Alliance
FOR AGING RESEARCH

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September 14, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert Humphrey Building, Room 445-G-200
Independence Avenue, SW
Washington, DC 20001

Dear Acting Administrator Slavitt,

The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. We thank the Centers for Medicare & Medicaid Services (CMS) for issuing the proposed rule change regarding Infection Prevention and Control Programs (IPCP) in long-term care facilities (LTCFs). IPCP guidance for CMS participating LTCFs has not been updated in 23 years; new requirements are long overdue. We commend the centers for acknowledging that "as a result of advances in the study and practice of infection prevention and control and given the impact of HAIs, we find that the current requirements for infection control in our requirements warrant updating and strengthening."

Older Americans receiving care in an LTCF are particularly susceptible to infections due to the prevalence of comorbidities in LTCF patients, sustained exposure to HAIs, and lower functioning immune systems. Strengthening the Federal standard of IPCPs in LTCFs is critical to improve the safety and health outcomes of older Americans.

Nursing homes, skilled nursing facilities, and assisted living facilities provide a variety of services, both medical and personal care, to people who are unable to manage independently in the community. More than 3 million Americans receive care in U.S. nursing homes and skilled nursing facilities each year and nearly one million persons reside in assisted living facilities. Data about healthcare-associated infections (HAIs) in these settings is limited, but the Centers for Disease Control and Prevention (CDC) estimates that:

- 1.6 to 3.8 million serious infections occur every year in LTCFs
- An estimated 380,000 people die of infections in LTCFs each year
- HAIs result in $673 million to $2 billion in additional healthcare costs annually

It should be noted that the data used to calculate the above figures was collected 15 years ago, a reflection of the lack of focus on this issue with long-term care. Until now, there have been no federal requirements for adequate surveillance and reporting of HAIs in long-term care facilities,

no federally standardized HAI prevention efforts for these facilities, and sporadic, voluntary antibiotic stewardship programs. We do not want to see another 20+ years go by before effective HAI surveillance/prevention and antibiotic stewardship programs are implemented. The proposed rule must go beyond its current broad strokes and be as prescriptive as is possible and reasonable for participant facilities to align with CDC-developed guidelines, because this is literally a life-and-death issue for our nation's LTC residents. **It is for this reason that the Alliance for Aging Research opposes any suggested delay in implementation for these new regulations and strongly supports full implementation within two years of the final rule.** Accordingly, the Alliance for Aging Research is submitting the following additional comments regarding section U. Infection Control (§483.80) of the proposed rule change.

The Importance of Surveillance

The proposed rule provides no directive as to how LTC facilities should conduct surveillance of HAIs. When facilities track infections, they can identify problems and track progress toward stopping infections. **The Alliance strongly supports mandating the CDC's National Healthcare Safety Network (NHSN) for surveillances of HAIs by LTC facilities.**

The CDC's NHSN provides long-term care facilities with a customized system to track infections on a monthly basis in a streamlined and systematic way. On the national level, data entered into NHSN will gauge progress toward national healthcare-associated infection goals. NHSN's long-term care component may be used by nursing homes, skilled nursing facilities, chronic care facilities, and assisted living and residential care facilities. The NHSN provides a secure way for healthcare facilities to track HAIs and take action to prevent infections. Progress is measured using the standardized infection ratio (SIR), a summary statistic that can be used to track HAI prevention progress over time. Researchers use the reported HAI data to calculate a SIR for each reporting state and facility. According to the CDC, research shows that when healthcare facilities, care teams, and individual practitioners are aware of infection problems and take specific steps to prevent them, rates of certain HAIs can decrease by more than 70 percent.

Infection data can give healthcare facilities and public health agencies information they need to design, implement, and evaluate prevention strategies that protect patients and save lives. Currently, 32 states and the District of Columbia are required by law to report HAI data to the NHSN, with more than 16,000 hospitals and healthcare facilities providing data.

We also believe NHSN data should be translated for use in CMS' Nursing Home Compare 5-star rating system to educate consumers about rates of infection by facility, as well as whether each facility implements a CDC-guided, evidence-based antibiotic stewardship program, modeled after the Core Elements of Hospital Antibiotic Stewardship. Nursing Home Compare has detailed information about every Medicare and Medicaid-certified nursing home in the country. Nursing home ratings come from health inspections, staffing, and quality measures. A star rating is provided for each of these 3 sources, which are then combined to calculate an overall rating. Since nursing homes vary in the quality of care and services they provide to their residents, this review of health inspection results, staffing data, and quality measure data are important ways to measure nursing home quality. Adding a rating for infection control and

antibiotic stewardship would educate consumers on an important aspect of health safety as they choose a facility.

We acknowledge that the Social Security Act requires that all persons (regardless of payer) who reside in a Medicare- or Medicaid-certified nursing facility must have a resident assessment, which includes use of a Minimum Data Set (MDS), completed at certain intervals (e.g., admission, quarterly, annually, when there is a significant change in the resident's condition, and at discharge). Using the MDS, nursing homes report data for all residents on urinary tract infections (UTIs) and catheters. Two National Quality Forum (NQF)–endorsed measures (684 and 686) have been developed from these MDS data and are used as part of the Nursing Home Quality Initiative for quality reporting and public reporting purposes. These quality measures apply to long-stay NH/SNF residents only; neither measure is endorsed for short-stay residents. We strongly advise against allowing LTC facilities to use the MDS for HAI surveillance. According to the U.S. Department of Health and Human Services (HHS) Office of Disease Prevention and Health Promotion's 2013 National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination, which CMS references in the proposed rule, there are significant limitations to relying on the MDS for surveillance of HAIs: "Despite refinements made to the MDS 3.0 that include documentation of the presence of UTIs, and use of devices such as urinary catheters, seasonal influenza and pneumococcal vaccinations, clinical assessments, care areas triggered, and care plans, there is a limitations to using MDS data as a universal data source to track HAI in nursing homes. Assessments provide snapshots of patients at a particular point in time, and the time between assessments may not capture important changes. For instance, assessments on long-stay residents may occur as infrequently as quarterly. Therefore, infection events could be missed between measurement periods." Additionally, the MDS is not capable of capturing multiple infections or timing of infections. The goal of counting infections should not be just to count, but rather to identify places to intervene, and NHSN would serve this role much more effectively than MDS.

The effect of NHSN with pay-for-performance in the hospital setting has been significant in a short period of time. The CDC's HAI Progress Report describes significant reductions reported at the national level in 2013 for nearly all infections. Central line-associated bloodstream infections and select surgical site infections show the greatest reduction, with some progress shown in reducing hospital-onset MRSA bacteremia and hospital-onset C. difficile infections. The Report shows an increase in catheter-associated urinary tract infections, signaling a strong need for additional prevention efforts.

Infection Prevention and Antibiotic Stewardship

The Alliance recognizes that the proposed rule language to require IPCPs to prevent and control infections and reduce the inappropriate use of antibiotics through stewardship programs is a huge step forward. However, the requirement should be more specific than "must follow accepted national standards, be based upon the facility assessment conducted according to proposed §483.70 and include, at a minimum, a system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual agreement." What are "accepted national standards"? Which "system" for prevention, control and

surveillance should be used? The latitude allowed here is troubling and programs should be much more clearly defined, both for the public health of residents as well as for review and inspection by surveyors. **The Alliance recommends that CMS work directly with the CDC to outline specific programs that LTCFs should follow to fulfill the mandates.**

The Alliance for Aging Research believes that CMS should mandate the CDC's soon-to-be-released Core Elements for Antibiotic Stewardship in LTCF. Antibiotic stewardship improves the use of antibiotics by addressing the over-prescribing of antibiotics and prolonging the efficacy period of antibiotics. The inappropriate use of antibiotics is a national healthcare concern that extends beyond LTCFs. These healthcare facilities are at the forefront of new antibiotic resistance. For example, UTIs are a major driver of antibiotic use in LTCFs and C. difficile presents in higher-than-average rates in LTCFs due to antibiotic-resistance. Stewardship programs are essential for reducing strains of antibiotic-resistant organisms and improving patient outcomes.

The CDC Core Elements for Hospitals allows for the reporting and tracking of antibiotic use measures in either Days of Therapy (DOT) or Defined Daily Dose (DDD). These metrics allows for the tracking and estimating of antibiotic use in hospitals by aggregating the total number of grams of each agent purchased, dispensed, and administered. Additionally, the CDC developed the Antibiotic Use (AU) Option that automatically collects and reports monthly DOT data on aggregate use, specific agent use, and location use. AU is available for facilities that are capable of submitting electronic medication administration records (eMar) or bar coding medication records (BCMA). CMS should encourage LTCFs to work with their information software providers to configure their systems to enroll in AU. Such a system would allow benchmarking that is helpful to reach Stewardship goals.

Infection Prevention and Control Officer

The Alliance for Aging Research agrees that every LTCF should have an Infection Prevention and Control Officer (IPCO) whom: is responsible for the IPCP, has specialized training in infection prevention and control, and is a member of the Quality Assurance and Assessment (QAA) team. Stewardship programs work best when they are led by an infection specialist whom has specific clinical knowledge in infections and proper antibiotic use. Most LTCFs lack the adequately trained and committed personnel necessary to properly run an IPCO. As it stands, most LTCHs have infection preventionists (IPs) on staff that only work part-time on infection control, and 2011 Maryland study found that only 8.1% of IPs working in an LTCF had received any specific ICP training.

An additional requirement the Alliance for Aging Research would like to see is the contact information for an IPCO to be made publically available for family members of LTCF patients in the final CMS rule. This would allow family members to contact the IPCO if there is a potentially infectious item, surface, or area that would otherwise go unnoticed.
We would also ask that special consideration for rural LTCFs be reflected in the final rule when the specific requirements for the IPCO are set forth, such as telehealth options. It is foreseeable that rural facilities will have difficulty in filling an IPCO that could fulfill all of the training requirements.

Tracking & Reporting Antibiotic Use Measures

The Alliance for Aging Research would like to see the Proposed Rule take on the standard set for monitoring antibiotic prescribing, use, and resistance set in the CDC's Core Elements of Hospital Antibiotic Stewardship Programs to extend beyond the Social Security Act's minimum data set. Monitoring and measuring is critical for Stewardship programs to be effective.

Influenza Vaccination

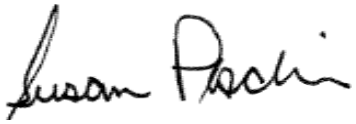
The Alliance for Aging Research agrees with the National Action Plan assessment that Federal programs should encourage LTCF healthcare workers to receive influenza vaccinations. According to a 2010 CDC survey, over a third of health care professionals working in LTCF did not receive a seasonal influenza vaccination. Over 90% of influenza-related deaths in the United States are in individuals age 65 and older. Residents of LTCF are particularly susceptible of contracting the influenza because their health care setting is often their home. **While the Alliance recognizes that a balance needs to be struck between the safety of patients and the rights of the health care workers, we believe CMS should provide language in the proposed rule mandating the use of influenza vaccinations among direct-contact health care workers in LTCFs and set targets for vaccination rates.**

Implementation Cost

While the Alliance for Aging Research does not have an issue over the cost of implementing the IPCP, we do believe that the cost estimates for the proposed rule change are unrealistically low, and do not provide LTCFs an accurate figure to plan future implementation of proposed rules. We would also suggest that pharmacy cost-savings from the implementation of a stewardship program be included in the cost estimates. Between 25 to 75 percent of antibiotic use in LTCFs is inappropriate. The reduction of inappropriate antibiotic prescriptions could result in notable savings for both patients and the facility. Consideration should be given to assessing the pace at which antibiotic costs were rising before the implementation of a stewardship program.

Thank you for releasing this Proposed Rule and your commitment to serving the healthcare needs of America's Medicaid and Medicare recipients. If you have any questions concerning our comments, please contact our Public Policy Assistant, Ryne Carney, at rcarney@agingresearch.org or (202) 293-2856, if you have any questions or would like to follow up on our recommendations.

Sincerely,



Susan Peschin, MHS
President and CEO