KEY STRATEGIES TO ENHANCE INFECTION PREVENTION AND ANTIBIOTIC STEWARDSHIP

REPORT WITH RECOMMENDATIONS FOR HUMAN AND ANIMAL HEALTH

SEPTEMBER 2018

PACCARB

Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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INTRODUCTION

The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB) was established in 2015 in consultation with the Secretaries of Defense (DoD), Agriculture (USDA), and Health and Human Services (HHS) as part of a coordinated effort by the U.S. government to respond to the threat of antimicrobial resistance (AMR).

Since its establishment in 2015, the PACCARB has created two reports. The [first report](#) evaluated the U.S. government's (USG) progress towards reducing and preventing the spread of AMR within the first 180-days of issuance of the National Action Plan on Combating Antibiotic-Resistant Bacteria (NAP). The [second report](#) proposed recommendations to incentivize the development of therapeutics, diagnostics, and vaccines for both humans and animals, while maximizing the return on investment (ROI) and encouraging appropriate stewardship and access to products. Building off the foundation of the first two PACCARB reports, the council has developed a high-level set of recommendations for effectively defining and evaluating the core principles of infection prevention and antibiotic stewardship (IP&AS). These recommendations are designed to ensure that the reduction and prevention of AMR in animals and people are conducted through well-supported federal and non-federal programs.

For this task, the PACCARB established a working group (WG) composed of council members and federal official subject matter experts (SMEs) in both human and animal domains to address IP&AS. Before attempting to generate recommendations regarding the core principles of IP&AS, the WG sought to identify examples of IP&AS practices being successfully implemented, and also to better understand the primary gaps contributing to barriers to the widespread implementation of IP&AS practices. Given the broad scope of the subject matter, three subgroups with more focused scopes were formed within the WG; these were charged with exploring: 1) gaps in current IP&AS research, the resolution of which would identify new best practices; 2) successes and challenges in the implementation of such best practices; and 3) workforce, education, and competencies (WEC) required to sustain effective IP&AS efforts. Recognizing the importance of a One Health approach when addressing issues related to AMR, each subgroup was led by two co-chairs, one with expertise in human health and one in animal health. To accomplish their tasks, each subgroup held a series of working group meetings and conference calls that drew on the topic-relevant expertise of both federal and non-federal leaders and SMEs.

The IP&AS WG recognized the complexity of the task to be completed and the limited time available to do so, and thus chose to constrain its inquiries to relatively narrow scopes identified and agreed upon by the co-chairs and members of the respective subgroups. These scopes of inquiry included:

- Best Practices: to identify and prioritize federal research needs for defining IP&AS best practices.
- Implementation: to identify successful implementation strategies for federal IP&AS programs.
- WEC: to identify and remedy shortages of trained individuals with expertise in IP&AS.

Based on the information gathered from both internal and external SMEs, subgroup members noted considerable overlap and an interconnectedness among the three subgroups. Therefore, this report describes the recommendations generated by the three subgroups as a cohesive whole under the IP&AS WG.

A variety of governmental and nongovernmental agencies have put significant effort into investigating and addressing the challenges of IP&AS to combat AMR. The subgroups reviewed publications, reports, and initiatives by such individuals and organizations. In particular, the WG acknowledges the recent advances and work currently in progress in IP&AS by the USG, notably by the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the DoD, the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the USDA, and the Veterans Health Administration (VHA).

The WG also recognizes the contributions of several professional organizations that have contributed to the WG's proceedings and put forth recommendations for improving and incentivizing IP&AS practices in all healthcare and animal health settings, including, but not limited to:

- American Animal Hospital Association (AAHA)
- American Veterinary Medical Association (AVMA)
- Association of American Veterinary Medical Colleges (AAVMC)
- Association for Professionals in Infection Control and Epidemiology (APIC)
- Infectious Diseases Society of America (IDSA)
- The Joint Commission (TJC)
- Society for Healthcare Epidemiology of America (SHEA)
- Society of Infectious Diseases Pharmacists (SIDP)

While ideas were shared across both human and animal health domains, as exemplified by the mirrored recommendations in the following table, for organizational purposes, the report addresses human health and animal health in separate sections. Each section of the report describes the issues and gaps identified regarding best practices, implementation, and WEC and the recommendations developed to address them. Additionally, each WG member reviewed the report as a whole and provided feedback and input on the final document. This summary report with recommendations was presented to the full PACCARB at the September 26, 2018 public meeting for further evaluation and discussion. At that meeting, the final version was approved unanimously for transmittal to the Secretary.

The PACCARB provides these recommendations for possible ways the USG could support implementation of IP&AS best practices, identified through evidence-based research activities, to the HHS Secretary and President of the United States. As illustrated in the figure below, the effective and efficient implementation of IP&AS in a wide variety of settings would ultimately drive the growth and maintenance of a workforce with robust education and competencies at multiple levels to carry out the needed work to combat antibiotic-resistant infections and promote antibiotic stewardship.

The Integration of Core Recommendations for Enhancing Infection Prevention and Antibiotic Stewardship in Human and Animal Health
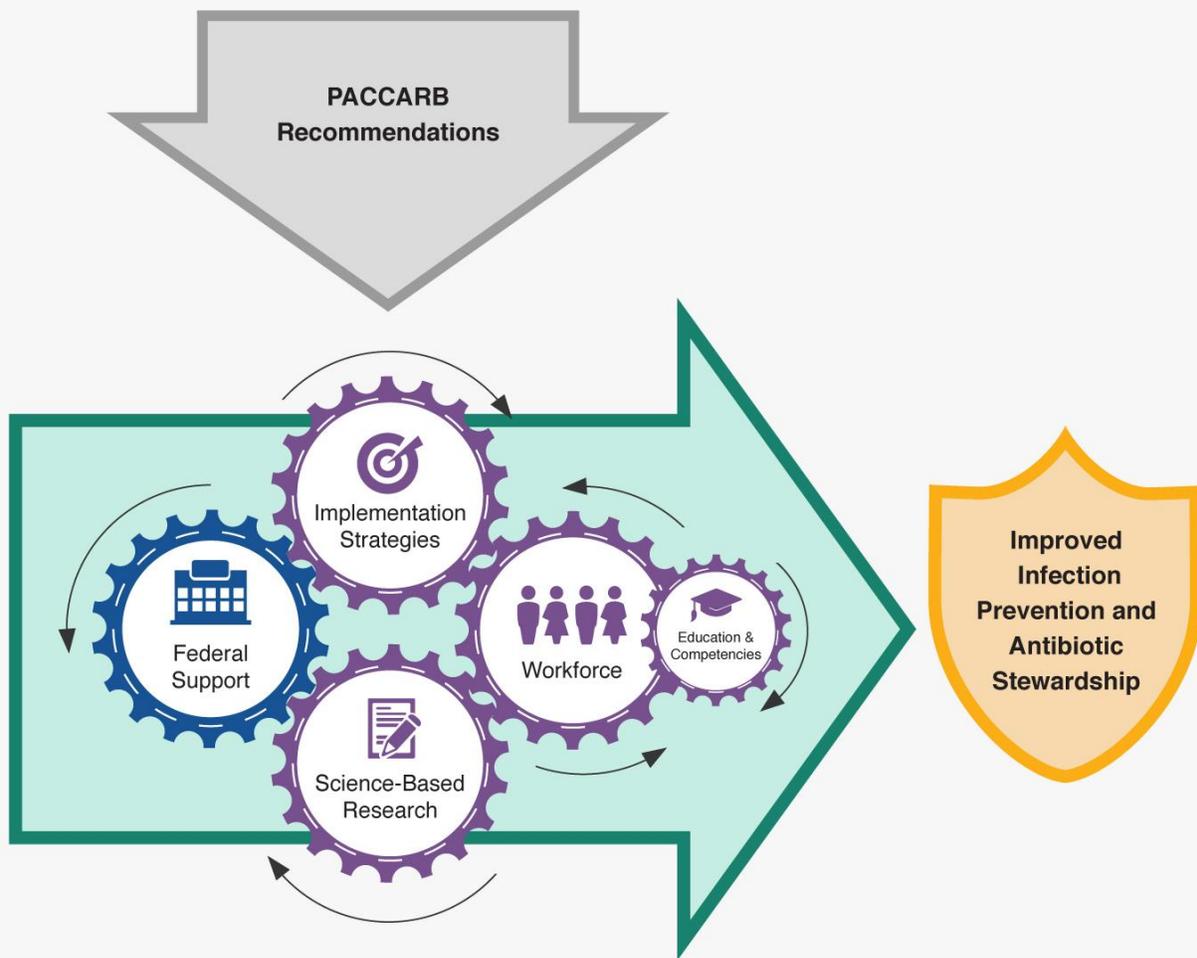
PACCARB SUMMARY RECOMMENDATIONS

I. Human Health

II. Animal Health

1

Support research on infection prevention and antibiotic stewardship.

1. Determine the IP&AS strategies that most impact clinical outcomes and antibiotic resistance in all healthcare settings, including post-acute and ambulatory care settings.
2. Evaluate current approaches and develop novel strategies for influencing provider behavior around antibiotic prescribing and infection prevention.
3. Determine optimal antibiotic treatments for common infections that best balance duration, efficacy, spectrum, and propensity to alter the microbiome or drive the development of antibiotic resistance, and develop approaches to ensure that patients receive these treatments.
4. Evaluate reasons for variability in antibiotic prescribing across prescribers and regions and identify strategies to increase consistency with best recommended practices.
5. Determine the most effective strategies for IP&AS in vulnerable populations such as neonates, immunocompromised patients, and post-acute care residents.

Support research on infection prevention and antibiotic stewardship.

1. Correlate antibiotic use, infection prevention, and antibiotic stewardship with clinical outcomes and antibiotic resistance for companion animals and food animals.
2. Understand prescribing behaviors and antibiotic use patterns in food animals and companion animals.
3. Develop novel strategies and evaluate current approaches to influence provider behavior around antibiotic prescribing and infection prevention.
4. Evaluate current on-farm and production system interventions that target animal production environments as possible sources of antibiotic-resistant bacteria that may cause infection.

2

Promote innovations for infection prevention and antibiotic stewardship.

1. Evaluate and implement innovative control measures that address the healthcare environment as a source of healthcare-associated infections (HAIs).
2. Evaluate effective and safe interventions to reduce carriage of *C. difficile*, multi-drug resistant organisms (MDROs), and other organisms causing HAIs.
3. Determine and implement optimal methods to detect, track, report, and control the regional spread of MDROs in all settings, including post-acute care facilities, especially long-term acute care hospitals (LTACHs) and skilled nursing facilities that care for patients on ventilators (vSNFs).
4. Assess and encourage the use of novel techniques to design, construct, and produce new products and pathways for treating, diagnosing, and preventing infections.

Promote innovations for infection prevention and antibiotic stewardship.

1. Develop alternative products for disease treatment, prevention, and control in animals, and for enhancing host immunity.
2. Assess and promote ongoing improvements and novel approaches to treat, diagnose, and prevent infections at the individual, flock, or herd level in food animal populations.
3. Develop approaches for assessing the efficacy of IP&AS programs and their return on investment for the agricultural producer.

I. Human Health

II. Animal Health

3

Improve metrics for infection prevention and antibiotic stewardship across all healthcare settings for benchmarking and public reporting.

1. Enhance existing metrics and develop new ones to assess and benchmark use and effectiveness of antibiotic therapy and the prevalence of antibiotic-resistant organisms in all healthcare settings.
2. Require hospital data reporting to CDC's NHSN Antibiotic Use and Resistance (AUR) module to allow a comprehensive analysis of antibiotic use and resistance for the creation of benchmarks and assessments.
3. Enhance existing metrics and develop new ones to assess and benchmark HAIs in post-acute and ambulatory care settings.
4. Require submission of select data on HAIs by facilities providing post-acute and complex ambulatory care to CDC's NHSN system to allow for benchmarking.
5. Refine and expand public reporting of risk-adjusted benchmarked rates of antibiotic use and HAIs and use these data for incentives for improvement.

Perform comparative analyses of infection prevention and antibiotic stewardship data.

1. Assess the effectiveness of antibiotic therapy in veterinary settings.
2. Develop and apply programs to allow peer comparison across settings and regions to determine drivers of variability in antibiotic prescribing and use, and ultimately identify strategies to control differences.
3. Devise new methods to collect antibiotic use data, in addition to sales data, and enable sector-specific comparative analyses.
4. Determine best approaches for the use of metrics as a basis for incentives and behavior modification to improve IP&AS practices.

4

Promote use of rapid diagnostic tests and diagnostic stewardship as mechanisms to reduce antibiotic misuse in both inpatient and outpatient settings.

1. Develop and encourage use of point-of-care (POC) tests, with shorter turn-around times.
2. Assess logistics, cost-benefit, acceptability, and appropriate integration into clinical practice of POC testing for existing and future tests.
3. Determine and evaluate which tests are being used inappropriately, and develop interventions to support more appropriate testing.

Promote diagnostic testing to support antibiotic stewardship and infection control.

1. Develop more identification diagnostic tests and additional clinical breakpoints for animal pathogens.
2. Support greater availability of diagnostic tests and promote more efficient dissemination of results for veterinarian use.
3. Assess logistics, cost-benefit, and acceptability of POC testing.
4. Produce guidelines and recommendations for revised diagnostic strategies for use by clinical diagnostic laboratory support.

I. Human Health

II. Animal Health

(5)

Develop new federal policies, standards, and payment methods to support infection prevention and antibiotic stewardship.

1. Immediately finalize the Medicare conditions of participation (CoP) requirements for antibiotic stewardship programs, as proposed in June of 2016, in hospitals and critical access hospitals.
2. Enforce the Medicare CoP requirements for antibiotic stewardship and infection control programs in long-term care facilities.
3. Make reporting of antibiotic use measures a mandatory component of the Merit-based Incentive Payment System (MIPS) for outpatient prescribers.
4. Determine approaches to require and incentivize activities to improve IP&AS in complex ambulatory settings.
5. Develop reimbursement approaches for IP&AS activities for hospitals and post-acute care institutions.

Develop new federal policies, standards, and guidelines to support infection prevention and antibiotic stewardship for all species.

1. Promote and encourage influential organizations and specialty boards to build on existing programs or establish and implement new standards and guidelines for IP&AS across the spectrum of animal species and veterinary practices.
2. Encourage the use of standardized medical records with an emphasis on electronic health records (EHR) that include detailed antibiotic use data.
3. Expand resistance surveillance activities to include animal pathogens and include the expansion of on-farm data collection and integration.
4. Support the new FDA five-year action plan, *Supporting Antimicrobial Stewardship in Veterinary Settings*, which is designed to include and promote stewardship in companion and food animal practices and ensure that these programs are integrated with other federal strategies.

(6)

Build resource capacity to implement actionable infection prevention and antibiotic stewardship programs.

1. Expand the role of and resources available to Hospital Improvement Innovation Networks (HIINs) and Quality Innovation Network-Quality Improvement Organizations (QIN/QIOs) to support IP&AS.
2. Expand the Antibiotic Resistance Solutions Initiative (ARSI) funding made available to the CDC to encourage the adoption and execution of IP&AS programs.
3. Determine staffing requirements in acute and post-acute care settings, especially LTACHs and vSNFs, and incorporate these as required elements for accreditation.
4. Institute and sufficiently fund student loan repayment and forgiveness programs for infectious disease (ID) physicians, ID pharmacists, and infection preventionists and ensure the government's continuation of the Public Service Loan Forgiveness Program (PSLF).
5. Develop funding for graduate medical, pharmacy, and nursing education that reinforce IP&AS.

Build resource capacity to implement infection prevention and antibiotic stewardship programs.

1. Ensure the government's continuation of the PSLF to encourage public service careers and build more expertise in AMR.
2. Financially support federal and state-based veterinary loan repayment programs to address shortages and help build an adequate veterinary workforce in rural areas.
3. Provide support for and establish more public-private partnerships to carry out IP&AS programs and leverage existing ones in academia and industry.

I. Human Health

II. Animal Health

7

Expand, standardize, and improve delivery of infection prevention and antibiotic stewardship education and training at all levels of the healthcare workforce.

1. Require education and training accrediting bodies to include a model curriculum in IP&AS that is taught at all levels of healthcare and continuing worker education. Incorporate existing recommended core competencies.
2. Highlight hand hygiene in curricula at all levels of training as a foundational requirement for successful infection prevention. Recognize and apply successful tactics for achieving high hand hygiene compliance in healthcare settings.

Expand, standardize, and improve delivery of infection prevention and antibiotic stewardship education and training at all levels of the veterinary medical workforce.

1. Determine core antibiotic stewardship competencies across all species.
2. Create a model curriculum in IP&AS based on core competencies across all species.
3. Collaborate with veterinary medical accreditation organizations to ensure that veterinary medical curricula include an integration of AMR content including IP&AS and that students acquire the necessary competencies to deliver effective IP&AS programs.
4. Work with state veterinary boards to develop continuing education requirements that include IP&AS.

I. HUMAN HEALTH

I-1. *Support Research on Infection Prevention and Antibiotic Stewardship.*

Successful infection prevention and antibiotic stewardship (IP&AS) policies and programs need to have a foundation based in sound scientific and clinical-epidemiologic principles and evidence. While much is known about antibiotic resistance and the mechanisms by which it contributes to serious negative patient outcomes, more studies are needed to improve existing IP&AS practices and to develop new strategies to combat antibiotic resistance. The NIH, CDC, and AHRQ should allocate funding, including for investigator-initiated research, to support study in the following areas.

I-1.1. Determine the IP&AS strategies that most impact clinical outcomes and antibiotic resistance in all healthcare settings, including post-acute and ambulatory care settings.

It is essential to determine what strategies in IP&AS are effective in achieving sustained improvements in clinical outcomes and antibiotic resistance metrics so that these approaches can be prioritized for implementation. Further, while work remains to elucidate these strategies in the acute care setting, an emphasis should also be placed on determining successful approaches in the post-acute and ambulatory care settings where less attention has been placed to date. Priority areas include strategies to reduce the spread of multi-drug resistant organisms (MDROs) from patient to patient and strategies to prevent emergence of MDROs and *Clostridium difficile* as adverse events in patients receiving antibiotics. Specific examples of needed investigations are noted in the sections below. This work should be performed via multicenter trials whenever possible to ensure greater generalizability of strategies and to assess their impact on rarer outcomes. In addition, it should support and inform the development of metrics that are correlated with improved patient outcomes and reduction in antibiotic resistance.

I-1.2. Evaluate current approaches and develop novel strategies for influencing provider behavior around antibiotic prescribing and infection prevention.

Best practices for IP&AS have been identified for many different healthcare settings, yet uptake remains low. In many cases, the appropriate guidelines are in place, but it remains a challenge to change the behavior of the healthcare provider to ensure adherence. For example, prescribers often feel pressure from patients to prescribe antibiotics even though they may not be warranted, whether due to the provider's perception that their patient is demanding an antibiotic, or the patient's actual demand. Similarly, proper hand hygiene is an essential component of effective infection control, yet many institutions struggle with low hand hygiene compliance. Specific funding should be provided to identify and evaluate strategies to influence provider behavior so that proper IP&AS practices will be more widely adopted.

I-1.3.   Determine optimal antibiotic treatments for common infections that best balance duration, efficacy, spectrum, and propensity to alter the microbiome or drive the development of antibiotic resistance, and develop approaches to ensure that patients receive these treatments.

Extended use of antibiotics allows for selection and propagation of antibiotic-resistant bacteria and should be avoided. The duration of many antibiotic therapy regimens has not been studied to determine whether a shorter regimen would be equally effective. If proven effective, a shorter duration could provide the added benefit of reducing antibiotic exposures that not only promote resistance, but may also threaten the continued effectiveness of the recommended regimen. Studies of specific treatment protocols, especially those for common diseases and those with a high frequency of resultant antibiotic resistance, should be funded and performed to determine when and how antibiotics can be de-escalated to narrower therapy or stopped completely, as well as the minimal effective duration of therapy. Further, studies of approaches to help clinicians recognize when antibiotics are not indicated are needed to reduce unnecessary antibiotic exposure.

Currently, treatment regimens often far exceed the recommended duration. Reasons include purposeful extension due to a prescriber's choice or accidental extension during transitions of care, when patients are discharged on antibiotics between units, to the home, or to another healthcare facility. Research that identifies approaches to mitigate the reasons that prescribers extend durations and to facilitate better communication to patients and practitioners who are assuming care for a patient who is completing a treatment regimen could reduce antibiotic use.

I-1.4.   Evaluate reasons for variability in antibiotic prescribing across prescribers and regions and identify strategies to increase consistency with best recommended practices.

Studies evaluating antibiotic use have identified significant, unexplained variability in antibiotic prescribing across providers and regions in the United States. There are also different rates at which MDROs are developing in different regions of the United States. Understanding the reasons for these variations is an important step in understanding drivers of antibiotic prescribing and a critical step in identifying what approaches may work to increase consistency and appropriateness of prescribing with best recommended practices. In higher use areas, the healthcare settings where antibiotic exposures are common and potentially excessive should be targets of setting-specific strategies that reduce inappropriate use.

I-1.5.   Determine the most effective strategies for IP&AS in vulnerable populations such as neonates, immunocompromised patients, and post-acute care residents.

Most IP&AS interventions have been developed for the acute-care setting for the general population. Vulnerable populations such as neonates, the immunocompromised, and post-acute care residents are particularly susceptible to healthcare-associated infections (HAIs) and infections with antibiotic-resistant bacteria, including MDROs. A better understanding of the unique needs of and risks to vulnerable populations is needed to enable the development of interventions specifically targeted for them.

I-2. *Promote Innovations for Infection Prevention and Antibiotic Stewardship.*

New techniques, products, and processes that use new approaches to combating antibiotic resistance are continually under development. Evaluation of such interventions and implementation of those deemed safe and effective should be an ongoing priority.

I-2.1. Evaluate and implement innovative control measures that address the healthcare environment as a source of healthcare-associated infections (HAIs).

Contamination of the healthcare environment with antibiotic-resistant organisms that subsequently infect or colonize patients is an important contributor to HAIs. Environmental contamination has been shown to contribute to colonization or infections with resistant bacteria and *C. difficile*, among other organisms. Better environmental treatments and strategies to clean and disinfect surfaces, equipment, air, and water can potentially reduce sources of HAIs and should be evaluated for their safety and efficacy, and implemented where appropriate.

I-2.2. Evaluate effective and safe interventions to reduce carriage of *C. difficile*, multi-drug resistant organisms (MDROs), and other organisms causing HAIs.

Humans carrying opportunistic, antibiotic-resistant pathogens that can cause serious and life-threatening infections have been established as reservoirs from which these organisms both cause infection and are transmitted. In addition, beneficial commensals can develop resistance during antibiotic exposures, serving as a reservoir for antibiotic resistance genetic elements that can be subsequently transferred to pathogens. Interventions directed at modifying the microbiome—including the use of specifically modified probiotics, bacteriophage modification of gut organisms, and feeding the microbiome to assure increased populations of helpful microbial populations—could reduce its contribution to antibiotic-resistant infections and other HAIs while enhancing its role in prevention of MDROs.

I-2.3. Determine and implement optimal methods to detect, track, report, and control the regional spread of MDROs in all settings, including post-acute care facilities, especially long-term acute care hospitals (LTACHs) and skilled nursing facilities that care for patients on ventilators (vSNFs).

A recognized driver of the spread of MDROs is the sub-optimal coordination of information about the presence of colonization and infection with these organisms at the time of transfers and medical visits. In particular, control of MDROs in acute care hospitals will not be achieved without tracking and addressing the considerable burden of MDRO carriage among LTACH and vSNF patients who often cycle through multiple healthcare facilities. Determining the optimal strategies for this work is critical and must be studied. Several initiatives are currently underway to enhance the ability to detect and track antibiotic-resistant organisms in patients and act upon this knowledge to reduce the risk of transmission. For the most part, these are funded by CDC and implemented by academic centers as partners with state and local health departments and state laboratories. However, there remains variability in the extent of reporting and coordination of information.

Additional funded work should be done by CDC and state health departments and labs to determine the best ways to track and benchmark the presence of resistant organisms in patients and coordinate the work being done at the facility, state, regional, and federal levels.

Development of registries of patients with MDROs that sites are required to report to and that can be accessed by regional healthcare institutions when a patient is transferred should be funded and expanded to cover all regions in the U.S. Approaches that increase provider access to electronic health record (EHR) data across care settings should be expanded. The role of active surveillance, in which patients and long-term care facility residents are uniformly cultured to detect the presence of resistant organisms and *C. difficile*, as a prevention strategy requires further study to determine if it enhances infection prevention efforts and/or has unintended consequences (e.g., cost or increases in unnecessary antibiotic therapy). State-mandated active surveillance that is not fully supported by CDC guidelines is strongly discouraged.

I-2.4. Assess and encourage the use of novel techniques to design, construct, and produce new products and pathways for treating, diagnosing, and preventing infections.

Nascent technologies to treat, prevent, or diagnose infections, including applications of CRISPR-Cas, nanoparticle delivery systems, interruption of quorum sensing with quenchers, targeted modification of pathogenicity islands, development and use of adjuvant molecules that help target or enhance the function of existing antibiotics, monoclonal antibodies, phage therapy, and new vaccines show promise for combating infections while minimizing the need for antibiotics. Further research and development of these and other novel approaches should be encouraged and supported.

I-3. *Improve Metrics for Infection Prevention and Antibiotic Stewardship across All Healthcare Settings for Benchmarking and Public Reporting.*

Standardized metrics that capture the amount and quality of antibiotic use, rates of HAI, and rates of colonization and infection with antibiotic-resistant bacteria are needed across all healthcare settings. These are important to allow for benchmarking within and among institutions and provider groups and to drive improvements in IP&AS activities. Revision of existing metrics and development of new metrics requires active involvement of CDC, CMS, and other relevant federal and non-federal stakeholders. Once standardized metrics are revised/developed and benchmarking implemented, additional requirements include adequate IP&AS staffing for collection and interpretation of resulting data. Additionally, the augmentation of EHR capabilities to allow for electronic submission of data to CDC's National Healthcare Safety Network (NHSN) system; improvements in risk-adjustment methodologies used by NHSN to ensure accuracy and fairness when benchmarking data; and public reporting of benchmarked data in conjunction with an interpretation guide explaining how the data should be understood and used for improvement, will work toward defining and promoting the use of appropriate benchmarks.

I-3.1. Enhance existing metrics and develop new ones to assess and benchmark use and effectiveness of antibiotic therapy and the prevalence of antibiotic-resistant organisms in all healthcare settings.

Currently, the only standardized metric for antibiotic use in the U.S. is the CDC's Standardized Antimicrobial Administration Ratio (SAAR), which compares observed to predicted days of antimicrobial therapy based on aggregated antibiotic use data reported to the CDC via the NHSN

Antibiotic Use and Resistance (AUR) Module. This metric is limited by the relatively low proportion of acute care hospitals that submit data (see recommendation I-3.2 below), the lack of data from post-acute care and ambulatory settings, and the lack of robust risk adjustment based on patient- and institution-level characteristics that impact the volume of antibiotics prescribed. Enhancements to the SAAR should be undertaken to address this latter issue. CDC should develop approaches to obtain and benchmark data on antibiotic use from the post-acute care and ambulatory settings. This will require capacity building in these sites to make the electronic collection of antibiotic use data possible.

In addition, metrics to assess the quality and appropriateness of antibiotic use should be developed. For example, using a chart sampling strategy (such as that employed in the Surgical Care Improvement Project Core Measure Set), measures such as the following could be developed and would allow for benchmarking of appropriate antibiotic use for these syndromes: assessment of the proportion of patients receiving antibiotic therapy for asymptomatic bacteriuria, the proportion of patients receiving non-recommended empiric therapy or greater than five days of therapy for community-acquired pneumonia, or the proportion of patients with bronchitis receiving antibiotics. These measures need to be collected as close to real-time as possible to facilitate provider feedback.

While the AUR Module was designed with the capacity to receive antibiotic susceptibility data, few hospitals are currently reporting this information, and no other systematic approaches for reporting on the proportions of antibiotic-resistant organisms in other healthcare settings exist. Approaches to expand the capacity for reporting of antibiotic resistance should occur in conjunction with those to expand the reporting of antibiotic use.

I-3.2. Require hospital data reporting to CDC's NHSN Antibiotic Use and Resistance (AUR) module to allow a comprehensive analysis of antibiotic use and resistance for the creation of benchmarks and assessments.

The majority of hospitals in the U.S. currently do not report antibiotic use or resistance data to the AUR Module because reporting is voluntary, and many institutions do not have the EHR capability that is required for submission of data to NHSN. Consequently, most hospitals are unable to benchmark their antibiotic use against other similar institutions to obtain data on potential targets for improvement. CDC and CMS should collaborate to develop a timeline for reporting to the AUR Module to be required. If this requirement is operationalized via the Hospital Inpatient Quality Reporting Program, the SAAR should remain a Pay for Reporting measure (and not progress to a Pay for Performance measure) until appropriate risk-adjustment methodology is determined by CDC. CDC must continue work with EHR vendors to guarantee electronic capability for reporting.

I-3.3. Enhance existing metrics and develop new ones to assess and benchmark HAIs in post-acute and ambulatory care settings.

Metrics and benchmarking for HAIs, including those caused by antibiotic-resistant bacteria, have been developed and implemented in the hospital setting and in some non-acute care settings such as dialysis centers and LTACHs, via reporting to the NHSN. There is a voluntary option for nursing homes (including SNFs) to report urinary tract infections and *C. difficile* events in NHSN, although currently only ~3,000 nursing homes are reporting these events. Other settings

such as high-risk ambulatory settings (e.g., ambulatory surgical centers, clinics that provide complex care to immunocompromised patients and patients receiving outpatient therapy via central catheters) do not have existing infection prevention metrics or benchmarks. Given that post-acute and ambulatory environments are increasingly recognized as reservoirs for resistant organisms and account for a growing proportion of medical care delivery, standardized metrics should be developed to track the HAIs (e.g., surgical site infections and central line associated bloodstream infections) and *C. difficile* infections that are most associated with patient harm. Metrics that are developed should account for differences in the data available for patients in these settings compared to the acute care setting. Further, benchmarking should be facilitated through increased funding for expansion of the NHSN system to allow for submission of relevant data from post-acute and ambulatory care settings to CDC.

I-3.4. Require submission of select data on HAIs by facilities providing post-acute and complex ambulatory care to CDC's NHSN system to allow for benchmarking.

To drive improvement in HAI prevention and prevention of the spread of resistant organisms, reporting of data on those HAIs identified by experts to be the most actionable from post-acute and ambulatory settings should be required by CMS rather than voluntary.

I-3.5. Refine and expand public reporting of risk-adjusted benchmarked rates of antibiotic use and HAIs and use these data for incentives for improvement.

Public reporting of antibiotic use and HAI metrics is an important element of antibiotic stewardship. With continued and expanded reporting, appropriate risk-adjustment of data is needed in order to understand and account for the drivers of antibiotic use and HAI rates at different sites. The risk-adjustment methodology and other information that is critical for interpretation of the data by healthcare institutions and the public must be included in a detailed document that accompanies all publicly-reported data. Data must be presented in a way that is understandable and usable by the general public and by healthcare institutions, who should use the data to inform and motivate IP&AS improvement efforts.

I-4. Promote Use of Rapid Diagnostic Tests and Diagnostic Stewardship as Mechanisms to Reduce Antibiotic Misuse in both Inpatient and Outpatient Settings.

Diagnostic tests are an important asset that can aid physicians and other healthcare providers in making informed decisions about antibiotic use. Diagnostic tests can be used to distinguish between viral and bacterial infections, identify infection-causing organisms, or determine the antibiotic susceptibility profile of infection-causing bacteria, among other uses. Infection prevention and control efforts can also be enhanced through utilization of rapid diagnostic testing, which would enable earlier and more targeted implementation of infection prevention activities. However, inappropriate use of diagnostic tests, including both lack of use and overuse as well as misinterpretation of test results, can lead to inappropriate treatment decisions and may contribute to disease spread, antibiotic resistance, and other potential harms. Linking diagnostic testing to antibiotic treatment via stewardship is critical to ensuring optimal outcomes for individuals and large patient populations, for resource utilization, and for the prevention of AMR.

I-4.1. Develop and encourage use of point-of-care (POC) tests, with shorter turn-around times.

As detailed in the [PACCARB Incentives Report](#) (p. 14), there is an unmet need for rapid POC tests that can distinguish between viral and bacterial infections or identify bacteria and provide antibiotic susceptibility information. Such tests are especially necessary in outpatient settings, where antibiotic use is high and fast turnaround is required for test results. A vast proportion of inappropriate antibiotic use in the United States originates in the outpatient setting, including physicians' offices, urgent care centers, dermatology offices, dental offices, and emergency rooms. The development of and use of rapid tests that can be used at the POC in the outpatient setting is expected to help decrease inappropriate antibiotic use.

I-4.2. Assess logistics, cost-benefit, acceptability, and appropriate integration into clinical practice of POC testing for existing and future tests.

Successful encouragement of use of existing POC tests involves overcoming several technical and operational challenges, including time constraints on patients and providers, and the potentially higher cost and lower sensitivity or specificity of POC tests compared to standard laboratory tests. Furthermore, use of POC tests requires proper training of staff, development of operational guidelines for how and when to use them, and methods for documentation and interpretation of results. Evaluation and assessment of these factors will help to identify existing barriers that prevent effective use of POC tests and inform efforts to increase their use when appropriate. The results of these evaluations should provide feedback and be integrated into clinical practice protocols and guidelines at institutional, local, and national levels. This will further inform and motivate continued development of POC diagnostic tests.

I-4.3. Determine and evaluate which tests are being used inappropriately, and develop interventions to support more appropriate testing.

When used appropriately, diagnostic tests can reduce unnecessary use of antibiotics, for example by distinguishing between viral and bacterial infections. However, inappropriate use of diagnostic tests can result in over-prescription of antibiotics, such as when colonization is mistaken for an infection based on the results of a culture test that was performed unnecessarily. All rapid diagnostics need to be evaluated to determine how best to integrate them into clinical practice, with appropriate clinical decision-making to decide whether to use the diagnostic. Determining which diagnostics are frequently used inappropriately will help to prioritize development of interventions focused on clinical decision-making (e.g. clinical guidelines and protocols) to improve use of these diagnostics, and thereby to reduce unnecessary antibiotic prescriptions while informing and supporting appropriate use of diagnostic tests to improve antibiotic stewardship.

I-5. Develop New Federal Policies, Standards, and Payment Methods to Support Infection Prevention and Antibiotic Stewardship.

Federal government entities have an important role in supporting IP&AS activities. As major regulators, CMS has an opportunity to leverage current programs to promote adoption of more robust standards among participating facilities. Furthermore, CMS is also uniquely positioned to

incentivize and enforce more robust standards through innovative payment reform and reimbursement.

I-5.1. Immediately finalize the Medicare conditions of participation (CoP) requirements for antibiotic stewardship programs, as proposed in June of 2016, in hospitals and critical access hospitals.

Finalizing the Medicare CoP requirements for antibiotic stewardship is a critical step in providing the impetus for creation and expansion of antimicrobial stewardship programs (ASPs) in acute and critical access hospitals. The Joint Commission (TJC) Antibiotic Stewardship Standard can be used as an example of how implementing and enforcing requirements in antibiotic stewardship can lead to improvements in antibiotic stewardship capacity. However, the Medicare CoP are necessary both to add support for hospitals that are accredited by TJC and to include hospitals that are not accredited by TJC, such as many critical access hospitals. In addition, CMS should engage with experts at CDC to develop detailed Interpretive Guidelines that outline the required elements of ASPs including all aspects of CDC's Core Elements of Hospital ASPs. CMS should develop training to ensure that surveyors are able to assess the quality and outcomes of ASPs in depth.

I-5.2. Enforce the Medicare CoP requirements for antibiotic stewardship and infection control programs in long-term care facilities.

The Medicare CoP requirements for antibiotic stewardship in nursing homes that went into effect in November 2017 and the expanded requirements for infection control programs that went into effect in November 2016 are significant steps forward in requiring and standardizing antibiotic stewardship and infection control activities in the post-acute care setting. Given the challenges of ensuring actionable antibiotic stewardship and infection control measures in this setting, continued attention by CMS to enforce the CoP requirements is essential, including assessment of surveyors' abilities to detect the depth and success of antibiotic stewardship and infection control activities at sites.

I-5.3. Make reporting of antibiotic use measures a mandatory component of the Merit-based Incentive Payment System (MIPS) for outpatient prescribers.

Several antibiotic use measures are currently options for reporting in the MIPS; however, prescribers are not obligated to select these measures for reporting. CMS should explore making the antibiotic use measures required for all specialties for which measures currently exist. CMS should also evaluate additional antibiotic use measures for specialties for which none currently exist. Of note, this does not address prescribing practice in settings with self-payment such as urgent care clinics, which fall outside of the CMS reimbursement mechanism; this remains a gap to be addressed.

I-5.4. Determine approaches to require and incentivize activities to improve IP&AS in complex ambulatory settings.

As noted in recommendation I-3.3, a significant proportion of medical care that previously resulted in inpatient admission is now being delivered in outpatient settings, including in ambulatory surgical centers, dialysis centers, clinics that provide complex care to immunocompromised patients, and patients receiving outpatient therapy via central catheters.

CDC and CMS should investigate approaches to enhancing antibiotic stewardship and infection control in these areas, including making payment contingent on successful demonstration of meeting antibiotic stewardship and infection control benchmarks.

I-5.5. Develop reimbursement approaches for IP&AS activities for hospitals and post-acute care institutions.

Currently, there is no specific reimbursement mechanism from CMS (e.g., evaluation and management codes) that would provide resources to hospitals and post-acute care facilities for enhanced IP&AS activities including adequate staffing of IP&AS programs. Indeed, hospitals that are struggling with higher HAI rates receive *less* reimbursement, which may negatively impact their ability to make needed improvements to prevent infection and optimize antibiotic use. CMS should investigate novel reimbursement strategies that specifically target provision of funds to hospitals and post-acute care institutions to enhance antibiotic stewardship and infection control.

I-6. Build Resource Capacity to Implement Actionable Infection Prevention and Antibiotic Stewardship Programs.

Expanding capacity for IP&AS activities across healthcare settings is an important step in combating antibiotic resistance. These efforts must include maintaining and expanding existing federal and state programs that coordinate and support IP&AS work and facilitating the development of a larger, more robust workforce with expertise in IP&AS.

I-6.1. Expand the role of and resources available to Hospital Improvement Innovation Networks (HIINs) and Quality Innovation Network-Quality Improvement Organizations (QIN/QIOs) to support IP&AS.

Providing additional federal support to HIINs and QIN/QIOs will help further disseminate and augment shared expertise in the implementation of IP&AS activities across all healthcare settings, as these entities serve as resources to drive regional assessments of care and practice improvements. HIINs and QIN/QIOs should be contractually required to staff appropriately trained individuals with specific expertise in IP&AS and implementation science to ensure that the programs they coordinate provide maximum benefit to healthcare institutions across acute, post-acute, and ambulatory settings. HIINs and QIN/QIOs should be encouraged to employ effective approaches and take advantage of available resources to guide implementation efforts. For example, AHRQ conducts nationwide implementation projects to promote the use of evidence-based methods for improving IP&AS, such as through the use of the Comprehensive Unit-based Safety Program (CUSP).

In addition, HIINs and QIN/QIOs should work in close collaboration with state health departments to implement IP&AS efforts, including assessments of the presence and quality of IP&AS activities in all healthcare settings. For example, QIN/QIOs could perform site visits at dialysis centers and ambulatory surgery centers to ensure that appropriate IP&AS strategies are in place and could provide mechanisms to track antibiotic use and clinical outcomes using CMS data in the ambulatory setting. Effective initiatives that result from work coordinated by HIINs and QIN/QIOs should be disseminated widely.

I-6.2. **Expand the Antibiotic Resistance Solutions Initiative (ARSI) funding made available to the CDC to encourage the adoption and execution of IP&AS programs.**

The role of the CDC's ARSI is to support national infrastructure to detect, respond, contain, and prevent resistant infections across healthcare settings, food, and communities. Expanding funding for this initiative will allow for the expansion of activities of state health departments across the U.S. in their efforts to track MDROs in all healthcare settings and intervene to prevent their spread through IP&AS. As with HIINs and QIN/QIOs, state health departments receiving funding should staff appropriately trained individuals with specific expertise in IP&AS and implementation science and should work in collaboration with HIINs and QIN/QIOs to assess the presence and quality of IP&AS activities in all healthcare settings and coordinate collection and dissemination of needed data.

I-6.3. **Determine staffing requirements in acute and post-acute care settings, especially LTACHs and vSNFs, and incorporate these as required elements for accreditation.**

There are two overriding staffing issues in IP&AS: insufficient numbers of staff to perform IP&AS work and insufficient numbers of front-line staff (e.g., nurses and aides) to provide direct patient care. While reasonable estimates for infection control staffing needs in acute care can be made (e.g., one infection preventionist needed per 100 acute care inpatient beds) studies are needed to determine antibiotic stewardship staffing requirements in acute care and IP&AS staffing requirements in post-acute and ambulatory settings. Estimates of requirements for direct care providers in ICUs and on general medical-surgical wards are also known, based on acuity of care of the specific patients on those units. However, optimal staffing levels in post-acute care settings are not known and current staffing is highly variable, with healthcare provider-to-patient ratios varying two-fold or more for similarly ill populations of ventilator-dependent patients in different types of facilities; ratios are often less favorable in vSNFs than in LTACHs. Studies are needed to determine what levels of staffing in post-acute care will allow timely delivery of needed patient care services and will insure adherence to IP&AS protocols.

Once there are well-vetted estimates of staffing requirements throughout the healthcare continuum, standards should be developed and adherence to these standards insured by accrediting organizations and healthcare payers.

I-6.4. **Institute and sufficiently fund student loan repayment and forgiveness programs for infectious disease (ID) physicians, ID pharmacists, and infection preventionists and ensure the government's continuation of the Public Service Loan Forgiveness Program (PSLF).**

The PSLF Program, which forgives the remaining balance on direct loans after a professional has worked for a qualifying employer, serves as a powerful incentive for government service and, when properly structured, can incentivize entry into needed fields. Increasing the workforce of trained ID physicians, ID pharmacists, and infection preventionists will decrease the spread of MDROs which in turn will decrease both their incidence and resulting medical complications and thus, the social and economic costs from these infections. Data suggest, but economic evaluations should be performed to confirm, that the decreasing cost of these medical complications will reveal that loan forgiveness and loan repayment programs save the

government money. The federal government should continue to fund the PSLF program, which is under consideration for cancellation.

I-6.5. Develop funding for graduate medical, pharmacy, and nursing education that reinforce IP&AS.

A mechanism to promote graduate, medical, pharmacy, and nursing school education directed at ID specialties through additional grants, scholarships, and fellowships should be considered. For example, the CMS pass-through funds provided for first year pharmacy residents should be provided to ID pharmacy residents as well. Financial support to students is a strong incentive to ultimately increase the number of IP&AS specialists.

I-7. Expand, Standardize, and Improve Delivery of Infection Prevention and Antibiotic Stewardship Education and Training at all Levels of the Healthcare Workforce.

IP&AS are critical activities that should be taught to all healthcare students and providers. This education must happen at all stages of medical education and healthcare training. Frequent and consistent education and training of IP&AS principles are needed to achieve full understanding and effective implementation.

I-7.1. Require education and training accrediting bodies to include a model curriculum in IP&AS that is taught at all levels of healthcare and continuing worker education. Incorporate existing recommended core competencies.

A model curriculum that provides standardized IP&AS content should be developed from existing identified core competencies such as the HICPAC Core Infection Prevention and Control Practices. Antibiotic resistance is a complex subject requiring a core curriculum that stresses systems dynamics, problem solving, and systems thinking, training which is not currently integrated uniformly in medical, pharmacy, or nursing schools. It is important to develop, plan, integrate, and deliver model curricula for medical, pharmacy, and nursing schools across didactic, laboratory, clinical, and practice-based education programs. Academic institutions should be tasked to develop a curriculum that better integrates IP&AS learning across disciplines, course offerings, and various pedagogy including inter-professional education. To ensure the curriculum is used consistently, it must be made a required component by accreditation bodies such as the Liaison Committee on Medical Education (LCME), the Accreditation Council for Graduate Medical Education (ACGME), the American Association of Colleges of Nursing (AACN), the National League for Nursing (NLN), and the Accreditation Council of Pharmacy Education (ACPE).

I-7.2. Highlight hand hygiene in curricula at all levels of training as a foundational requirement for successful infection prevention. Recognize and apply successful tactics for achieving high hand hygiene compliance in healthcare settings.

Proper hand hygiene, including proper use of gloves, is an essential component of infection prevention, yet in many healthcare settings it is still not fully practiced. Barriers to high levels of hand hygiene compliance include lack of knowledge of its importance, lack of belief in its importance, and lack of available materials to make it easy and efficient. To overcome these

barriers, the importance of and indications for hand hygiene must be taught at all levels of training for all healthcare staff, and staff must be held accountable for performing hand hygiene. Further, methods to make performing hand hygiene easier should be adopted in all healthcare settings such as improving the availability and accessibility of dispensers and sinks and providing cues to perform hand hygiene. Several studies and examples of successful implementation of hand hygiene programs exist and should be leveraged to produce the behavioral changes needed to achieve complete adoption of the practice in all healthcare settings, including acute care hospitals, long-term care facilities, and outpatient settings.

II. ANIMAL HEALTH

II-1. *Support Research on Infection Prevention and Antibiotic Stewardship.*

Sound scientific evidence is a critical foundation for successful IP&AS programs. Within animal health, there are major gaps in knowledge of current prescribing behaviors as well as of the mechanisms contributing to negative outcomes with regard to antibiotic resistance. The PACCARB suggests the following as priority areas for study.

II-1.1. Correlate antibiotic use, infection prevention, and antibiotic stewardship with clinical outcomes and antibiotic resistance for companion animals and food animals.

In both companion and food animal medicine, the impacts of IP&AS interventions on antibiotic use and subsequent clinical and resistance outcomes for animal pathogens have not been clearly determined. There is a need for agricultural producers to actively monitor treatment and resistance outcomes and use them to refine stewardship practices. However, technological challenges severely limit the availability of accessible treatment records. The USG, along with other federal, state, and local partners, should fund the necessary research and work with public and private partners to harmonize data systems and create incentives for the review and analysis of treatment and resistance outcomes.

Furthermore, there is a significant gap in our understanding of AMR usage and the connectivity among different sectors and populations; especially the establishment of causation from retail meats to antibiotic-resistant infections in humans. The FDA's National Antimicrobial Resistance Monitoring System Review Committee (NRC) has looked at this issue in their 2017 report (see page 5) and has made recommendations that would strengthen a One Health approach to data sampling in an effort to better understand the human and animal health link. The PACCARB supports the NRC's recommendations and also encourages additional on-farm, environmental, and human studies through the utilization of modern and evolving research methods that can generate data to further our understanding of such relationships. This understanding will enable the identification of specific opportunities to modify practices that are expected to have the greatest effect on reducing selection for antibiotic-resistant bacteria while preserving animal health and welfare.

II-1.2. Understand prescribing behaviors and antibiotic use patterns in food animals and companion animals.

Currently, information on antibiotic use patterns in both food and companion animal health settings is sparse. National estimates of antibiotic use in food animals are derived from annual sales data submitted by pharmaceutical companies under the Animal Drug User Fee Act. However, aggregate sales data lack specific information, including dose, duration, and specific purpose for administration, and therefore are of limited value for informing stewardship. FDA's commitment to enhancing monitoring of antimicrobial drug use in animals, including finalizing a method for applying a denominator to available antimicrobial sales and distribution data and developing a long-term strategy for implementing a functional and efficient antimicrobial use monitoring and reporting system for veterinary settings, are encouraging steps in the right

direction. Moreover, voluntary surveys conducted as part of USDA's National Animal Health Monitoring Program can provide nationally representative information on antibiotic use and stewardship practices, although they are dependent on funding and the voluntary participation of agricultural producers.

There is currently no mechanism for estimating antibiotic use in companion animals, although voluntary programs by individual animal hospital systems provide valuable proof-of-concept data and should be expanded. In order to advance antibiotic stewardship in animal health, more detailed information is needed regarding current antibiotic use practices, prescribing behaviors, and the decision-making process around adoption of IP&AS interventions as well as antibiotic alternatives across the spectrum of veterinary medicine and animal health. FDA's recent commitment to fostering stewardship in veterinary settings is encouraging and voluntary initiatives by veterinary, producer, and other groups can help close these data gaps.

II-1.3. Develop novel strategies and evaluate current approaches to influence provider behavior around antibiotic prescribing and infection prevention.

Although several IP&AS principles for animal health have been described, studies to understand current prescribing behavior in veterinary medicine are needed to underpin IP&AS initiatives and should be supported by public funding from agencies such as USDA and CDC. Infection prevention in companion animal medicine is most analogous to human health settings, while for food animal populations, prevention of infectious diseases encompasses the design and operation of farms, including multiple facets such as selection and sourcing of animals, hygiene, biosecurity, and preventive use of antibiotics. Veterinarians, like human health professionals, can experience pressure from clients to prescribe antibiotics. In managing the health of herds and flocks of food animals, producers face numerous economic obstacles to implementing good infection prevention practices, including a lack of return on investment and the potential negative animal health and economic consequences of delaying or withholding antibiotic therapy when needed. New strategies developed by USDA in close collaboration with veterinary and producer associations as well as other key stakeholders will be needed to address these hurdles and promote good IP&AS practices.

II-1.4. Evaluate current on-farm and production system interventions that target animal production environments as possible sources of antibiotic-resistant bacteria that may cause infection.

Expand research on new or improved environmental interventions of on-farm and production systems including disease prevention, biosecurity, hygiene, management practices, effective vaccine use, and housing and transportation changes. In addition to effectiveness, the interventions should be evaluated for their safety and any barriers to implementation, and innovative approaches should be proposed. Interventions during processing that improve food safety should continue to be improved.

II-2. Promote Innovations for Infection Prevention and Antibiotic Stewardship.

Novel approaches are needed to provide non-antibiotic options that will contribute to a reduction in the need to use antibiotics in animals. A shift toward non-antibiotic disease interventions and infection prevention innovations also requires feasibility of implementation by veterinarians and

their clients, particularly in livestock settings, and should be considered in funding decisions for antibiotic alternatives research.

II-2.1. Develop alternative products for disease treatment, prevention, and control in animals, and for enhancing host immunity.

Non-antibiotic products that directly target specific bacterial pathogens associated with key animal diseases can include bacteriophage or bacteriocins, while modulation of the microbiome through probiotics or other methods can help combat many bacterial pathogens. Strengthening the immune system which serves as a primary defense system is accomplished by vaccines, adjuvants, and immunopotentiators. Preventing disease caused by viruses (e.g., porcine reproductive and respiratory syndrome virus, or PRRSv) may often reduce secondary bacterial infections which would otherwise require antibiotic treatment. Public-private partnerships can provide funding for these important initiatives.

II-2.2. Assess and promote ongoing improvements and novel approaches to treat, diagnose, and prevent infections at the individual, flock, or herd level in food animal populations.

Production practices such as 'backgrounding' of cattle that emphasize biosecurity, appropriate housing, nutrition, and movement or commingling of groups of animals to prevent diseases can be strengthened in the near term. One way to accomplish this is for processors, retailers, and quick service restaurants to provide market signals that indicate economic premiums for the use of adequate production practices, and for organizations such as USDA Economic Research Service to provide research quantifying the economic benefits of these production practices. The latest research tools and techniques, such as baculovirus insect cell systems, CRISPR-Cas, genomics, metagenomics, and the microbiome should underpin innovative research in the animal sector with the goal of reducing the need for antibiotics and for optimizing essential treatments; increased federal funding for this research will be important to foster progress. Traditional genetic approaches to the selection of desirable traits in production animals may be augmented by new techniques for the identification of genes associated with increased resistance to disease. Gene-editing techniques should also be applied to identify opportunities to increase disease resistance in food animal species. Ultimately, the application of such technologies will result in a reduction in research and development (R&D) time, manufacturing costs, and improved effectiveness.

II-2.3. Develop approaches for assessing the efficacy of IP&AS programs and their return on investment for the agricultural producer.

Food animal producers participate mostly in commodity markets and are attentive to input costs for their businesses. Therefore, analytic demonstrations of the cost-benefit of the implementation of any program is likely to be a powerful motivator for changing behaviors and practices. Briefly, this might be achieved by evaluating data on the economic return of marketed animals and factoring in variables such as disease costs, antibiotic costs, infection prevention expenses, and externalities like resistance pressure and adverse effects on animal health of treatment options. Organizations, associations, or most appropriately, federal agencies, should make funding available for these types of research and require economic analyses as part of research grants where applicable.

II-3. *Perform Comparative Analyses of Infection Prevention and Antibiotic Stewardship Data.*

Practices and principles of IP&AS in animal health mirror those in human health, but are applied across more diverse settings and with a more limited evidence base. Establishment and adoption of improved practices will require targeted clinical research in multiple practice settings.

II-3.1. Assess the effectiveness of antibiotic therapy in veterinary settings.

Progress can be made toward reducing antibiotic use in veterinary medicine by identifying situations where antibiotics may not be necessary or fail to be effective (e.g., because the bacterium is not susceptible to the chosen antibiotic), or where treatment protocols can be minimized without detrimental effects on animal health or welfare. The application of consensus-based treatment guidelines for common companion animal diseases (e.g., urinary tract infections, dermatological infections) has played an important role in establishing an evidence basis to optimize treatment durations. Professional organizations can and should play a leadership role in the development of these consensus-based guidelines. Targeted clinical research of diseases that are typically treated with antibiotics is needed to provide veterinarians with better evidence for therapeutic judgments about the initial need for antibiotic use and efficacy of prophylactic antibiotic use, and for optimizing treatment decisions that seek to balance risks to animal health against the potential for selection for antibiotic-resistant bacteria. This is particularly important for flock and herd-level treatments.

II-3.2. Develop and apply programs to allow peer comparison across settings and regions to determine drivers of variability in antibiotic prescribing and use, and ultimately identify strategies to control differences.

Marked variability in prescribing practices and antibiotic use occurs across all prescribing professions. The lack of an objective framework for peer comparison impedes self-assessment and revision of antibiotic use practices. Due to the diversity of species covered by veterinary medicine, any peer comparison programs need to be species- or sector-specific (e.g., dairy and beef cattle) and must account for geographic differences in disease incidence. FDA and USDA, in close collaboration with producer and veterinary associations and in collaboration with private industry partners that provide data solutions to veterinarians and producer operations, can provide the data and infrastructure needed to support effective and appropriate peer comparison. FDA's commitment to developing an antimicrobial use monitoring and reporting system for the veterinary setting is especially encouraging. Establishment of species/sector specific data sharing is a prerequisite to successful research aimed at understanding sources of variability in prescribing practices and opportunities to reduce it, and the contributions of animal producers will play a key role in this work.

II-3.3. Devise new methods to collect antibiotic use data, in addition to sales data, and enable sector-specific comparative analyses.

Aggregate sales data on antibiotic use are not sufficiently granular to analyze and understand prescribing practices in animal health. While the current data sources are useful, including FDA's recent efforts to provide species-specific antibiotic sales estimates, more detailed information is required to advance stewardship efforts and enable meaningful benchmarking for

the purpose of comparative analyses. Ongoing consolidation of veterinary services in several sectors (e.g., corporate veterinary practices, integrated livestock companies) as well as new recordkeeping requirements imposed by FDA's Veterinary Feed Directive (VFD) may provide opportunities for voluntary and confidential sharing of antibiotic use data, including via public/private partnerships. FDA, in partnership with other federal, state, local, and private partners, should work to collect and analyze the data.

II-3.4. Determine best approaches for the use of metrics as a basis for incentives and behavior modification to improve IP&AS practices.

Unlike in the practice of human medicine, no payment or reimbursement mechanisms exist to drive behavioral changes in the practice of veterinary medicine. Furthermore, in livestock and poultry in particular, investments in infection prevention interventions must be economically viable, and may be stimulated by market opportunities. Objective comparative data and metrics on antibiotic use practices at a species/sector level should prove valuable for education regarding antibiotic stewardship and provide some stimulus for the revision and reduction of less effective treatment approaches. FDA, in collaboration with USDA and other partners, should provide funding for these crucial initiatives.

II-4. Promote Diagnostic Testing to Support Antibiotic Stewardship and Infection Control.

Diagnostic laboratory support provides veterinarians with essential information on both the identity of pathogens causing disease in the animals under their care as well as a characterization of those pathogens' susceptibility to antibiotics. Advances in diagnostic techniques and their appropriate application should enable more informed and targeted use of antibiotics in veterinary medicine.

II-4.1. Develop more identification diagnostic tests and additional clinical breakpoints for animal pathogens.

New or improved diagnostic tests that identify pathogens rapidly and with greater sensitivity and specificity, including those that can be performed on-site or at the point-of-care (POC), such as a barn, feed yard, or office, are needed (see also the PACCARB Incentives Report, p. 32). The development of additional antimicrobial susceptibility testing methods and the definition of clinical breakpoints for the application of antibiotics approved for use in treating animal disease will fill an unmet need. Professional societies and other stakeholders should play a leadership role in initiating the development of these new tools. Improvements in diagnostic tests are expected to improve the efficiency of antibiotic use.

II-4.2. Support greater availability of diagnostic tests and promote more efficient dissemination of results for veterinarian use.

On-site diagnostic testing will enable the identification of pathogens in real-time, resulting in more rapid and appropriate treatment decisions. For antimicrobial susceptibility testing performed in diagnostic laboratories, turnaround time to provide results to veterinarians should be minimized; increasing research on new diagnostic methods will promote this.

II-4.3. Assess logistics, cost-benefit, and acceptability of POC testing.

Currently, collected samples are transported to a diagnostic laboratory and then tested, with the results reported to the inquiring veterinarian in two to four days. In contrast, on-site diagnostic tests would generate actionable test results in minutes to hours. The veterinarian's client, as a payer, would be encouraged to use POC tests by having data on the cost-benefit in comparison to the current testing paradigm.

II-4.4. Produce guidelines and recommendations for revised diagnostic strategies for use by clinical diagnostic laboratory support.

Laboratory diagnosticians follow standardized protocols to complete their tasks. As new methods are introduced, guidelines and recommendations for revised diagnostic strategies will be necessary. FDA, in close collaboration with relevant professional societies, should develop this guidance. POC tests, which are typically non-culture-based, are an example of where developing new diagnostic strategies will be important due to the different operational context of these tests. In addition, work to extend antimicrobial susceptibility testing capabilities should continue to be an area of emphasis.

II-5. Develop New Federal Policies, Standards, and Guidelines to Support Infection Prevention and Antibiotic Stewardship for all Species.

Developing new federal policies, standards, and guidelines for IP&AS is important for promoting the adoption of and the effective implementation of IP&AS programs. As a unifying body, federal agencies are uniquely positioned to convene and encourage influential stakeholders to adopt and promote more robust guidelines, as well as to further efforts for greater surveillance and data standardization across providers.

II-5.1. Promote and encourage influential organizations and specialty boards to build on existing programs or establish and implement new standards and guidelines for IP&AS across the spectrum of animal species and veterinary practices.

Federal agency support of veterinary practitioner and food animal production associations is critical to enabling these associations to expand and disseminate current programs related to IP&AS which define standards and educate members. FDA's recent commitment to fostering stewardship in veterinary and agricultural settings is encouraging in this respect. Involvement of these organizations in species-specific antimicrobial use benchmarking programs can be federally supported through funding of data collection platforms and efforts, as well as providing staffing resources to bring benchmarking results back to practitioners and their clients.

II-5.2. Encourage the use of standardized medical records with an emphasis on electronic health records (EHR) that include detailed antibiotic use data.

Veterinary medical records include both those records kept by practitioners and those kept by animal caretakers; both should describe antimicrobials administered under veterinary oversight. At the caretaker-level, these record-keeping activities would be promoted by ensuring the availability and affordability of such programs for small-scale caretakers, as well as by facilitating interactions with the involved veterinarians. The ability to assimilate antibiotic use data from all record types into useful, supporting data for IP&AS depends on the development

and use of a standardized approach to data formatting and reporting structures. FDA and USDA, in close collaboration with other relevant professional associations, should encourage the use of standardized, electronic systems to achieve these goals.

II-5.3. Expand resistance surveillance activities to include animal pathogens and include the expansion of on-farm data collection and integration.

Existing veterinary diagnostic laboratory integration networks such as the Veterinary Laboratory Investigation and Response Network (Vet-LIRN) and the National Animal Health Monitoring System (NAHMS) can be leveraged to report and investigate antibiotic resistance in animal pathogens and potential foodborne pathogens. A critical link, which is currently missing, is the presence of staffing resources in diagnostic laboratories that would permit investigations of management practices and antibiotic use associated with resistant animal pathogens. Other programs such as the National Antimicrobial Resistance Monitoring System (NARMS) for enteric bacteria and the current FDA Center for Veterinary Medicine (CVM) cooperative agreements for antimicrobial use monitoring in food animal production could be expanded and combined to couple granular antibiotic use data on farms with antimicrobial resistance data from surveys, at slaughter and at retail, on sentinel bacterial species. FDA's recent commitment to implement recommendations from the Science Board review of the NARMS program and to improve inter-operability of diagnostic networks is a good next step.

II-5.4. Support the new FDA five-year action plan, *Supporting Antimicrobial Stewardship in Veterinary Settings*, which is designed to include and promote stewardship in companion and food animal practices and ensure that these programs are integrated with other federal strategies.

Steps should be taken to ensure that antibiotic use and stewardship issues in companion animals are addressed by the appropriate veterinary and companion animal owner associations, as well as centralized institutions such as the previously proposed Innovation Institute (see the PACCARB Incentives Report). Federal agencies should support the same level of IP&AS initiatives for companion animal antimicrobial use as are supported for use in food animals.

II-6. Build Resource Capacity to Implement Infection Prevention and Antibiotic Stewardship Programs.

Veterinary professionals are a key resource in IP&AS efforts. It is imperative that veterinarians, both in training and as providers, are educated in these programs and able to implement them effectively. In addition, it is important to address the shortage of veterinarians, especially in rural areas, that further inhibit effective IP&AS by limiting access to appropriate animal care.

II-6.1. Ensure the government's continuation of the PSLF to encourage public service careers and build more expertise in AMR.

Debt from veterinary school, commonly coupled with relatively low starting salaries, results in the inability of veterinarians to achieve financial freedom for much of their careers and is a significant driver in career choice. While capacity needs to be built for more front-line professionals, there is also a paucity of veterinarians in government service, non-profits, military organizations, and other positions that are eligible for the Public Service Loan Forgiveness

(PSLF), which forgives the remaining loan balance on direct loans after the applicant has worked for minimum time (10 years) at a qualifying employer. Although the program is a significant incentive that helps students with large debts who take lower paying public service jobs, its future is uncertain as the current administration is considering ending the program. This important program must be continued to help build capacity to focus on AMR issues and programs.

II-6.2. Financially support federal and state-based veterinary loan repayment programs to address shortages and help build an adequate veterinary workforce in rural areas.

There is a special and urgent need to increase the number of food animal practitioners and help ensure that they are available for clients and patients in rural communities and other high priority veterinary shortage areas. The Veterinary Medicine Loan Repayment Program (VMLRP), run by the National Institute of Food and Agriculture (NIFA) of the USDA, offers an important incentive to help meet this national need by offsetting a significant portion of student debt in return for service in designated veterinary shortage areas. Increasing the number of veterinarians in these areas, especially food animal practitioners, is important for addressing key public health and food safety issues. The delivery of IP&AS programs is a critical need, especially since the recent change to the VFD that dictates the need for ongoing veterinarian-client relationships when using antibiotics was put into place. As the number of veterinary shortage areas grows, there is a need for Congress to significantly expand and increase funds for the VMLRP.

II-6.3. Provide support for and establish more public-private partnerships to carry out IP&AS programs and leverage existing ones in academia and industry.

In some areas of the U.S., a substantial gap exists between the number of competent front-line animal health professionals needed to deliver effective IP&AS programs across all animal populations and the number of well-prepared professionals available to deliver these services. The majority of veterinary practitioners in the U.S. are companion animal practitioners, with a much smaller percentage being food animal practitioners who are serving the nation's substantial populations of livestock and poultry. While colleges of veterinary medicine are making progress to better prepare new graduates to deliver IP&AS programs, the ability and need to bring existing practitioners up to speed in these programs may be the most pressing need in capacity building. Organizations and other USG agencies should collaborate to offer the opportunity for veterinary practitioners to access high-quality continuing education programs.

Implementation of the FDA CVM judicious use guidance and regulations (Guidance for Industry #209 and #213) and the VFD has now placed food animal veterinarians in a better position than companion animal veterinarians to understand and implement IP&AS activities in their practice. While recent surveys suggest that companion animal practitioners understand the importance of antibiotic resistance, many do not perceive themselves as responsible or accountable for the antimicrobial resistance problem, nor do they face restrictions to the use of antibiotics in small animals. Additionally, few are familiar with existing international guidelines for the judicious use of antibiotics. Organizations such as the AVMA and AAHA are trying to change this situation; however, much more needs to be done to demonstrate that judicious use is associated with quality practice and consistent with standards of care. Strong public-private partnerships are

needed to help build competencies and create a sense of urgency for companion animal practitioners.

II-7. *Expand, Standardize, and Improve Delivery of Infection Prevention and Antibiotic Stewardship Education and Training at all Levels of the Veterinary Medical Workforce.*

IP&AS are critical activities for veterinarians, yet education and training in this area is lacking. Currently, education efforts are needed across the spectrum of curricula development, from determining core competencies to developing continuing education requirements. Education in IP&AS must happen at all stages of veterinary workforce education to affect appropriate understanding and allow effective implementation. Veterinarians and other animal health professionals should further work with clients and patients to implement effective IP&AS activities across the variety of different species and production systems involved.

II-7.1. Determine core antibiotic stewardship competencies across all species.

While many studies and research projects have defined essential competencies, there is no consensus on what the core or essential competencies that transcend healthcare and various practice systems are. A list of such core competencies should be developed to help with the design of curricula, establish learning objectives and outcomes, and serve as the focus for continuing education and certificate programs. An agreement on core competencies will lead to standardization for basic and continuing education and help ensure that veterinarians acquire the minimal level of essential competencies for delivering IP&AS programs. Core competencies should include not only technical knowledge but also leadership and communication skills. Once developed, core competencies could be disseminated through establishment of a national educational website.

II-7.2. Create a model curriculum in IP&AS based on core competencies across all species.

Veterinary medical education lacks a standardized curriculum to serve as a model of knowledge and skills that students are expected to acquire so that they can successfully implement IP&AS activities. Veterinary medicine, like human medicine, has progressively become more fragmented and siloed; as such, it needs over-arching and cohesive models to pull together the various groups and aspects on important societal issues like AMR. The work done by an earlier team from the AAVMC and the Association of Public and Land-grant Universities on establishing learning objectives is applauded, including the progress made by the AVMA and other professional organizations and associations that contributed to design models and competency-based learning education. However, there is no consensus on the definitive content and development of a core curriculum; this is the next logical step that would inform and link competencies with learning objectives (what a student will be able to do) and outcomes assessments (demonstrating measurable results).

A model curriculum also needs to be planned, integrated and delivered across didactic, clinical, and practice-based education programs (interns, residents, and continuing education) and experiential learning. Antibiotic resistance is a complex and difficult subject that needs a core

curriculum that stresses system dynamics, problem solving, and systems thinking. Meanwhile, academic institutions need to better integrate learning across disciplines, course offerings, and various pedagogy including inter-professional education.

II-7.3. Collaborate with veterinary medical accreditation organizations to ensure that veterinary medical curricula include an integration of AMR content including IP&AS and that students acquire the necessary competencies to deliver effective IP&AS programs.

The important concepts, processes, and competencies regarding IP&AS must be advanced and be made more specific by adding requirements and metrics into the existing accreditation standards. Specifically, IP&AS content should be added to curriculum requirements (Standard 9 of the AVMA Council on Education's accreditation requirements). Likewise, demonstrated competencies in IP&AS should be included in outcomes assessment requirements (Standard 11). This is critical since accreditation ensures that students are prepared to enter practice and are aware of the public health and safety concerns through science and veterinary medicine that are being advanced through contemporary curricula.

II-7.4. Work with state veterinary boards to develop continuing education requirements that include IP&AS.

Since most practicing veterinarians have not received formal training in their veterinary education for IP&AS, especially companion animal practitioners, continuing education offerings are an essential strategy for their acquisition of the knowledge and skills needed to implement effective IP&AS programs. This is especially crucial due to the recent FDA CVM requirements (see recommendation II-6.3 above) for veterinarian oversight of the use of medically important antibiotics for food animals, expansion of the VFD, and prescription requirements for water-soluble antibiotic products. Along with California, a few states have already required continuing education training on the judicious use of medically important antibiotics. Other state boards need to adopt this requirement for their respective states at this critical time for veterinary professionals.

ANNEX I – WORKING GROUP MEMBERSHIP

WORKING GROUP CO-CHAIRS

Michael D. Apley, DVM, PhD, DACVCP
Professor, Department of Clinical Sciences
Kansas State University
College of Veterinary Medicine
Manhattan, KS

Sara E. Cosgrove, MD, MS
Professor of Medicine and Epidemiology
Division of Infectious Diseases,
Johns Hopkins University School of Medicine
Johns Hopkins Bloomberg School of Public Health
Director, Johns Hopkins Hospital Department of
Antimicrobial Stewardship
Baltimore, MD

BEST PRACTICES SUBGROUP

CO-LEAD, Peter Robert Davies, BVSc, PhD
Professor of Swine Health and Production
University of Minnesota
St. Paul, MN

CO-LEAD, Robert A. Weinstein, MD
The C. Anderson Hedberg, MD Professor of Internal
Medicine
Rush University Medical Center
Chairman Emeritus, Department of Medicine
Cook County Health and Hospitals System
Chicago, IL

Martin J. Blaser, MD
Muriel and George Singer Professor of Medicine
Professor of Microbiology
Director, Human Microbiome Program
NYU School of Medicine
New York City, NY

Kent E. Kester, MD, FACP, FIDSA, FASTMH
Vice President and Head
Translational Science and Biomarkers
Sanofi Pasteur
Swiftwater, PA

Ramanan Laxminarayan, PhD, MPH
Director and Senior Fellow
Center for Disease Dynamics, Economics and Policy
Washington, DC

Tiffany Lee, DVM, PHD, MS
Designated Representative
North American Meat Institute
Washington, DC

Anthony (Tony) Fiore, MD, MPH
Chief, Epidemiology Research and Innovations Branch
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious
Diseases
Centers for Disease Control and Prevention
Washington, DC

William Flynn, DVM, MS
Deputy Director for Science Policy
Center for Veterinary Medicine
U.S. Food and Drug Administration
Rockville, MD

Clayton Huntley
Antibacterial Resistance Program Officer
Bacteriology and Mycology Branch
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Rockville, MD

Dawn Sievert, PhD, MS
Associate Director for Antimicrobial Resistance
Office of the Director
Division of Foodborne, Waterborne, and Environmental
Diseases
National Center for Emerging and Zoonotic Infectious
Diseases
Centers for Disease Control and Prevention
Atlanta, GA

Cathie Plouzek, PhD
Scientific Program Manager
Health Services Research and Development
Veterans Health Administration
Washington, DC

David Atkins, MD, MPH
Director
Health Services Research and Development
Veterans Health Administration
Washington, DC

Naomi Tomoyasu, PhD
Deputy Director
Health Services Research and Development
Veterans Health Administration
Washington, DC

Darryl T. Gray, MD, ScD, FACC, FAHA
Medical Officer
Division of Healthcare-Associated Infections
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research & Quality
Rockville, MD

Kali Crosby, MSN, RN
Nurse Consultant
Division of Healthcare-Associated Infections
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research & Quality
Rockville, MD

James Cleeman, MD
Senior Medical Officer
Director, Division of Healthcare-Associated Infections
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research & Quality
Rockville, MD

IMPLEMENTATION SUBGROUP

CO-LEAD, Helen W. Boucher, MD, FIDSA, FACP
Director, Infectious Diseases Fellowship Program
Director, Heart Transplant and Ventricular Assist
Device Infectious Disease Program
Professor of Medicine
Tufts University School of Medicine
Division of Geographic Medicine and Infectious
Diseases
Tufts Medical Center
Boston, MA

CO-LEAD, Thomas R. Shryock, PhD
Chief Scientific Officer and Managing Member
Antimicrobial Consultants, LLC
Greenfield, IN

John H. Rex, MD
Chief Medical Officer, F2G Ltd.
Eccles, UK & Wellesley, MA

Alice L. Johnson, DVM
Designated Representative
National Turkey Federation
Washington, DC

Elaine Larson, PhD, RN, FAAN
Designated Representative
American Nurses Association
Silver Spring, MD

Kathryn L. Talkington
Designated Representative
The Pew Charitable Trusts
Washington, DC

Denise M. Toney, PhD
Designated Representative
Association of Public Health Laboratories
Washington, DC

Neena Anandaraman, DVM, MPH
Senior Advisor for Animal Health and Production
Products
Office of the Chief Scientist
U. S. Department of Agriculture
Washington, DC

Arjun Srinivasan, MD
Captain, USPHS
Associate Director for Healthcare Associated Infection
Prevention Programs
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious
Diseases
Centers for Disease Control and Prevention
Atlanta, GA

Paige Waterman, MD, FACP, FIDSA
COL, MC, USA
Director, Translational Medicine
Walter Reed Army Institute of Research
Bethesda, MD

William Flynn, DVM, MS
Deputy Director for Science Policy
Center for Veterinary Medicine
U.S. Food and Drug Administration
Rockville, MD

Anita Thomas, PharmD
Quality Improvement and Innovation Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Baltimore, MD

Yolanda Jones, RN
Quality Improvement and Innovation Group
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Baltimore, MD

Cathie Plouzek, PhD
Scientific Program Manager
Health Services Research and Development
Veterans Health Administration
Washington, DC

David Atkins, MD, MPH
Director
Health Services Research and Development
Veterans Health Administration
Washington, DC

Naomi Tomoyasu, PhD
Deputy Director
Health Services Research and Development
Veterans Health Administration
Washington, DC

Melissa Miller, MD, MS
Medical Officer
Division of Healthcare-Associated Infections
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research & Quality
Rockville, MD

Dale Burwen, MD, MPH
Medical Officer
Division of Healthcare Associated Infections
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research & Quality
Rockville, MD

James Cleeman, MD
Senior Medical Officer
Director, Division of Healthcare-Associated Infections
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research & Quality
Rockville, MD

WORKFORCE EDUCATION AND COMPETENCIES SUBGROUP

CO-LEAD, Aileen M. Marty, MD, FACP
Professor, Infectious Diseases
Department of Medicine, Family Medicine, and
Community Health
Director, Health Travel Medicine Program and Vaccine
Clinic
Florida International University
Miami, FL

CO LEAD, Lonnie J. King, DVM, MS, MPA,
DACVPM
Professor and Dean Emeritus
College of Veterinary Medicine
Ohio State University
Columbus, OH

Randall Singer, DVM, MPVM, PhD
Professor of Epidemiology
Department of Veterinary and Biomedical Sciences
University of Minnesota
St. Paul, MN

Angela Caliendo, MD, PhD, FIDSA
Professor and Executive Vice Chair of Medicine
Director of the Division of General Internal Medicine
Alpert Medical School
Brown University
Providence, RI

Alicia R. Cole
Founder
Alliance for Safety Awareness for Patients
Sherman Oaks, CA

Alice L. Johnson, DVM
Designated Representative
National Turkey Federation
Washington, DC

Melissa Schaefer, MD
Medical Officer
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious
Diseases
Centers for Disease Control and Prevention
Atlanta, GA

Marjory Cannon, MD
Medical Officer
Office of Clinical Standards and Quality
Quality Improvement Group
Centers for Medicare and Medicaid Services
Baltimore, MD

ANNEX II – PACCARB MEMBERSHIP ROSTER

Robert A. Weinstein, MD
The C. Anderson Hedberg, MD Professor of Internal
Medicine
Rush University Medical Center
Chairman Emeritus, Department of Medicine
Cook County Health and Hospitals System
Chicago, IL

LIAISON MEMBERS

The Pew Charitable Trusts
Designated Representative:
Kathryn L. Talkington
Washington, DC

National Turkey Federation
Designated Representative:
Alice L. Johnson, DVM
Washington, DC

American Nurses Association
Designated Representative:
Elaine Larson, PhD, RN, FAAN
Silver Spring, MD

North American Meat Institute
Designated Representative:
Tiffany Lee, DVM, PHD, MS
Washington, DC

Association of Public Health Laboratories
Designated Representative:
Denise M. Toney, PhD
Washington, DC

EX OFFICIO MEMBERS

U. S. Department of Agriculture

Agricultural Research Service
Jeffrey Silverstein, PhD
Deputy Administrator
Animal Production and Protection
Office of National Programs
Washington, DC

Animal and Plant Health Inspection Service
Brian J. McCluskey, DVM, MS, PhD, Dip. ACVPM
Executive Director
Science, Technology and Analysis Services
Fort Collins, CO

Food Safety and Inspection Service
David Goldman, MD
Chief Medical Officer and Assistant Administrator
Office of Public Health Science
Washington, DC

U. S. Department of Defense

Walter Reed Army Institute of Research
Paige Waterman, MD, FACP, FIDSA
COL, MC, USA
Director
Translational Medicine
Bethesda, MD

U.S. Department of Health and Human Services

Centers for Disease Control and Prevention
Rima Khabbaz, MD
Director, National Center for Emerging and Zoonotic
Infectious Diseases
Acting Director, Office of Infectious Diseases
Acting CDC Deputy Director, Infectious Diseases
Atlanta, GA

Centers for Medicare and Medicaid Services
Shari Ling, MD
Deputy Chief Medical Officer
Center for Clinical Standards and Quality
Baltimore, MD

National Institutes of Health
Dennis M. Dixon, PhD
Chief, Bacteriology and Mycology Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Rockville, MD

Office of Global Affairs
Lawrence D. Kerr, PhD
Director, Office of Pandemics and Emerging Threats
Washington, DC

Office of the Assistant Secretary for Preparedness and Response
Christopher Houchens, PhD
Acting Director, Division of CBRN Countermeasures
Biomedical Advanced Research and Development
Authority
Washington, DC

U.S. Food and Drug Administration
Daniel W. Sigelman, JD
Senior Advisor
Office of Public Health Strategy and Analysis
Office of the Commissioner
Silver Spring, MD

ADVISORY COUNCIL STAFF

MacKenzie Robertson
Alternate Designated Federal Officer
Presidential Advisory Council on Combating
Antibiotic-Resistant Bacteria
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

Ayah O. Wali, MPH
Committee Management Officer
Presidential Advisory Council on Combating
Antibiotic-Resistant Bacteria
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

Mark Kazmierczak, PhD
Subject Matter Expert
Gryphon Scientific
Washington, DC

Sarah McClelland, MPH
ORISE Fellow
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
Washington, DC

ANNEX III – PACCARB CHARTER AND AUTHORIZING LEGISLATION

CHARTER

PRESIDENTIAL ADVISORY COUNCIL
ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Authority

Executive Order 13676, dated September 18, 2014, requires establishment of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The Advisory Group is currently operating under the authority given in Executive Order 13708, dated September 30, 2015. .Activities of the Advisory Council are governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Objectives and Scope of Activities

Executive Order 13676 directs the Secretary of Health and Human Services (Secretary) to establish the Advisory Council in consultation with the Secretaries of Defense and Agriculture. The Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy) and the National Action Plan for Combating Antibiotic-Resistant Bacteria (Action Plan). The Advisory Council shall function solely for advisory purposes.

Description of Duties

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to:

1. Preserve the effectiveness of antibiotics by optimizing their use;

2. Advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship;

3. Strengthen surveillance of antibiotic-resistant bacterial infections;

4. Prevent the transmission of antibiotic-resistant bacterial infections;

5. Advance the development of rapid point-of-care and agricultural diagnostics;

6. Further research on new treatments for bacterial infections;

7. Develop alternatives to antibiotics for agricultural purposes;

8. Maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and

9. Improve international coordination of efforts to combat antibiotic resistance.

Agency or Official to Whom the Committee Reports

As stipulated in Executive Order 13676, the Advisory Council provides advice, information, and recommendations to the Secretary. The Secretary will provide the President with all written reports created by the Advisory Council.

Support

To the extent permitted by law and subject to the availability of appropriations, the Department of Health and Human Services (HHS) shall provide the Advisory Council with such funds and support as may be necessary for the performance of its functions. Management and support services provided to the Advisory Council will be the responsibility of the Office of the Assistant Secretary for Health (OASH), which is a coordinating and program office within the Office of the Secretary.

To the extent permitted by law, the agencies that comprise the Task Force for Combating Antibiotic-Resistant Bacteria shall provide the Advisory Council with such information as it may require for purposes of carrying out its functions.

Estimated Annual Operating Costs and Staff Years

The estimated annual cost for operating the Advisory Council, including compensation and travel expenses for members, but excluding staff support is $586,117. The estimate for annual person years of staff support required is 5.0, at an estimated annual cost of $538,883.

Designated Federal Officer

The Assistant Secretary for Health (ASH), in consultation with the Secretary, will select the Designated Federal Officer (DFO) from among full-time or permanent part-time staff within OASH or another organizational component within the HHS, who have knowledge of the subject matter and skills and experience necessary to manage the Advisory Council. The ASH may appoint an Alternate DFO, who will carry out the assigned duties in the event that the DFO cannot fulfill the assigned responsibilities for the Advisory Council. In the absence of a DFO

or Alternate DFO, the ASH will temporarily appoint one or more permanent full-time or part-time program staff to carry out the assigned duties.

The DFO will schedule and approve all meetings of the Advisory Council and of its respective subcommittees. The DFO will prepare and approve all meeting agendas. The DFO may collaborate with the Advisory Council Chair in this activity, and when deemed appropriate, with chairs of any existing subcommittees that have been established by the Advisory Council. The DFO, Alternate DFO, or designee will attend all meetings of the Advisory Council and all meetings of any subcommittees/working groups that have been assembled to assist the Advisory Council. The DFO has authority to adjourn meetings, when it is determined to be in the public interest, and the DFO can be directed by the Secretary or designee to chair meetings of the Advisory Council.

Estimated Number and Frequency of Meetings

The Advisory Council will meet, at a minimum, two times per fiscal year depending on the availability of funds. Meetings will be open to the public, except as determined otherwise by the Secretary, or other official to whom authority has been delegated, in accordance with guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c). Notice of all meetings will be provided to the public in accordance with the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.). Meetings will be conducted and records of the proceedings will be kept, as required by applicable laws and Departmental policies. A quorum is required for the Advisory Council to meet to conduct business. A quorum will consist of a majority of the Advisory Council's voting members.

When the Secretary or designee determines that a meeting will be closed or partially closed to the public, in accordance with stipulations of Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report will be prepared by the DFO that includes, at a minimum, a list of the members and their business addresses, the Advisory Council's functions, date and place of the meeting, and a summary of the Advisory Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

Duration

There is a continuing need for the Advisory Council. However, it is subject to terminate pursuant to Executive Order 13708, dated September 30, 2017.

Termination

Unless extended by the President, the Advisory Council will terminate on September 30, 2017. Unless renewed by appropriate action, the charter for the Advisory Council will expire two years from the date it is filed.

Membership and Designation

The Advisory Council will consist of not more than 30 members, including the voting and non-voting members and the Chair and Vice Chair. The Secretary will designate the Chair and Vice Chair from among the voting public members of the Advisory Council who have demonstrated ability both to lead the work of similar bodies and to work effectively in partnership with federal agencies and partner organizations.

Voting Members. There will public voting members selected from individuals who are engaged in research on, or implementation of, interventions regarding efforts to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up–to-date information on the appropriate and proper use of antibiotics to the general public and human and animal health care providers; and improve international coordination of efforts to combat antibiotic resistance.

The public voting members will represent balanced points of view from human biomedical, public health, and agricultural fields to include surveillance of antibiotic-resistant infections, prevention and/or interruption of the spread of antibiotic-resistant threats, or development of rapid diagnostics and novel treatments. The public voting members may be physicians, veterinarians, epidemiologists, microbiologists, or other health care professionals (e.g., nurses, pharmacists, others); individuals who have expertise and experience as consumer or patient advocates concerned with antibiotic resistance, or in the fields of agriculture and pharmaceuticals; and they also may be from State or local health agencies or public health organizations. The voting public members will be appointed by the Secretary, in consultation with the Secretaries of Defense and Agriculture. All public voting members will be classified as special government employees (SGEs).

Ex-officio Members (non-voting). The Advisory Council will include members selected to represent various federal agencies, including HHS, DoD, and USDA, that are involved in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. The federal *ex-officio* members shall possess the knowledge, skills, experience, and expertise necessary to generate informed and intelligent recommendations with respect to the issues mandated by Executive Order 13676. Federal agencies will be invited to participate as non-voting *ex-officio* members of the Advisory Council, as it is deemed necessary by the Secretary, in consultation with the Secretaries of Defense and Agriculture, to accomplish the mission of the Advisory Council.

Liaison Representatives (non-voting). The Advisory Council structure also may include non-voting liaison representatives from organizations and/or interest groups that have involvement in the development, testing, licensing, production, procurement, distribution, and/or use of antibiotics and/or antibiotic research. Individuals from among the following sectors may be invited to serve as non-voting liaison representatives:

- Professional organizations representing: infectious disease; epidemiology; infection control; physicians; nurses; pharmacists; microbiologists; veterinarians
- Public health organizations representing laboratories, health officials, or epidemiologists (state/territorial, county, or local)
- Organizations advocating for patients and consumers
- Organizations representing state departments of agriculture
- Hospitals
- Foundations with an interest in antibiotic resistance and promoting antibiotic stewardship
- National Preparedness and Response Science Board
- Pharmaceutical industry – human health
- Pharmaceutical industry – animal health
- Vaccines
- Food producer (livestock)
- Food producer (poultry)
- Food producer (seafood)
- *In vitro* diagnostics
- Food retailer
- Food processor
- Animal feed producers
- Farm bio-security

Invitations may be extended to other organizations and/or interest groups to participate as non-voting liaison representatives, as it is deemed necessary by the Secretary or designee to accomplish the established mission of the Advisory Council.

Terms and Compensation. The public voting and non-voting liaison representative members will be appointed to serve for overlapping terms of up to four years. Any member who is appointed to fill the vacancy of an unexpired term will be appointed to serve for the remainder of that term. The Chair and Vice Chair will be appointed to serve for three years, unless otherwise specified. Terms of more than two years are contingent upon renewal of the Advisory Council charter by appropriate action prior to its expiration. A member may serve after the expiration of their term until their successor has taken office, but no longer than 180 days.

Pursuant to an advance written agreement, the public voting members shall receive no stipend from the federal government for the services they perform during their tenure on the Advisory

Council. However, the public voting members are entitled to receive per diem and reimbursement for travel expenses incurred for attending meetings of the Advisory Council, as authorized by 5 U.S.C. Sec. 5703, as amended, for persons who are employed intermittently in the Government service. The non-voting liaison representatives may be allowed to receive per diem and any applicable expenses for travel that is performed to attend meetings of the Advisory Council in accordance with federal travel regulations.

Subcommittees

With approval or recommendation of the Secretary or designee, the Advisory Council may establish standing and *ad hoc* subcommittees to provide assistance for carrying out its function. These subcommittees may consist of members of the Advisory Council, as well as other individuals (federal and non-federal) who are concerned and knowledgeable about antibiotic-resistant bacteria and other topics pertaining to the Advisory Council mission.

The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be provided information on its name, membership, function, and estimated frequency of meetings. All reports and recommendations of a subcommittee must be reported back to the full Advisory Council for action. No activity of a subcommittee can be given directly to the Secretary without being provided for discussion by the full Advisory Council.

Recordkeeping

Records of the Advisory Council and the respective subcommittees or working groups will be handled in accordance with General Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

Filing Date: JAN 1 8 2017

Approved:

JAN 1 8 2017
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Date   *Sylvia M. Burwell*
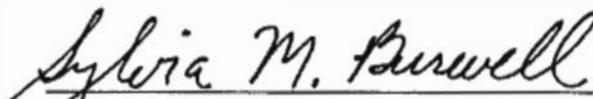
                                           Sylvia M. Burwell

Presidential Documents

Executive Order 13676 of September 18, 2014

Combating Antibiotic-Resistant Bacteria

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby order as follows:

Section 1. *Policy.* The discovery of antibiotics in the early 20th century fundamentally transformed human and veterinary medicine. Antibiotics save millions of lives each year in the United States and around the world. The rise of antibiotic-resistant bacteria, however, represents a serious threat to public health and the economy. The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) estimates that annually at least two million illnesses and 23,000 deaths are caused by antibiotic-resistant bacteria in the United States alone.

Detecting, preventing, and controlling antibiotic resistance requires a strategic, coordinated, and sustained effort. It also depends on the engagement of governments, academia, industry, healthcare providers, the general public, and the agricultural community, as well as international partners. Success in this effort will require significant efforts to: minimize the emergence of antibiotic-resistant bacteria; preserve the efficacy of new and existing antibacterial drugs; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance efforts in public health and agriculture; develop and promote the use of new, rapid diagnostic technologies; accelerate scientific research and facilitate the development of new antibacterial drugs, vaccines, diagnostics, and other novel therapeutics; maximize the dissemination of the most up-to-date information on the appropriate and proper use of antibiotics to the general public and healthcare providers; work with the pharmaceutical industry to include information on the proper use of over-the-counter and prescription antibiotic medications for humans and animals; and improve international collaboration and capabilities for prevention, surveillance, stewardship, basic research, and drug and diagnostics development.

The Federal Government will work domestically and internationally to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria and help ensure the continued availability of effective therapeutics for the treatment of bacterial infections.

Sec. 2. *Oversight and Coordination.* Combating antibiotic-resistant bacteria is a national security priority. The National Security Council staff, in collaboration with the Office of Science and Technology Policy, the Domestic Policy Council, and the Office of Management and Budget, shall coordinate the development and implementation of Federal Government policies to combat antibiotic-resistant bacteria, including the activities, reports, and recommendations of the Task Force for Combating Antibiotic-Resistant Bacteria established in section 3 of this order.

Sec. 3. *Task Force for Combating Antibiotic-Resistant Bacteria.* There is hereby established the Task Force for Combating Antibiotic-Resistant Bacteria (Task Force), to be co-chaired by the Secretaries of Defense, Agriculture, and HHS.

(a) Membership. In addition to the Co-Chairs, the Task Force shall consist of representatives from:

(i) the Department of State;

(ii) the Department of Justice;

(iii) the Department of Veterans Affairs;

(iv) the Department of Homeland Security;

(v) the Environmental Protection Agency;

(vi) the United States Agency for International Development;

(vii) the Office of Management and Budget;

(viii) the Domestic Policy Council;

(ix) the National Security Council staff;

(x) the Office of Science and Technology Policy;

(xi) the National Science Foundation; and

(xii) such executive departments, agencies, or offices as the Co-Chairs may designate.

Each executive department, agency, or office represented on the Task Force (Task Force agency) shall designate an employee of the Federal Government to perform the functions of the Task Force. In performing its functions, the Task Force may make use of existing interagency task forces on antibiotic resistance.

(b) *Mission.* The Task Force shall identify actions that will provide for the facilitation and monitoring of implementation of this order and the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy).

(c) *Functions.*

(i) By February 15, 2015, the Task Force shall submit a 5-year National Action Plan (Action Plan) to the President that outlines specific actions to be taken to implement the Strategy. The Action Plan shall include goals, milestones, and metrics for measuring progress, as well as associated timelines for implementation. The Action Plan shall address recommendations made by the President's Council of Advisors on Science and Technology regarding combating antibiotic resistance.

(ii) Within 180 days of the release of the Action Plan and each year thereafter, the Task Force shall provide the President with an update on Federal Government actions to combat antibiotic resistance consistent with this order, including progress made in implementing the Strategy and Action Plan, plans for addressing any barriers preventing full implementation of the Strategy and Action Plan, and recommendations for new or modified actions. Annual updates shall include specific goals, milestones, and metrics for all proposed actions and recommendations. The Task Force shall take Federal Government resources into consideration when developing these proposed actions and recommendations.

(iii) In performing its functions, the Task Force shall review relevant statutes, regulations, policies, and programs, and shall consult with relevant domestic and international organizations and experts, as necessary.

(iv) The Task Force shall conduct an assessment of progress made towards achieving the milestones and goals outlined in the Strategy in conjunction with the Advisory Council established pursuant to section 4 of this order.

Sec. 4. *Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria.* (a) The Secretary of HHS (Secretary), in consultation with the Secretaries of Defense and Agriculture, shall establish the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The Advisory Council shall be composed of not more than 30 members to be appointed or designated by the Secretary.

(b) The Secretary shall designate a chairperson from among the members of the Advisory Council.

(c) The Advisory Council shall provide advice, information, and recommendations to the Secretary regarding programs and policies intended to: preserve the effectiveness of antibiotics by optimizing their use; advance

research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance. The Secretary shall provide the President with all written reports created by the Advisory Council.

(d) Task Force agencies shall, to the extent permitted by law, provide the Advisory Council with such information as it may require for purposes of carrying out its functions.

(e) To the extent permitted by law, and subject to the availability of appropriations, HHS shall provide the Advisory Council with such funds and support as may be necessary for the performance of its functions.

Sec. 5. *Improved Antibiotic Stewardship.* (a) By the end of calendar year 2016, HHS shall review existing regulations and propose new regulations or other actions, as appropriate, that require hospitals and other inpatient healthcare delivery facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those identified by the CDC. HHS shall also take steps to encourage other healthcare facilities, such as ambulatory surgery centers and dialysis facilities, to adopt antibiotic stewardship programs.

(b) Task Force agencies shall, as appropriate, define, promulgate, and implement stewardship programs in other healthcare settings, including office-based practices, outpatient settings, emergency departments, and institutional and long-term care facilities such as nursing homes, pharmacies, and correctional facilities.

(c) By the end of calendar year 2016, the Department of Defense (DoD) and the Department of Veterans Affairs (VA) shall review their existing regulations and, as appropriate, propose new regulations and other actions that require their hospitals and long-term care facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those defined by the CDC. DoD and the VA shall also take steps to encourage their other healthcare facilities, such as ambulatory surgery centers and outpatient clinics, to adopt antibiotic stewardship programs.

(d) Task Force agencies shall, as appropriate, monitor improvements in antibiotic use through the National Healthcare Safety Network and other systems.

(e) The Food and Drug Administration (FDA) in HHS, in coordination with the Department of Agriculture (USDA), shall continue taking steps to eliminate the use of medically important classes of antibiotics for growth promotion purposes in food-producing animals.

(f) USDA, the Environmental Protection Agency (EPA), and FDA shall strengthen coordination in common program areas, such as surveillance of antibiotic use and resistance patterns in food-producing animals, interspecies disease transmissibility, and research findings.

(g) DoD, HHS, and the VA shall review existing regulations and propose new regulations and other actions, as appropriate, to standardize the collection and sharing of antibiotic resistance data across all their healthcare settings.

Sec. 6. *Strengthening National Surveillance Efforts for Resistant Bacteria.* (a) The Task Force shall ensure that the Action Plan includes procedures for creating and integrating surveillance systems and laboratory networks to provide timely, high-quality data across healthcare and agricultural settings, including detailed genomic and other information, adequate to track resistant bacteria across diverse settings. The network-integrated surveillance

systems and laboratory networks shall include common information requirements, repositories for bacteria isolates and other samples, a curated genomic database, rules for access to samples and scientific data, standards for electronic health record-based reporting, data transparency, budget coordination, and international coordination.

(b) Task Force agencies shall, as appropriate, link data from Federal Government sample isolate repositories for bacteria strains to an integrated surveillance system, and, where feasible, the repositories shall enhance their sample collections and further interoperable data systems with national surveillance efforts.

(c) USDA, EPA, and FDA shall work together with stakeholders to monitor and report on changes in antibiotic use in agriculture and their impact on the environment.

(d) Task Force agencies shall, as appropriate, monitor antibiotic resistance in healthcare settings through the National Healthcare Safety Network and related systems.

Sec. 7. *Preventing and Responding to Infections and Outbreaks with Antibiotic-Resistant Organisms.* (a) Task Force agencies shall, as appropriate, utilize the enhanced surveillance activities described in section 6 of this order to prevent antibiotic-resistant infections by: actively identifying and responding to antibiotic-resistant outbreaks; preventing outbreaks and transmission of antibiotic-resistant infections in healthcare, community, and agricultural settings through early detection and tracking of resistant organisms; and identifying and evaluating additional strategies in the healthcare and community settings for the effective prevention and control of antibiotic-resistant infections.

(b) Task Force agencies shall take steps to implement the measures and achieve the milestones outlined in the Strategy and Action Plan.

(c) DoD, HHS, and the VA shall review and, as appropriate, update their hospital and long-term care infectious disease protocols for identifying, isolating, and treating antibiotic-resistant bacterial infection cases.

Sec. 8. *Promoting New and Next Generation Antibiotics and Diagnostics.* (a) As part of the Action Plan, the Task Force shall describe steps that agencies can take to encourage the development of new and next-generation antibacterial drugs, diagnostics, vaccines, and novel therapeutics for both the public and agricultural sectors, including steps to develop infrastructure for clinical trials and options for attracting greater private investment in the development of new antibiotics and rapid point-of-care diagnostics. Task Force agency efforts shall focus on addressing areas of unmet medical need for individuals, including those antibiotic-resistant bacteria CDC has identified as public and agricultural health threats.

(b) Together with the countermeasures it develops for biodefense threats, the Biomedical Advanced Research Development Authority in HHS shall develop new and next-generation countermeasures that target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

(c) The Public Health Emergency Medical Countermeasures Enterprise in HHS shall, as appropriate, coordinate with Task Force agencies' efforts to promote new and next-generation countermeasures to target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

Sec. 9. *International Cooperation.* Within 30 days of the date of this order, the Secretaries of State, USDA, and HHS shall designate representatives to engage in international action to combat antibiotic-resistant bacteria, including the development of the World Health Organization (WHO) Global Action Plan for Antimicrobial Resistance with the WHO, Member States, and other relevant organizations. The Secretaries of State, USDA, and HHS shall conduct a review of international collaboration activities and partnerships, and identify and pursue opportunities for enhanced prevention, surveillance, research and development, and policy engagement. All Task Force

agencies with research and development activities related to antibiotic resistance shall, as appropriate, expand existing bilateral and multilateral scientific cooperation and research pursuant to the Action Plan.

Sec. 10. *General Provisions.* (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.) (the ''Act''), may apply to the Advisory Council, any functions of the President under the Act, except for that of reporting to the Congress, shall be performed by the Secretary in accordance with the guidelines issued by the Administrator of General Services.

THE WHITE HOUSE,
September 18, 2014.

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ANNEX IV – ACRONYMS AND ABBREVIATIONS

AAHA	American Animal Hospital Association
AAVMC	Association of American Veterinary Medical Colleges
ACGME	Accreditation Council for Graduate Medical Education
AHRQ	Agency for Healthcare Research and Quality
AMR	Antimicrobial Resistance
APIC	Association for Professionals in Infection Control and Epidemiology
ARSI	Antibiotic Resistance Solutions Initiative
AS	Antibiotic Stewardship
ASP	Antimicrobial Stewardship Program
AUR	Antibiotic Use and Resistance module
AVMA	American Veterinary Medical Association
CE	Continuing Education
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CoP	Medicare Conditions of Participation
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CVM	Center for Veterinary Medicine
DoD	U.S. Department of Defense
EHR	Electronic Health Records
FDA	Food and Drug Administration
HAI	Healthcare-Associated Infection
HIIN	Hospital Improvement Innovation Network
HHS	U.S. Department of Health and Human Services
IC	Infection Control
ID	Infectious Disease
IDSA	Infectious Diseases Society of America
IP&AS	Infection Prevention and Antibiotic Stewardship
LCME	Liaison Committee on Medical Education
LTACH	Long-Term Acute Care Hospital
MDRO	Multi-Drug Resistant Organism
MIPS	Merit-based Incentive Payment System
NAHMS	National Animal Health Monitoring System
NAP	National Action Plan
NARMS	National Antimicrobial Resistance Monitoring System
NIH	National Institutes of Health
NHSN	National Healthcare Safety Network
PACCARB	Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria
POC	Point-of-Care

PRRSv	Porcine Reproductive and Respiratory Syndrome Virus
PSLF	Public Service Loan Forgiveness Program
QIN/QIO	Quality Innovation Network-Quality Improvement Organization
R&D	Research and Development
ROI	Return on Investment
SAAR	Standardized Antimicrobial Administration Ratio
SHEA	Society for Healthcare Epidemiology of America
SIDP	Society of Infectious Diseases Pharmacists
SME	Subject Matter Expert
TJC	The Joint Commission
USDA	U.S. Department of Agriculture
USG	U.S. government
VFD	Veterinary Feed Directive
VHA	Veterans Health Administration
VMLRP	Veterinary Medicine Loan Repayment Program
Vet-LIRN	Veterinary Laboratory Investigation and Response Network
vSNF	Skilled Nursing Facility that cares for patients on ventilators
WEC	Workforce, Education, and Competencies
WG	Working Group