistant bacteria. The National Action Plan details the steps for implementing the National Strategy for Combating Antibiotic Resistance Bacteria (published September, 2014). This plan includes actions taken on behalf of the U.S. Government, as well as other public health partners in a common effort to address urgent drug-resistant threats affecting people within the United States and around the world. Implementation of the National Action Plan also supports the World Health Assembly resolution (67.25/Antimicrobial Resistance).

The DoD is directly supporting the President’s Executive Order under the OASD(HA) with policy and clinical care refinements, task force representation, and *ex officio* membership on the President’s Advisory Council on Combating Antibiotic-Resistant Bacteria. The President’s FY

2016 Budget Proposal nearly doubles the amount of Federal funding for combating and preventing antibiotic resistance to over \$1.2 billion. The funding is designated to improving antibiotic stewardship, antibiotic resistance risk assessment, surveillance and reporting capabilities, and research innovation in human and agricultural sectors. Funding increases for the DoD are to address issues related to antibiotic resistance in healthcare settings.

The direct care component of the Military Healthcare System (MHS) is comprised of 54 inpatient medical treatment facilities (MTF) and an additional 362 outpatient clinics; antibiotics are prescribed at all of these facilities. The MHS is regionally aligned in each service (Army, Navy, Air Force) with each region including a tertiary care facility as the anchor for smaller centers. Tertiary care MTFs include Microbiology laboratories as well as infectious disease medical staff, infection control, and clinical pharmacology staff. Smaller facilities often rely on primary care specialties and referable laboratory capabilities. Each service has an infection control plan, although not all have an ASP.

Based upon the complexities in determining appropriateness of antibiotic prescribing practices, the DoD will first initiate overarching policy guidance highlighting the importance of the issue and planned MTF-level programs. Necessary inclusion into regionally-based ASP committees will include the following: infectious disease physician, clinical pharmacologist, and Credentialed Infection Control practitioner. Smaller MTFs and clinics will be organized with the identified senior medical provider of a primary care specialty (pediatrics, internal medicine, family practice) serving in the medical capacity. Communication processes will be streamlined from clinics/community hospitals to the regional medical center anchors for both routine and unexpected transfer of information.

Through the efforts detailed above, based upon the CARB National Action Plan, the DoD already collects and analyzes most of the antibiotic resistance microbiological data through the Multidrug-resistant Organism Repository & Surveillance Network (MRSN) and Navy Marine Corps Public Health Center – Epidemiological Data Center (NMCPHC-EDC). Once codified as a tri-service entity, isolate collection processes will be complete. Using FY 2015 funds, algorithms are being developed for the collection of antibiotic use data (inpatient data collection will precede outpatient data collection) by the Pharmacovigilance Center (PVC). The NMCPHC-EDC and PVC are actively developing methods to centralize submission efforts of these data to the National Healthcare Safety Network (NHSN) and the Office of the Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight (ODASD(HRP&O)) for service and department analysis as well as subsequent goal and policy modification. The MRSN and Global Emerging Infection Surveillance (GEIS) Antimicrobial Resistance division of the Armed Forces Health Surveillance Center (AFHSC) already plays a prominent role in the analysis of the available resistance, drug use trends and relevant outcomes with its staff of infectious disease physicians, epidemiologists, microbiologists, and bioinformaticists. Initial funding approval was granted for all of the above work in the FY 2016-2020 program objective memorandum (POM) to sustain these efforts.

Given the natural continuum that exists between many DoD and Veterans Affairs (VA) patients, efforts are underway to initiate relevant microbiological data exchange between the two agencies. Standardization of drug and bacterial codes is nearly complete, with a planned pilot exchange of data on shared patients between two facilities to follow.

2.0 DoD ASP Action Plan

The following sections list the eight DoD Actions being taken to carry out the ASP at medical facilities of the DoD.

A. DoD Action 1: ASP DoD Policy

- a. Review National Action Plan for Combating Antibiotic-Resistant Bacteria and President issued EO 13676, CARB (completed)
- b. Review existing related DoD policies and guidelines (completed)
- c. Draft Defense Health Agency (DHA) procedural instruction (PI) (3rd quarter FY 2016)
- d. Route completed DHA PI for approval (3rd quarter FY 2016)
- e. Fully implement ASP DHA PI (FY 2017)
 - i. Service specific implementation at all levels of facilities (inpatient and outpatient)
 - ii. Creation of ASP subject matter expert (SME) working group per DHA PI
 - iii. Creation of regional stewardship teams per DHA PI
 - iv. OASD(HA), ODASD(HRP&O) will serve as principal advisor and receipt of reporting from the ASP working group, including summary trends from both antibiotic resistance and use data collection and analyses.
 - v. Update policy, as needed, based upon working group monitoring and evaluation

B. DoD Action 2: DoD and VA Collaboration

- a. Establish working group of SMEs, including clinical, bioinformatics, and information technology members from DoD and VA (completed)
- b. Continue established quarterly conference calls to organize actions
- c. Amend current DoD-VA Memorandum of Understanding (MOU) for Sharing PII/PHI to allow data sharing of patient-related antibiotic resistance data (4th quarter FY 2016)
- d. Develop standardized drug and bacterial codes (4th quarter FY 2015)
- e. Establish a database platform for joint data storage and/or access (evaluating use of existing system) (4th quarter FY 2016).
 - i. Identify facilities within each agency to pilot joint data storage (Tripler Army Medical Center and the Honolulu VA have been proposed as the first pilot sites).
 - ii. Complete pilot study to identify pitfalls and gaps to be analyzed with centralize data storage and/or data accessibility features
 - iii. Expand centralized data storage and/or data accessibility features to additional facilities

C. DoD Action 3: Reduction of antibiotic use within outpatient facilities

- a. Complete antibiotic use data collection algorithms (PVC is identified centralized agency)
- b. Approve Services contracting actions (pending for FY 2015 for PVC – at SCA)
- c. Establish access to Electronic Data Interchange Person Identifier (EDIPI)
 - i. Available from current PVC databases
 - ii. May need linkage from Social Security Number (SSN) to populate historic data
 - iii. Requires semi-annual updates to data dictionary mapping hospital facilities to services provided
 - iv. May require assistance of Pharmacoeconomic Center
 - v. Data will be forwarded to working group (currently located at AFHSC-GEIS and Walter Reed Army Institute of Research(WRAIR)/MRSN) for correlation with antibiotic resistance data
- d. Develop process and funding for algorithm updates and ongoing implementation (funding approved in FYs 2015-2020)
- e. Establish goals for reducing antibiotic use in outpatient facilities based on analysis of data by fourth quarter FY 2016.

D. DoD Action 4: Reduction of antibiotic use within inpatient facilities

- a. Complete antibiotic use data collection algorithms (PVC is identified centralized agency) (4th quarter FY 2015).
- b. Receive approval of services contract (4th quarter FY 2015)
- c. Gain access to EDIPI (1st quarter FY 2016)
 - i. Available from current PVC databases
 - ii. May need linkage from SSN to populate historic data via Defense Manpower Data Center (DMDC)
 - iii. Requires semi-annual updates to data dictionary mapping hospital facilities to services provided
 - iv. Requires MTF assignment of responsible staff to run monthly reports and perform quality assurance assessments at each site
 - v. Will ultimately require long-term solution for direct data delivery to PVC
 - i. Requires input of Inpatient systems developers for programming
 - vi. Data will be forwarded to working group (lead located at AFHSC-GEIS/WRAIR-MRSN) for correlation with antibiotic resistance data
- d. Requires funding for development of algorithms and ongoing implementation (approved in FYs 2016-2020 POM)
- e. Establish goals for reducing antibiotic use in inpatient facilities based on analysis of data (4th quarter FY 2016)

E. DoD Action 5: Collection of antibiotic resistance data throughout all of MHS

- a. Obtain approval of contract for work to be performed by NMCPHC-EDC – (Completed)
- b. Create/modify existing algorithms to ensure necessary information collected (4th quarter FY 2015)
- c. Coordinate with the MRSN for laboratory confirmation/exclusion of reported results within MHS (1st quarter FY 2016)
 - i. Required to be accepted tri-service entity
 - 1. Proposal has been endorsed at the level of the Medical Operations Group
 - 2. Proposal endorsed at Tri-Service Specialty Care Advisory Board
 - 3. Proposal will likely require Medical Deputies Action Group and Policy Advisory Council approval
 - 4. Creation of a DHA PI is required
 - 5. Requires enduring programmatic funding for ongoing surveillance, advanced characterization, reporting, cryopreservation (approved FYs 2015-2020)
- d. Obtain a data sharing MOU with MRSN (Completed)
- e. Obtain funding for development of algorithms and ongoing implementation (NMCPHC) (approved)
- f. Obtain access to EDIPI (1st quarter FY 2016)
 - i. Available from existing databases (uses Health Level 7 formatted information)
 - ii. May need linkage from SSN to populate historic data (via DMDC)
 - iii. Requires semi-annual updates to data dictionary mapping hospital facilities to services provided
- g. Forward data to the working group (lead located at AFHSC-GEIS) for correlation with antibiotic use data (1st quarter FY 2016)

F. DoD Action 6: DoD Participation in NHSN

- a. MTFs will complete application process for NHSN number and participation (2nd quarter FY 2016).
- b. Coordinate with CDC to ensure proper data submission format on behalf of MTFs (2nd quarter FY 2016; in progress)
- c. NHSN membership will be a mandatory requirement of DHA Stewardship PI
- d. Design a centralized process for the submission of antibiotic use data to NHSN (2nd quarter FY 2016)
- e. Antibiotic resistance data to be submitted by the NMCPHC-EDC (with confirmation by MRSN) – test site near completion 4th quarter FY 2015
- f. Antibiotic use data to be submitted by the PVC – (3rd quarter FY 2016)

- g. Provide accessible data to the working group as well as other subject matter experts for monitoring and evaluating the DoD's ASP (4th quarter FY 2016)

G. DoD Action 7: Strengthen Surveillance Efforts

- a. The MRSN will make available a representative sample of characterized isolate data, accessible by authenticated users (4th quarter FY 2015)
 - i. Data sharing in progress via CDC and National Center for Biotechnology Information
 - ii. MRSN Database first release expected in FY 2015, with relevant microbiological data available for authenticated users
- b. The MRSN will continue its mission of identification, collection, characterization, preservation, and reporting on targeted multidrug-resistant bacterial pathogens (Ongoing)
- c. The MRSN will provide laboratory confirmation of all bacterial isolate submissions from the MHS to the NMCPHC for entry/correction into the CDC's NHSN (Ongoing)
- d. The AFHSC-GEIS will support bacterial surveillance efforts in its partner laboratories within and outside the continental United States (Ongoing)

H. DoD Action 8: Education and Training

- a. Participate in the White House sponsored Antimicrobial Resistance Forum on June 2, 2015, which will address how best to tackle these issues
- b. Contribute to and participate in planned roll-out of educational materials over the coming year, though primarily focused on the consumers of antibiotics and agricultural food producers (FY 2015 – FY 2016)
- c. The DoD should work to develop specific goals and objectives in this regard once data is available to provide a reasonable baseline of the appropriateness of its current antibiotic use in the context of antibiotic resistance patterns (FY 2016 – FY 2017)

I. DoD Action 9: Strategic Communication Plan

- a. Annual reporting of milestones by the CARB task force (September 2015) required by the National Action Plan will be routed through each agency to the Executive Branch.
- b. Periodic sharing and reporting of policy and data trends by DoD representation (includes OASD(HA)/ODASD(HRP&O)) in the chartered Federal Advisory Committee, established by the National Action Plan (inaugural meeting planned in September 2015).
- c. Annual reporting of analysis of NHSN metrics by the Infection Prevention and Control Panel.

- d. Annual reporting by the participating collaborators: AFHSC-GEIS, WRAIR, NMCPHC-EDC, and PVC as required as part of funded efforts.
- e. Engage Surgeons General in above reporting lines to foster success of program.

3.0 Summary

The National Action Plan addresses the five goals addressed in EO 13676 as well as the National Strategy and President’s Council of Advisors on Science and Technology report in the fight against microbes on both human and animal health. The actions and plan above reflect those specific to the DoD with respect to antimicrobial stewardship and serve as a guide for the working group implementation, modification, and maintenance of the antimicrobial stewardship program. DoD SMEs are actively planning and completing tasks required that include establishing an ASP in all DoD inpatient and outpatient facilities. Additional actions are planned by DoD SMEs that address all five goals within the National Action Plan and are intended to maximize clinical support decisions, quality of care, and patient safety.

List of References

CDC Antibiotic Resistance Threats in the United States, 2013:
<http://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf>

Executive Order 13676 to Combat Antibiotic Resistant Bacteria:
https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf

National Strategy for Combating Antibiotic Resistant Bacteria:
https://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf

PCAST Report on Combating Antibiotic Resistant Bacteria:
https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_carb_report_sept2014.pdf

WHO Antimicrobial resistance global report on surveillance, 2014:
http://apps.who.int/iris/bitstream/10665/112642/1/9789241564748_eng.pdf