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October 14, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities [CMS-3260-P]

Dear Mr. Slavitt:

On behalf of the Infectious Diseases Society of America (IDSAs), thank you for the opportunity to comment on the proposed regulations relating to Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities. IDSAs represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, serious health care acquired infections antibiotic resistant bacterial infections as well as emerging infections such as Middle East Respiratory Syndrome coronavirus (MERS-CoV) and Ebola virus disease. These individuals have undergone extensive training and board certification in both the specialty of Internal Medicine and the subspecialty of Infectious Diseases, and these individuals have the specific training, experience, and clinical expertise in recognition, diagnosis and treatment of serious infections that make them the ideal individuals to oversee the many facets of infection prevention programs and antimicrobial stewardship programs that increase quality of care and health-care outcomes while reducing unnecessary health care costs.

IDSAs members are committed to improving the quality and safety of patient care throughout the integrated health care delivery system, recognizing that despite unique challenges across the various types of facilities, efforts must align with the National Quality Strategy's three-part aim of better care, affordable care, and healthy people in healthy communities. The proposed rule to Reform Requirements for Long-Term Care (LTC) Facilities represents the latest effort that CMS has put forth as part of that strategy, specific to nursing homes, skilled nursing facilities and other post-acute sites of care. This proposed rule draws attention to the importance of infection prevention and issues the call for antimicrobial stewardship within this care setting, as well as applies standards related to Quality Assurance and Performance Improvement (QAPI) that exist in other areas of health care. These are issues of great importance to IDSAs. Below we submit our comments on the specific changes proposed in the rule.

The Growing Threat of Antimicrobial Resistance

As you are aware, there has been a significant increase in antibiotic use in hospitals and long term care facilities over the past several decades, consequently increasing the prevalence of antimicrobial-resistant pathogens.^{1,2} Adding to this increase in resistant pathogens, antibiotics are often prescribed sub-optimally or inappropriately.³ Antibiotics are often administered needlessly, continued when they are no longer necessary, or prescribed at the wrong dose. Broad-spectrum antibiotics may be administered unnecessarily against bacteria that are susceptible to narrow-spectrum agents or an ineffective antibiotic may be used to treat a particular infection. As a consequence, this inappropriate and sub-optimal use of antibiotics leads not only to poorer individual health outcomes from inadequately treated infections but also to increased rates of serious diseases such as *Clostridium difficile* infection.⁴ Moreover, the misuse of antibiotics can also result in preventable adverse events.

The overuse and inadequate dosing of antibiotics, in particular, leads to resistance among pathogens and this resistance leads to adverse outcomes, including mortality. The healthcare sector has seen bacteria that are resistant to first-line treatments or extensively resistant to multiple drugs, and these bacteria spread widely among patients in all healthcare settings. In some cases, these pathogens have been resistant to all available antibiotics. The unique nature of antibiotics, in which the use of a particular drug in one patient can impact the effectiveness of the drug in a different patient, makes antibiotic overuse and misuse a serious patient safety issue and public health threat. In fact, the World Health Organization has characterized antibiotic resistance as “a crisis that has been building up over decades, so that today common and life-threatening infections are becoming difficult or even impossible to treat.”⁵ Infections caused by resistant bacteria not only result in increased morbidity and mortality, but also increased economic burden.^{6,7,8} For example, studies have shown that infections caused by resistant bacteria are associated with longer lengths of stay and increased mortality, both in the hospital and in intensive care units (ICUs). Choosing the wrong antibiotic for initial treatment results in increased mortality. Combined with a dramatic drop in the development and approval of new antibacterial agents over the last 20 years and a rapidly dwindling antimicrobial armamentarium, it is becoming increasingly difficult to treat what were once considered “routine” infections.

The Importance of Antimicrobial Stewardship

Antibiotic stewardship (AS) is the optimal use of antimicrobials to achieve the best clinical outcomes while minimizing adverse events, limiting factors that lead to antimicrobial resistance,

¹ Pakyz AL, MacDougall C, Oinonen M, et al. Trends in antibacterial use in US academic health centers: 2002 to 2006. *Arch Intern Med* 2008;168:2254-60.

² Talbot GH, Bradley J, Edwards JE Jr., Gilbert D, Scheld M, Bartlett JG. Bad bugs need drugs: an update on the development pipeline from the Antimicrobial Availability Task Force of the Infectious Diseases Society of America. *Clin Infect Dis* 2006;42:657-68.

³ Hecker MT, Aron DC, Patel NP, et al. Unnecessary use of antimicrobials in hospitalized patients: current patterns of misuse with an emphasis on the antianaerobic spectrum of activity. *Arch Intern Med* 2003;163:972-8.

⁴ Dellit T.H., R.C. Owens, J.E. McGowan, et al. “Infectious Disease Society of America and the Society for Healthcare Epidemiology of America: Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship.” *Clinical Infectious Diseases* (Jan. 2007) 44: 159–177

⁵ [The evolving threat of antimicrobial resistance](#) - Options for action, The World Health Organization

⁶ Wenzel RP, Bearman G, Edmond MB. Screening for MRSA: a flawed hospital infection control intervention. *Infect Control Hosp Epidemiol* 2008;29:1012-8

⁷ Vincent JL, Rello J, Marshall J, et al. International study of the prevalence and outcomes of infection in intensive care units. *JAMA* 2009;302:2323-9

⁸ European Centre for Disease Prevention and Control, European Medicines Agency. ECDC/EMA Joint Technical Report: the bacterial challenge: time to react.

and reducing excessive costs attributable to suboptimal antimicrobial use. AS involves five key steps, described as the 5 “Ds”: correct diagnosis, correct drug, correct dose, correct duration of therapy, and appropriate de-escalation when microbiologic data are available; these are the specific areas in which physicians dedicated to the subspecialty of Infectious Diseases train and, thus, Infectious Diseases specialists are able to bring the appropriate knowledge and clinical experience to add value as the leader of a multidisciplinary team. Fortunately, AS can minimize antimicrobial resistance and hospital-acquired infections (HAIs) and improve clinical outcomes.⁹ Multiple published studies have indicated that AS programs provide significant cost savings or at least offset the cost of AS programs through reduction in drug acquisition costs, correlating with improved clinical outcomes.¹⁰ AS has significance across the continuum of care and relies heavily on multi-disciplinary and collaborative approaches to care, which are high priorities for both the public and private sector. AS aligns with the Department of Health and Human Services’ [National Action Plan to Prevent HAIs](#).

Antibiotic stewardship programs have been demonstrated to reduce the percentage of antibiotic-resistant organisms in a facility, reduce the occurrence of *C. difficile* infections, improve patient outcomes, decrease toxicity, and reduce pharmacy costs. Stewardship programs need not be burdensome for healthcare facilities. They can be operated utilizing existing staff with access to key health care professionals such as Infectious Diseases specialists assisted by ID-trained pharmacists, and clinical microbiologists.

Ongoing advocacy, led by IDSA, has called attention to the issue of AR and the importance of AS, leading to recent activity at the national level. In September of 2014, the President’s Council of Advisors on Science and Technology (PCAST) released its [Report to the President on Combating Antibiotic Resistance](#). This was followed by the President’s [Executive Order 13676](#) which calls for HHS to promote the implementation of robust antibiotic stewardship programs across health care facilities. In March of 2015, the White House then issued its [National Action Plan for Combating Antibiotic-Resistant Bacteria \(CARB\)](#), which set forth the specific goals such as the “Establishment of antibiotic stewardship programs in all acute care hospitals and improved antibiotic stewardship across all healthcare settings” and “Reduction of inappropriate antibiotic use by 50% in outpatient settings and by 20% in inpatient settings” by 2020. Stewardship programs are one of the most critical mechanisms for achieving these reductions. We also note the [commitment of the National Quality Forum](#) (NQF) in establishing an action team focused on antimicrobial stewardship and the efforts of the American Hospital Association (AHA) in developing its [antimicrobial stewardship toolkit](#) for its members. IDSA, in collaboration with the Society for Healthcare Epidemiologists of America (SHEA), is leading efforts to develop quality measures for antimicrobial stewardship with the NQF action team. Finally, IDSA has formed the U.S. Stakeholder Forum on Antimicrobial Resistance (S-FAR) to convene partners on areas of mutual collaboration, across both human and animal health.

From all this, it is clear that the interest in antimicrobial stewardship is gaining momentum at the national level. We are encouraged to see CMS advance efforts through the rule-making process, drilling down to more detailed levels on how best to implement antimicrobial stewardship across

⁹ Davey P, Brown E, Charani E, Fenelon L, Gould IM, Holmes A, Ramsay CR, Wiffen PJ, Wilcox M. Interventions to improve antibiotic prescribing practices for hospital inpatients. *Cochrane Database Syst Rev*. 2013 Apr 30;4:CD003543.

¹⁰ MacDougall C, Polk RE. Antimicrobial Stewardship Programs in Health Care Systems. *Clin Microbiol Rev*. 2005, 18(4):638.

the health care delivery system, beginning with this proposed rule on long-term care facilities. We acknowledge CMS's intent behind the proposed changes as being in the spirit of current HHS cross-cutting quality initiatives aimed at reducing avoidable hospitalizations, reducing health care associated infections, reducing health care associated costs, promoting care planning, and ensuring quality improvement and performance improvement (QAPI). We share the same intent in providing our comments on the ideal implementation of antimicrobial stewardship in long-term facilities. Our recommendations are well aligned with the [Core Elements of Hospital Antibiotic Stewardship Programs](#) and the [Core Elements of Antibiotic Stewardship Programs for Nursing Homes](#), developed by the Centers for Disease Control and Prevention (CDC), which include a commitment of leadership and financial resources, accountability, drug expertise, action, tracking, reporting, and education. We hope that CDC's recommendations will also be explicitly incorporated into the final rule or associated guidelines. We outline below several core aspects of our position with supporting rationale.

- Antimicrobial Stewardship is a patient safety program, separate and distinct from Infection Prevention, yet complementary. The training required to appropriately implement and maintain an antimicrobial stewardship program is distinct from the training related to infection control and prevention. Moreover, the resources required to effectively implement antimicrobial stewardship are different from those needed to effectively achieve infection prevention. AS requires clinical intervention and guidance, often accomplished by direct physician-to-physician dialogue. Since AS programs require clinical experience and judgment to determine the appropriate antibiotic for care of individual patients, we propose that AS programs are best led by a physician trained and experienced in the subspecialty of Infectious Diseases.
- For this reason, we believe that stewardship programs should be led by Infectious Diseases (ID) specialists who, as part of their routine training, are skilled in antimicrobial stewardship, who will hold accountability for effective performance, and who are able to provide clinical knowledge and judgment in peer-to-peer consultations involving the diagnosis of infection and the prescription of antimicrobial treatments. ID specialists have the requisite clinical training necessary to recognize and correctly diagnose serious infections, to assess the correct antimicrobial agent, including dose and duration, to evaluate data from the clinical microbiology laboratory in the patient context to decide on de-escalation of therapy when warranted, and to review the facility-specific antibiogram in order to provide the leadership and decision-making to achieve success in patient populations specific to individual facilities. This has been demonstrated specifically in an LTC setting.¹¹ We suggest that ID specialist leadership in these programs is desirable to drive appropriate clinical use of antimicrobial agents and change inappropriate use, where necessary. In particular, we posit that physicians accept suggestions for change of therapy better from colleague physicians.
- Stewardship involves a multi-disciplinary team-based approach, also involving ID-trained pharmacists, clinical microbiologists and other providers and leveraging health care information technology systems. ID-trained pharmacists provide an integral component to stewardship through activity such as prospective audit with intervention and feedback (PAIF). Clinical microbiologists provide expertise in rapid diagnostic

¹¹ Jump RL, Olds DM, Seifi N, et al. Effective antimicrobial stewardship in a long-term care facility through an infectious disease consultation service: keeping a LID on antibiotic use. *Infect Control Hosp Epidemiol.* 2012;33:1185–1192

testing and antibiogram (compilation of aggregate antimicrobial susceptibility data) development.¹² This integrated team-based activity requires ID specialist leadership to synthesize disparate data and to ensure accountability, as called for in the CDC's Core Elements of Antibiotic Stewardship Programs.¹³ As well, this team-based activity aligns with the recently published CDC's Core Elements of [Antibiotic Stewardship for Nursing Homes](#).

- To further differentiate AS programs from Infection Prevention Programs, we recognize the distinct role that nurses and infection preventionists play in the educational awareness activities necessary to effectively achieve infection prevention. Under the leadership of Infectious Diseases specialists, infection prevention teams focus on the promotion of health care worker vaccinations, hand hygiene, contact isolation, and environmental cleaning across health care settings. In the event of outbreaks, these teams respond rapidly to identify the source and ensure procedural compliance to prevent transmission of communicable disease to patients and health care workers. It is our position that the leadership required to engage the medical staff of a facility and, when necessary, to liaise with outside public health entities, rests with the Infectious Diseases specialist.
- Effective stewardship programs cover not only the judicious use of antimicrobial treatments but also ongoing education and training efforts to other stakeholders involved in care delivery.
- Effective stewardship programs should reduce inappropriate antibiotic use at the facility level and contribute to the goal in the CARB National Action Plan of a 20% reduction nationwide of inappropriate antibiotic use in inpatient settings by 2020.

Keeping these points in mind, we comment on the specific changes in the proposed rule below:

Infection control (§483.80)

CMS recognizes the impact of HAIs on residents in LTC facilities as well as increased costs for the healthcare system, making reference to published estimates that hold between 1.6 and 3.8 million HAIs in nursing homes every year. CMS acknowledges the fact that antibiotic resistance has emerged as a national healthcare concern and suggests that LTC facilities are the next frontier where new antibiotic resistant organisms may emerge and flourish. CMS notes that antibiotics may account for approximately 40 percent of the drugs given in nursing homes. Since 1992, CMS has required LTC facilities to establish and maintain infection control programs designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection. In this rule that has particular emphasis on the importance of infection prevention and surveillance, CMS has proposed that each facility's infection prevention and control program (hereby referred to as infection prevention programs) include an antibiotic stewardship program, which includes antibiotic use protocols and antibiotic monitoring. Specifically, CMS has proposed to revise the regulatory description of the infection control program to reflect the following:

- include infection prevention, identification, surveillance, and antibiotic stewardship;

¹² Avdic E, Carroll KC. "The role of the microbiology laboratory in antimicrobial stewardship programs." *Infect Dis Clin North Am*. 2014 Jun;28(2):215-35.

¹³ CDC's Core Elements of Antibiotic Stewardship Programs. <http://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html>, (August 10, 2015)

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- require each facility to periodically review and update its program; require performance of an analysis of their resident population and facility;
- designate an infection prevention and control officer(s) (IPCO)
- require that the IPCO be a healthcare professional with specialized training in infection prevention and control beyond their initial professional degree;
- integrate the IPCO with the facility's quality assurance and performance improvement (QAPI) program as well as include them in the facility's QAA committee;
- establish written policies and procedures for the infection prevention programs;
- provide the facility staff with education or training related to the Infection Prevention Programs.

To allow for LTC facilities to exercise some flexibility, CMS has indicated that facilities should be free to determine the qualifications of and the time/resources needed for an IPCO to devote to the Infection Prevention Programs based on the facility assessment.

IDSA appreciates CMS's efforts to bolster existing infection control activities within LTC facilities by proposing additional requirements outlined above. CMS refers to LTC facilities as the next frontier for AR; rather, we would argue that they are a current battleground. As such, we look to these facilities as "reservoirs" that demand attention, given the nature of the care they provide over extended periods of time and the potential for spread of resistant pathogens between patients and to other long-term and acute care facilities. We support much of what has been proposed with the exception of the inclusion of an antimicrobial stewardship program **within** the infection prevention program, for which we will provide our rationale below. Specific to the IPCO, we believe that an Infectious Diseases trained physician is the ideal health care professional to serve in that role. Moreover, we assert that the particular training and expertise that the ID specialist possesses best prepare him/her to develop the policies and procedures for the infection prevention programs that CMS specifically calls for in this proposed rule, including but not limited to, a system of surveillance designed to identify possible communicable disease or infections, standard and transmission-based precautions to be followed to prevent spread of infections; circumstances in which contact-isolation should be used for a resident; the circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food; and the hand hygiene procedures to be followed by all staff as indicated by accepted professional practice.

As we indicated above, we believe antimicrobial stewardship is a patient safety program, which should be considered **separate and distinct from, yet complementary** to, an infection prevention program. The resources required to effectively implement antimicrobial stewardship are different from those needed to implement an effective infection prevention program. Specifically, we identify the importance of the Infectious Diseases-trained physician in providing expert direction on antibiotic use as well as the critical role that an ID-trained pharmacist plays within an effective antimicrobial stewardship program. Furthermore, the clinical microbiologist plays a role in antimicrobial stewardship that is very different than the role they may play in an infection prevention program. These roles empower and extend the ability of the ID specialist to affect prescriber behavior, which is very different than the interventions carried out by an infection prevention program. We feel strongly about this distinction because the two areas, AS and Infection Prevention, are key activities, equal in importance, in the overall effort to combat

antimicrobial resistance. We are concerned that to not recognize these two distinct activities may impede achieving the health care goals of CMS and, in turn, discount the programs' respective importance and impact. Therefore, we request that CMS delineate the requirements for the AS program with an Antimicrobial Stewardship Program Lead (ASPL) as an Infectious Diseases specialist to be distinct from the requirements for the IPCO and the infection prevention program.

As we have previously indicated, it is the position of IDSA that AS programs and infection prevention programs should be led by Infectious Diseases specialists, based on their training which provides them with the clinical experience and judgment to determine the appropriate antimicrobial for care of individual patients. We understand that there may likely be some dispute on this point, citing challenges in securing access to ID specialists in the LTC setting. We acknowledge that currently there are varying degrees of ID specialist involvement within skilled nursing facilities and nursing homes for a number of reasons, including personnel and resource availability. We would like to take this opportunity to highlight the feasibility of antimicrobial stewardship through tele/web-based technology that enables access to “remotely located” integrated team members within an antimicrobial stewardship program.^{14,15} In addition, LTC facilities should consider accessing ID specialists to provide leadership as IPCOs and as ASPLs in LTC facilities within a region, whereby one ID specialist has cognizance and responsibility over several facilities and possibly leveraging telehealth resources. As well, a team-based approach can be applied to several facilities as has been demonstrated.¹⁶ Telehealth is rapidly gaining acceptance across the country. CMS recognizes the potential of telehealth services as evident in allowing more broad use within accountable care organizations through its recent final rule on the Medicare Shared Savings Program. IDSA believes that leveraging the expertise of ID specialists using tele/web-based technology to lead AS programs across healthcare systems or to rural LTCs greatly extends the ability of specialists in this area to reach any site and every resident/patient and would prove to be a viable and better quality solution for LTC facilities when local experts are not available. We believe similar access can be established to ID-trained pharmacists and clinical microbiologists as well.

Pharmacy Services (§483.45)

Currently, the LTC requirements require that each resident's drug regimen be reviewed by a pharmacist at least once a month (§483.60(c)). Based on the belief that there are specific circumstances under which the pharmacist must at least periodically review the resident's medical record concurrently with the drug regimen review, CMS proposes to require prompt pharmacist review when a resident is on an antimicrobial medication in order to facilitate the detection of irregularities and to contribute to the goal of ensuring that these medications are used only when medically appropriate for the resident. IDSA supports this change as it is in alignment with effective antimicrobial stewardship. By requiring pharmacist review of all

¹⁴ Yam P, Fales D, Jemison J, Gillum M, Bernstein M. “Implementation of an antimicrobial stewardship program in a rural hospital.” *Am J Health Syst Pharm.* 2012 Jul 1;69(13):1142-8

¹⁵ McMahon C, Siddiqui J, Kutza C. “Telemedicine-Based Antimicrobial Stewardship Program Improves Prescribing, Reduces Bacterial Resistance to Antibiotics at Rural Hospital.” AHRQ Healthcare Innovations Exchange. Service Delivery Innovation Profile. Available at <https://innovations.ahrq.gov/profiles/telemedicine-based-antimicrobial-stewardship-program-improves-prescribing-reduces-bacterial#contactInnovator>

¹⁶ Avramovski N, Gaul D, James W, Jensen C, Jones B, Lin J, Gibson G. Impact of a City-Wide Collaborative Antimicrobial Management Program Involving All Acute Care Hospitals in Savannah, Georgia. Poster presented at IDWeek 2014, Philadelphia, PA.

antimicrobial usage with a LTC, the audit and feedback function will be well established as a key stewardship activity.

The current LTC requirements also require that the pharmacist conducting the monthly drug regimen review must report any irregularities to the attending physician and the director of nursing. The term “irregularities” is not defined in the regulation and no examples are given. CMS proposes to define “irregularities” to include unnecessary drugs which meet the following criteria:

- (1) In excessive dose (including duplicate drug therapy); or
- (2) For excessive duration; or
- (3) Without adequate monitoring; or
- (4) Without adequate indications for its use; or
- (5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
- (6) Any combinations of the reasons stated in (1) through (5) above

Here again, IDSA is supportive of this requirement that would qualify as an “irregularity” the inappropriate use of an antimicrobial. Antimicrobial stewardship has often been characterized as getting the right drug, at the right dose to a patient with a correctly-diagnosed infection, and then modifying the drug treatment as needed for the right duration. By defining “irregularities” as proposed, this will further establish effective stewardship activities in LTC facilities.

Laboratory, Radiology, and Other Diagnostic Services (§483.50)

Current regulations ((§483.75(j)(a)(2)(i) and §485.75(k)(2)(i)), require that a facility must provide or obtain laboratory and radiology and other diagnostic services “only when ordered by the attending physician.” CMS has proposed to clarify these requirements by removing the phrase, “the attending physician” and to permit that the ordering physician, physician assistant, nurse practitioner, or clinical nurse specialist be notified of laboratory results. In addition, CMS has proposed that the laboratory must promptly notify the ordering professional if results fall outside of clinical reference or expected “normal” ranges, unless the orders for the test or the facility’s policies and procedures require otherwise. IDSA is supportive of these proposed changes as they align with effective stewardship principles.

With respect to diagnostic testing, we would like to take this opportunity to highlight the role of the ID specialist as a leader in diagnostic stewardship. ID specialists help provide guidance on the correct utilization and interpretation of standard culture methods, helping to decide when to order cultures and when what, if any, antimicrobial therapy should be prescribed in response. Recognizing that many advanced molecular diagnostic tests are becoming more available, there is some concern about ensuring that the appropriate diagnostic test is coupled with the appropriate interpretation of the test result, especially when the advanced test is more costly. ID specialists can ensure the appropriate adoption of such technology into the evolving clinical practice to enable cost-effective care delivery.

Quality assurance and performance improvement (QAPI) (§483.75)

Current regulations require a facility to maintain a quality assessment and assurance (QAA) committee, consisting of the director of nursing services, a physician designated by the facility,

and at least three other members of the facility staff. In this rule, CMS has proposed to enhance the existing QAA requirements to conform with current health care industry standards that proactively design quality improvement at the outset, monitor data, identify root causes of problems, and direct performance improvement projects (PIPs) towards areas of need. Specifically, CMS has proposed that a facility be required to develop, implement, and maintain an effective, comprehensive, data-driven QAPI program that focuses on systems of care, outcomes and services for residents and staff. The QAPI program would be designed to monitor and evaluate performance of all services and programs of the facility, including services provided under contract or arrangement. Furthermore, CMS has proposed that the Infection Prevention and Control Officer (ICPO) be included as a member of the QAA.

CMS has also proposed that QAPI program activities would be required to include Performance Improvement Projects (PIPs), whereby each facility would be required to implement at least one project annually that focused on a high risk or problem prone area identified through the required data collection and analysis. CMS has raised the issue as to whether *specific* PIPs be mandated or whether facilities should be allowed to commission their own PIPs based on their particular needs or available resources.

IDSA supports the establishment of data-driven QAPI programs within LTC facilities, under the oversight of a facility's QAA committee. The QAPI program should reflect a culture of relentless enthusiasm towards improving health outcomes for residents, with ongoing project activity and an efficient communications function to widely disseminate best practices derived through PIPs. As well, IDSA is supportive of the requirement to have ICPOs as members of the QAA committee and suggests that AS Program Leads (ASPL) should also be members of the QAA committee. This seems reasonable given the importance of reducing HAIs and promoting antimicrobial stewardship within LTC facilities. On the issue of specific mandated PIPs, IDSA recognizes that much of what is proposed in this rule may pose operational challenges to LTC facilities and that requiring specific projects may prove burdensome and counterproductive. However, we do believe CMS should encourage PIPs on high risk or problem areas that lead to hospital readmissions and HAIs. As well, we suggest that projects aimed at achieving effective antimicrobial stewardship be prioritized in the near-term to speed the implementation. For example, we believe it to be in the interest of all LTC facilities to conduct PIPs aimed at reducing inappropriate use of antibiotics, measurable in terms of average days-on-therapy, costs, or other metrics as compared to baseline, under the leadership of an ID specialist. Such PIPs will be essential in evaluating whether stewardship programs at individual LTC facilities are actually achieving the desired goals and pinpointing where improvements are needed. As well, we believe LTC facilities would be well-served to commission a PIP aimed at providing timely education and training to key personnel on the importance of antimicrobial stewardship. We would also like to take this opportunity to request that CMS consider the PIPs that might be done within LTC facilities to count for eligible providers (EPs) as Clinical Practice Improvement Activities under the new Merit-based Incentive Payment System (MIPS), created with the passage of the Medicare Access and CHIP Re-authorization Act (MACRA). We believe this would create a mutually beneficial opportunity for EPs who are Infectious Diseases specialists and LTC facilities where both have a shared interest in quality improvement.

Information Collection Requirements (ICRs) Regarding Quality Assurance and Performance Improvement (§483.75):

In this rule, CMS estimated the one-time cost for each LTC facility to establish a QAPI program to be approximately \$4,500 and the ongoing annual costs for each facility to be approximately \$3,000. These estimates reflect the assumptions of physician time (4 hours) that CMS believes to be accurate in establishing a QAPI program. Furthermore, CMS estimated that the cost to an LTC facility to support an IPCO on an annual basis to be approximately \$18,000. This estimate is based on the assumption that a registered nurse would be designated as the IPCO in an LTC facility and that he/she would dedicate 15% of his/her time to the infection prevention programs. As well, this estimate also assumes that the antimicrobial stewardship program would be included in the infection prevention programs.

As we have indicated above, we believe ID specialists are best suited to lead Infection Prevention Programs and antimicrobial stewardship programs. We cannot present cost estimates associated with implementing programs according to our ID-led model. Recognizing that these models may appear daunting to LTC facilities, we feel it is important to consider three important factors when assessing the costs. First, AS programs have been proven to achieve cost-savings by effectively reducing inappropriate antimicrobial use that, in turn, promote improved quality of care and health outcomes. Second, having well-structured infection prevention programs and AS programs, led by ID specialists, will help LTC facilities to avoid payment penalties associated with avoidable readmissions and HAIs. Finally, we believe that the costs associated with having ID-led infection prevention programs and ID-led AS programs can be distributed across several LTC facilities on a regional basis, providing sufficient coverage by leveraging telehealth technology.

In addition to the associated costs required to comply with much that is contained in this proposed rule, we would also like to discuss the timeline for implementation. IDSA respectfully requests that CMS take into account the scope and resources involved in establishing effective infection prevention programs above what already exists in LTC facilities as well as in starting up appropriately staffed AS programs (under the leadership of an ID specialists and including ID-trained pharmacists and clinical microbiologists) in order to have in place a viable structure that can reasonable achieve the goals set forth in the CARB National Action Plan. This work will take careful planning over a considerable amount of time as LTC facilities vary greatly in their ability and available resources to comply with the proposed changes. IDSA asks that CMS lay out a reasonable timeline that will allow LTC facilities to adapt to the changes when finalized.

Infection control (§483.80)

We are concerned that CMS proposes to eliminate the exception that is currently located at §483.25(v) regarding pneumococcal immunization without a plan for replacing the provision with language reflecting the current standard of care. Pneumonia is responsible for over a million hospitalizations and 50,000 deaths each year in the United States. Vaccines are an effective intervention against the high cost of medical care and rates of preventable death associated with this disease, particularly among medically vulnerable populations and the elderly. We acknowledge that different intervals between PCV13 and PPSV23 have been

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disparate by age group and risk conditions, and have been confusing to providers. However, at its June meeting, the Advisory Council for Immunization Practices (ACIP) voted unanimously to change the interval between PCV13 and PPS23 from “6-12 months” to “1 year or longer” in healthy persons ≥ 65 years of age. We therefore urge CMS to reflect this change in revised language rather than eliminating the exception altogether.

IDSA appreciates the efforts of CMS to promote improved patient safety and better quality of care through changes as set forth in LTC Facilities Conditions of Participation Proposed Rule. We welcome further discussion with CMS and other stakeholders on how best to implement effective infection prevention programs as well as antimicrobial stewardship programs under ID specialist leadership. If you have any questions, please feel free to contact Andrés Rodríguez, Director for Practice & Payment Policy, at 703-299-5146 or arodriguez@idsociety.org.

Sincerely,

A handwritten signature in black ink that reads "Johan S. Bakken". The signature is written in a cursive style with a prominent initial 'J'.

Johan S. Bakken, MD, PhD. FIDSA
President, IDSA