STATEMENT OF

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ON

NEXT STEPS FOR PATIENT SAFETY:

ASSURING HIGH VALUE HEALTH CARE ACROSS ALL POINTS OF CARE

BEFORE THE

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Thank you, Senator Blumenthal, for the opportunity to appear today to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to improve patient safety for nursing home residents. CMS has a number of initiatives underway to improve care across settings, including by ensuring better care transitions. As director of the Director of Nursing Homes in the Survey and Certification Group in CMS' Office of Clinical Standards, I will speak specifically about patient safety in nursing homes, a single component of CMS' multiple initiatives. CMS is committed to ensuring that every Medicare and Medicaid beneficiary receives seamless, high-quality health care, both within health care settings such as nursing homes, and among health care settings during care transitions.

As you may know, more than 3 million Americans rely on services provided by nursing homes at some point during the year and 1.4 million Americans reside in the nation's 15,800 nursing homes on any given day. Those individuals, and an even larger number of their family members, friends, and relatives, must be able to count on nursing homes to provide reliable, high quality, safe care. A number of divisions within CMS work together to promote nursing home safety and quality improvement, address reimbursement issues, and enforce Medicare Conditions of Participation. The combined levers of technical assistance, payment reform, oversight, and enforcement create a powerful system that promotes safety and quality care in nursing homes.

Background

To ensure that nursing homes meet both Federal and State standards, CMS conducts initial and ongoing inspections of all facilities participating in the Medicare and Medicaid programs. The Survey and Certification process plays a critical role in ensuring basic levels of quality and safety for Medicare and Medicaid beneficiaries by monitoring nursing home compliance with Federal and State requirements. Within the Survey and Certification Group, the Division of Nursing Homes focuses on optimizing the health, safety, and quality of life for people living in nursing homes, through close coordination with other divisions. Approximately 5,000 Federal and State surveyors conduct on-site surveys of certified nursing homes on average every 12 months to assure basic

levels of quality and safety for beneficiaries. CMS has undertaken several initiatives over the past several years to improve the effectiveness of the annual nursing home surveys, as well as to improve the investigations prompted by complaints from consumers or family members about nursing homes.

However, no single approach can fully assure better nursing home care. Rather, CMS acts to combine, coordinate, and mobilize many people and techniques through a partnership approach. Survey Agencies, Ombudsmen, Quality Improvement Organizations (QIOs), and other partners are committed to the common endeavor of promoting quality and safety in nursing homes. Although these entities have different responsibilities, their distinct roles can be coordinated in a number of ways to achieve better results than can be achieved by any one agency alone. Collectively, CMS' work to enhance quality and safety in nursing homes is focused in five major areas: 1) enhancing consumer engagement; 2) strengthening survey processes, standards and enforcement; 3) promoting quality improvement; 4) creating strategic approaches through partnerships; and 5) advancing quality through innovation and demonstrations. Through coordinating and aligning these initiatives, CMS is working to spearhead ongoing improvements in quality and safety in nursing homes.

Prior to becoming the Director of Nursing Homes in the Survey and Certification Group in CMS' Office of Clinical Standards, I worked in clinical practice as a geriatric nurse practitioner for more than 20 years. As a clinician working in the field of geriatrics, I understand the key role of interdisciplinary partnerships in nursing home care, where safe, reliable care depends on close collaboration among nurses, certified nursing assistants, social workers, therapists, primary care providers, specialists, and, most importantly, the residents and families.

I have also seen first-hand the importance of balancing safety with the need for a resident in a nursing home to have a voice in his or her own care, to be autonomous, to make choices that affect their daily routines, and other basic rights. CMS encourages facilities to examine their organization's values, structures, and practices to transform traditional institutional approaches to those that are person-centered. The adoption of person-centered care principles can improve both the resident and the family's experience of care.

In the following sections, I would like to highlight some specific, recent activities that CMS has undertaken to improve quality and safety for nursing home residents in the areas of antipsychotic medication use, managing fall risk, quality assurance and performance improvement, nursing home oversight of special focus facilities, and care transitions across long-term care settings.

Addressing Inappropriate Antipsychotic Medication Use

Nursing homes play an important role in providing care for those with dementia; any discussion of how to best improve the quality of health care for Alzheimer's disease and dementia patients must necessarily involve this component of the health care delivery system. According to the Alzheimer's Association, 75 percent of people with Alzheimer's will be admitted to a nursing home by age 80. While there is still much we do not understand about the causes, diagnosis, and treatment of Alzheimer's disease, there is a compelling and growing body of scientific evidence suggesting that the use of certain medications, including atypical antipsychotics, to treat the behavioral symptoms of Alzheimer's or other dementias may not be appropriate. CMS recognizes that a crucial component to improving the quality of care for beneficiaries with dementia is eliminating the inappropriate or harmful use of these medications.

In September 2006, CMS implemented substantial improvements to onsite surveys to help address concerns about antipsychotic medication use. Specifically, CMS revised interpretive guidelines for unnecessary medications, including clarifying several aspects of medication management and developing a new medication table that includes medications that are problematic for nursing home populations. These Survey and Certification guidelines are designed to assist regulators in determining whether residents receive only medications that are clinically indicated in an appropriate dose and duration, whether non-pharmacological interventions are considered, and whether gradual dose reduction is attempted when clinically appropriate. Examples of noncompliance can include excessive dosing of medication, prolonged use of antipsychotic medications without attempting dose reduction, or failure to implement behavioral interventions in an attempt to eliminate or reduce antipsychotic medication. This process is carefully balanced with the need to protect the ability of physicians to make clinical decisions on the use of atypical antipsychotic medications in people with dementia, based on the individual patient's needs.

¹ <u>http://www.alz.org/documents_custom/2011_Facts_Figures_Fact_Sheet.pdf</u>

Since the implementation of this guidance in December 2006, the percent of surveys with citations for unnecessary medication use has increased significantly. In the seven years prior to implementation of this change, 12.6 percent to 14.0 percent of facilities were cited for unnecessary medication use; this has grown to 18.2 percent in 2007² and 19.2 percent using data from the most recent facility survey (calendar years 2011 through 2012). Accurate detection is the first stage in identifying potential harm and eliminating it. CMS is working with our State partners, using this information to target educational programs and technical assistance to providers in States or regions with high citation rates for unnecessary medication use.

CMS has also worked to ensure that as part of routine onsite reviews, Survey and Certification personnel have the tools and resources necessary to effectively monitor nursing homes' compliance with these policies. For example, offsite preparation in advance of the survey includes a review of the rate of antipsychotic medication use for that facility. This enables surveyors to identify specific residents, families and staff (including physicians), to interview during the onsite survey.

Providing appropriate care to beneficiaries with dementia is more complex than simply avoiding the inappropriate use of medication. CMS also requires providers to use non-pharmacological interventions to help address behavioral or psychological issues. Possible interventions may include talking with families or previous caregivers about the person's previous coping mechanisms and ways that they used to deal with stress, using consistent staff assignment so that staff is very familiar with a resident, increasing exercise or time outdoors for the patient, managing acute and chronic pain, or planning individualized activities for patients.

In data collected from nursing homes between July and September 2010, nearly 2 in 5 (or 39.4 percent) of nursing home residents nationwide, who had cognitive impairment and behavioral problems but no diagnosis of psychosis or related conditions, received antipsychotic drugs.³ In

³ CMS, MDS Quality Measure/Indicator Report, Psychotropic Drug Use, July/September 2010, Measure 10_1_HI, http://www.cms.gov/apps/mds/mds_notemp/qm_start.asp?isSubmitted=qm3&group=10&qtr=23

² Federal Register, Volume 76, No. 196, October 11, 2011. Pg. 63039.

another study, over 17 percent had daily doses exceeding the recommended levels and over 17 percent had both inappropriate indications and high dosing.⁴

In order to address this issue, on May 30, 2012, CMS announced the CMS National Partnership to Improve Dementia Care: Rethink, Reconnect, Restore. This initiative creates a public-private partnership and a multidimensional approach to dementia care. The multidimensional strategy for this initiative includes raising public awareness, strengthening regulatory oversight, providing technical assistance and training, improving public reporting to increase transparency, and conducting research. Our goal for this national initiative is to reduce the use of antipsychotic drugs in nursing home residents by 15 percent by the end of the 2012.

CMS and industry and advocacy partners are taking several steps to achieve this goal of improved care:

- Enhanced training: CMS has developed Hand in Hand, a training series for nursing homes
 that emphasizes person-centered care, prevention of abuse, and high-quality care for
 residents. CMS is also providing training focused on behavioral health to state and federal
 surveyors;
- Increased transparency: CMS is making data on each nursing home's antipsychotic drug use available on Nursing Home Compare starting in July of this year, and will update this data; and
- Alternatives to antipsychotic medication: CMS is emphasizing non-pharmacological
 alternatives for nursing home residents, including potential approaches such as consistent
 staff assignments, increased exercise or time outdoors, monitoring and managing acute and
 chronic pain, and planning individualized activities.

The model for CMS' multidimensional approach to improving dementia care and reducing inappropriate antipsychotic medication use in nursing homes is based on other recent successful initiatives, such as the overall reduction in physical restraints and pressure ulcers. In those initiatives, the Office of Survey and Certification, nursing home advocates, the QIOs, and other

⁴http://www.cms.gov/apps/media/press/release.asp?Counter=4368&intNumPerPage=10&checkDate=&checkKey=&src hType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C +5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date

organizations such as the Advancing Excellence in Long Term Care Collaborative worked together to significantly reduce rates of physical restraints over several years. For example, between 1991 and 2009 the percentage of long-stay nursing home residents that were physically restrained dropped from 21 percent to 4 percent. Similar results were achieved for pressure ulcer reduction as well.

Implementing Quality Assurance and Performance Improvement

CMS has undertaken an initiative to broaden quality activities in nursing homes. The provisions added by section 6102 of the Affordable Care Act (P.L. 111-148 together with P.L. 111-152) provide the opportunity for CMS to mobilize some of the best practices in nursing home quality and to identify technical assistance needs, in advance of a new quality assurance and performance improvement (QAPI) regulation implementing these provisions. The amendments under section 6102 provide that CMS shall establish and implement a QAPI program for facilities that includes development of standards related to quality assurance and performance improvement and provision of technical assistance on the development of best practices in order to meet those standards. This new provision significantly expands the level and scope of currently required activities to ensure that facilities continuously identify and correct quality deficiencies as well as promote and sustain performance improvement.

With the passing of the Affordable Care Act, CMS embarked on a mission to develop a QAPI program by December 31, 2011. During the initial phase, CMS and our contractors:

- Reviewed available tools to help manage QAPI processes in nursing homes;
- Established a Technical Expert Panel (TEP) to assist CMS contractors in developing and applying a QAPI prototype based on existing literature and practice;
- Launched a demonstration project in September 2011 in 17 nursing homes across four states to test implementation strategies and effectiveness of QAPI tools and resources;
- Engaged stakeholders in a dialogue around dissemination strategies for national rollout. These
 active discussions continue on a frequent basis with multiple stakeholders from around the
 country; and
- Appointed onsite technical assistance liaisons to visit each nursing home in the demonstration and provide them with individualized technical assistance.

The national QAPI rollout is currently underway and advancing. QAPI tools, resources, and technical assistance that are currently being tested in the demonstration will be available to all nursing homes this summer. Materials will assist nursing homes in improving their current quality programs using best practices and local learning collaboratives.

In addition to the national rollout, CMS distributed a 20-minute questionnaire to a representative sample of 4,200 randomly selected nursing homes in June 2012. We will use the results of this questionnaire to establish a baseline of QAPI practices in nursing homes, gather information on the challenges and barriers to implementing effective QAPI programs, and help shape the direction and content of the QAPI tools and resources provided by CMS to all nursing homes.

Beginning in August 2012, all stakeholders, including nursing home providers, residents, advocates, and regulators will have access to an online resource library and website that contains information about this transformative initiative. The online library provides resources and training materials that will facilitate stakeholders' understanding and implementation of QAPI. CMS plans to further these efforts with rulemaking during 2013.

Improving Care Transitions

There are significant safety risks associated with the transition of frail elders from the hospital to the nursing home. Currently, care transitions are often fragmented, with nursing home providers lacking the information that they need from hospitals to properly care for residents. This may result in medication errors or other adverse events, such as delirium and rehospitalization. Similarly, when residents are transferred from the nursing home to the emergency department (ED) for care, information that ED clinicians need from the nursing home is often lacking.

One in four residents admitted to a skilled nursing facility (SNF) is readmitted to the hospital within 30 days at a cost to Medicare of \$4.3 billion per year. Many factors contribute to rehospitalization, including resident factors, absent or limited communication with families, unclear goals of care or lack of advance care planning, lack of available providers in the SNF to see a sick resident, misaligned financial incentives and other factors. One study suggests that up to 45 percent of

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⁵ Mor V, Intrator O, Feng Z, Grabowski DC. The revolving door of rehospitalization from skilled nursing facilities. Health Affairs. 2010;29:57–64. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2826971/?report=abstract

readmissions of nursing home residents to the hospital may be inappropriate.⁶ Programs to enhance nursing assessment and early identification of change in condition and to improve communication between settings are part of technical assistance provided by the QIOs to individual nursing facilities under the current QIO scope of work.

The Survey and Certification Group is currently revising guidance related to regulatory requirements for admission, discharge, and transfer of residents to better focus on nursing homes' accountability for ensuring safe and effective care transitions to and from the acute care setting. CMS is working to develop new quality measures that will track 30-day hospital readmissions among newly admitted nursing home residents.

We are also working closely with the Department of Health and Human Services (HHS) Office of Inspector General (OIG) as it begins two studies examining aspects of nursing home resident safety. First, the OIG has recently begun analyses examining the rate, preventability, and associated costs to the Medicare program of hospitalizations among nursing home residents. The OIG is also, in a separate study, examining the rate of adverse events among nursing home residents. The Division of Nursing Homes is working closely with the OIG on both of these studies to ensure that the data can inform our multiple initiatives to improve nursing home resident safety.

Managing the Risk for Falls

Each year, one out of three adults over the age of 65 falls.^{7,8} Rates of falls in nursing home residents are much higher. Falls by nursing home residents may lead to hip fractures and other serious injuries, and may cause severe disability among survivors. Injuries from falls may also lead to fear of falling, increased sedentary behavior, impaired function, and lower quality of life for seniors, particularly those living in nursing homes. Falls are the leading cause of death due to unintentional injury among older adults, but many of these deaths and injuries could be prevented if multiple risk factors were addressed, including the misuse of certain medications.

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⁶ Saliba D, Kingston R, Buchanan J, et al. Appropriateness of the decision to transfer nursing facility residents to the hospital. *J Am Geriatr Soc.* 2000;48:154-163.

⁷ Hornbrook MC, Stevens VJ, Wingfield DJ, et al. Preventing falls among community-dwelling older persons: Results from a randomized trial. Gerontologist. 1994 Feb;34(1):16-23.

⁸ Hausdorff JM, Rios DA, Edelberg HK. Gait variability and fall risk in community-living older adults: A one-year prospective study. Arch Phys Med Rehabil. 2001 Aug;82(8):1050-6.

Provider education about safe prescribing practices, including for opioid and narcotic prescriptions, may help reduce adverse reactions or falls by minimizing or eliminating the dizziness and confusion that opioids may cause, which could increase the risk of falls. In 2011, the Administration outlined an action plan to improve prescription drug safety, titled "Epidemic: Responding to America's Prescription Drug Abuse Crisis." The plan calls for education of patients, providers, and community members concerning proper prescribing and risks associated with these medicines. It also calls for providers to utilize State prescription drug monitoring programs to manage medications and identify patients who may be at risk for addiction and misuse.

CMS is posting a new quality measure on Nursing Home Compare this summer that will report the percentage of falls with serious injury in nursing home residents by facility. These data will enable professional associations, culture change coalitions, QIOs and other organizations to target technical assistance and fall risk reduction programs to nursing homes with the highest fall rates.

Nursing Home Oversight Activities to Promote Safety and Quality: the Special Focus Facility Program

Between 2005 and 2010, CMS certified an average of 16,050 nursing homes each year for participation in the Medicare and/or Medicaid programs. While many nursing homes meet minimum nursing home requirements either upon the survey or within a short period thereafter, some nursing homes pass one survey, only to fail the next survey for issues identified previously and give rise to repeated cycles of serious deficiencies.

In recognition of this phenomenon, CMS created the Special Focus Facilities (SFF) program in 1998 as one of the initiatives of the Nursing Home Oversight and Improvement Program. The purpose of the SFF program was to decrease the number of persistently poor performing nursing homes by directing more attention to nursing homes with a record of poor survey performance. In January 1999, CMS instructed State Survey Agencies to conduct two standard surveys per year for each SFF instead of the one required by law. CMS also requested that State Survey Agencies submit a monthly status report listing surveys, revisit surveys, or complaint investigations of SFFs they conducted in that month.

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⁹ http://www.whitehouse.gov/sites/default/files/ondcp/issues-content/prescription-drugs/rx_abuse_plan_0.pdf

In collaboration with the States, CMS identified areas where the SFF program could be improved. Since December 2004, CMS has been working to continually improve the SFF program and increase its effectiveness by:

- *Increasing the Number of Nursing Homes in the SFF program:* We increased the total number of facilities by about 30 percent, with larger States having more SFFs than smaller States (instead of focusing on two nursing homes in every State);
- *Enabling Better Selection*: Improving the data and methods by which poor performing nursing homes are identified, thereby enabling States to move on to other nursing homes on the candidate list if the original nursing homes show significant improvement;
- *Strengthening Enforcement*: Implementing more robust enforcement for nursing homes that fail to make progress;
- *Reducing Reporting Burden*: Removing the monthly reporting requirement for States; current requirements for surveying each SFF twice a year remain unchanged; and
- *Building in Timeframes for Action*: Requiring that nursing homes have three standard surveys to make improvements and either graduate from the program, make significant improvement, or face termination from the Medicare program.

In fiscal year (FY) 2008, CMS made further improvements to the SFF initiative by requiring that States notify nursing homes that they are designated as a SFF and requiring that States notify other accountable parties of this designation, such as owners, governing parties, and other additional parties such as the State Ombudsman, the State Medicaid Agency, and a State's QIO.

The second improvement was posting the names of all SFF nursing homes on CMS' Nursing Home Compare website. ¹⁰ SFF's names are organized so consumers and families can distinguish between nursing homes that have significantly improved and those that have not, have graduated, or have terminated participation in the Medicare program, as well as SFF nursing homes that have recently been added to the SFF initiative. The third improvement was the inclusion of a SFF icon for those nursing homes on Nursing Home Compare website that are part of the SFF initiative.

¹⁰ http://www.medicare.gov/NHCompare/

In FY 2011, CMS made further improvements to the SFF initiative by initiating quarterly calls to the CMS Regional Offices to discuss the status of any nursing home that continues on the SFF program for a time exceeding 24 months. CMS staff focus on enforcement remedies, quality assurance programs such as the Advancing Excellence in Long Term Care Collaborative's program conferences with ownership and management of the facility, potential assistance from the State Survey Agency and Regional Office, and enforcement recommendations such as termination from Medicare. Approximately 50 percent of the nursing homes in the SFF program significantly improve their quality of care within 24 to 30 months after being selected for the SFF initiative, while about 16 percent tend to be terminated from Medicare and Medicaid. CMS closely oversees the remaining proportion's status through the quarterly calls mentioned above. Overall, enhanced oversight of these low performing facilities has led to safer care for many nursing home residents.

Next Steps

CMS is continuing our efforts to be a driving force in health care change and a partner for our stakeholder communities in improving health care for all Americans. As a former geriatric nurse practitioner, I personally take this commitment to serve and improve our health system very seriously. In order to meet this commitment, CMS is focused on the activities highlighted above, as well as looking ahead to future care improvements.

CMS is working to improve quality and safety for nursing home residents in the areas of inappropriate antipsychotic medication use, managing fall risk, quality assurance and performance improvement, nursing home oversight of special focus facilities, and care transitions across long-term care settings. CMS plans to expand these activities by increasing the goals within the CMS National Partnership to Improve Dementia Care and Reduce Antipsychotic Drug Use in 2013 and by spreading QAPI to all nursing homes nationwide through a national rollout. We are also working to transform the nursing home survey process with continued movement towards a more effective, computer-assisted, data-driven process (such as the Quality Indicator Survey (QIS) model) for 100 percent of our nursing home surveys in the years to come.

Additionally, we are collaborating across CMS as well as HHS in order to provide the perspective on how certain programs can better meet the needs of residents in nursing homes. For example, we are working with the Center for Medicare and Medicaid Innovation and the Federal Coordinated

Health Care Office (Medicare-Medicaid Coordination Office) on the Initiative to Reduce Avoidable Hospitalizations Among Nursing Facility Residents. This initiative supports the Partnership for Patients' goal of reducing hospital readmission rates by 20 percent by the end of 2013. CMS is also contributing the development of the next stages of meaningful use criteria for long-term and post-acute care providers in the Electronic Health Record Incentive Program. Finally, we continue to lead the work on behalf of the HHS Action Plan for Healthcare Acquired Infections (HAIs) and collaborating with the Centers for Disease Control and Prevention on tracking State initiatives to reduce HAIs. These collaborations and future goals show CMS's commitment to continual improvements in quality and safety in nursing homes.

Conclusion

I appreciate the Committee's ongoing interest in improving the quality of care for all of our nation's citizens. Thank you for the opportunity to discuss the work CMS has been doing to improve patient safety and care in the nursing home setting.