March 7, 2014

Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS-4159-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Officers of the Centers for Medicare and Medicaid Services:

RE: CMS-4159-P

The Gerontological Society of America (GSA) is pleased to submit these comments in response to a proposed rule by the Centers for Medicare & Medicaid Services (“CMS”), CMS-4159-P, Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, published in the Federal Register on January 10, 2014 (79 FR 1917).

GSA is the largest multidisciplinary professional membership organization of researchers studying all facets of aging on a national and international scale. The Society’s members include physicians, nurses, biologists, psychologists, social workers, economists, health policy experts and others interested in expanding scientific knowledge related to aging. Because of the breadth and depth of our members’ interests and scholarship in gerontology and geriatric practice, GSA’s strengths in this knowledge domain may be of benefit to CMS in finalizing the above-referenced proposed rule changes, especially as such changes concern older adults’ unique needs. The following comments have been developed with input from GSA members in medicine, nursing, health policy, social work and the law, and ethics.

Purposes of Proposed Rule
The purposes of the proposed rule, CMS-4159-P, which makes revisions to the Medicare Advantage Program (Part C) and the Medicare Prescription Drug Benefit Program (Part D) regulations, as well as implements certain provisions of the Affordable Care Act, are identified as necessary to clarify program participation requirements; strengthen Medicare beneficiary protections and the ability of CMS to identify applicants for Part C and Part D program participation; remove or exclude poor performers; and improve payment accuracy.

GSA directs its focus to the last of these enumerated purposes, namely, improving payment accuracy through revocation of enrollment in the Medicare Program. More specifically, the comments that follow address proposed changes to Part 424, Conditions for Medicare Payment, Section 424.535, Revocation of enrollment in the Medicare Program.

Comments on Section 424.535 Revocation of enrollment in the Medicare program.
The proposed rule would add the following language to Section 424.535:

(14) Improper prescribing practices. CMS determines that the physician or eligible professional has a pattern or practice of prescribing Part D drugs that falls into one of the following categories:
(i) The pattern or practice is abusive and represents a threat to the health and safety of Medicare beneficiaries.

Under Section 424.535 (14)(i), the following are the first three factors listed by CMS among those it will consider in making the determination:
(A) Whether there are diagnoses to support the indications for which the drugs were prescribed.
(B) Whether there are instances when the necessary evaluation of the patient for whom the drug was prescribed could not have occurred (for example, the patient was deceased or out of state at the time of the alleged office visit).
(C) Whether the physician or eligible professional has prescribed controlled substances in excessive dosages that are linked to patient overdoses.

GSA expresses serious concern about both the breadth of these provisions, and their vagueness, and believes they may have a chilling effect on appropriate prescribing practices, especially among primary care practitioners who serve older adult patients living with serious illness, pain and suffering at a time when the expansion of primary care services has become critical to the successful implementation of health reform. In addition, the proposed rule does not support individualized person-centered treatment planning for effective pain management based on a careful risk/benefit analysis for each patient.

These concerns are heightened by the lack of comprehensive education and training in pain assessment and management available for generalist-level practitioners who constitute the primary care workforce, and the equally glaring absence of well-developed prescribing protocols for practitioners to follow.

GSA also believes that the proposed rule may run counter to Medicare regulations that protect patient rights, creating the possibility that systematic limitations on prescribing practices may constitute a violation of patients’ rights to pain assessments, palliative care, and the provision of hospice care. We address these concerns more fully below.

Pain Needs of Older Adults
The pain needs of older adults are of paramount concern to us. In the fall of 2011, GSA issued two special publications to our members, the first highlighting the Institute of Medicine’s (IOM) groundbreaking report, Relieving Pain in America (2011), and the second focusing on changes made by the U.S. Food and Drug Administration (FDA) on acetaminophen dosing and the impact of those changes on older adults. This past year we published a special report on studies of pain in older adults by GSA members. GSA also participated in the recent meeting of the Pain Action Alliance to Implement a National Strategy (PAINS) held in Washington, DC, at which policy issues concerning a national pain agenda were discussed in follow up to the 2011 IOM Report. In light of this high level of engagement by our members with issues that concern older adults’ access to adequate pain management, GSA is highly attuned to the importance of balancing the needs of the public for an adequate, affordable and appropriate drug supply with reducing risks of drug misuse, abuse and diversion.
Generally, it is the position of GSA at this time that existing regulatory structures and safeguards are adequate to protect individuals, especially older adults, from potential threats and risks posed by drug abuse and drug diversion. State policy and regulation are robust in this area. Most states have prescription monitoring programs (Deyo et al., 2013), and many require training for health care practitioners in pain management to assure that patients receive comprehensive pain assessment and adequate pain management. A critical issue for the older adult population is engaging in care planning and establishing appropriate goals of care including pain management goals. Goals of care and care planning should guide decision making about older adults’ pain and analgesic needs. If more resources are invested in pain programs, they should be invested in additional training for health care practitioners to strengthen their pain assessment and pain management skills.

In keeping with the principle of balance established by the United Nations’ Single Convention on Narcotic Drugs of 1961 (Single Convention, 1961) that promotes dual goals of public health and public safety, GSA is opposed to broad-based regulations that would have a deleterious impact on older adults’ access to pain care, and likely a chilling effect on health care practitioners’ prescribing practices. Instead, GSA supports a public health approach to the complex issue of non-medical use of prescription drugs including opioids, and the promotion of intersectoral collaborations to address the identification of sources of such non-medical use and targeted interventions, the unintended effects of policies that restrict access to drugs, and more effective utilization of already existing drug control programs.

There are also unintended downstream consequences of potentially impeding access to appropriate prescribing practices for older adults such as erecting barriers to high quality palliative and end-of-life care for seriously ill patients. The proposed regulations would create an environment of fear among prescribing practitioners in an already uncertain environment that would disproportionately impact older adults with severe chronic or life-limiting illness. Research evidence shows a strong association between chronic illness, multimorbidity and pain prevalence and intensity, especially among aging Americans (Atlas & Skinner, 2010; IOM, 2011). A critical factor to consider in weighing issues of access to pain medications such as opioids is that the use of these drugs is not necessarily only for the treatment of pain, but also plays an important role in effective symptom management for a very sick population including management of highly-burdensome symptoms such as shortness of breath (American Geriatrics Society [AGS], 2012). Threats to prescribing practices would potentially limit access to opioids and negatively impact quality symptom management goals for individuals with chronic and end-stage cardiopulmonary disease, cancers, and other advanced stage diseases.

Scientific Evidence on Pain Needs of Older Adults
The fastest growing segment of the population is those over 65 years, with 10,000 new persons achieving this landmark each day (Administration on Aging, 2012). By 2030, 75 million older adults will challenge our health care system in managing multiple comorbid conditions, many of which contribute to pain and its consequences. Chronic diseases, including cardiovascular disease, diabetes mellitus, degenerative joint disease, osteoporosis, cancer, peripheral neuropathies, are more prevalent in older adults and are often associated with persistent pain problems (Bruckenthal, Reid & Reisner, 2009).

Pain is a common enemy of older persons with a prevalence of persistent pain ranging from 25-50% in community dwelling (MacFarlane, 2011; Tsai, Liu, Chung SC, 2010) and 50-85% in institutionalized older adults (Smith, Cenzer, et al., 2010; Tse, Leung & Ho, 2012). Untreated or ineffectively treated moderate to severe persistent pain can cause great harm in older persons, resulting in loss of functional
independence, disability and impaired physical function, impaired social interactions, increased anxiety and depression, impaired cognitive function, altered nutrition and sleep and overall decreased quality of life—all contributing to increased use of health care resources and costs (Griffin, Harmon & Kennedy, 2012; IOM, 2011; Johansen, et al 2012; Shega et al., 2012). Disparities in pain management for vulnerable elderly persons have been widely recognized as a public health problem (Mayday Fund, 2009; IOM, 2011).

Older adults’ medication needs including pharmacokinetics and their low risks for drug diversion and opioid abuse.

Clinicians caring for older adults with persistent pain are particularly challenged to balance concerns about medication harms with benefits to function and quality of life, and older persons are more vulnerable to both the potential harm of unrelieved pain and the medications used to treat it (Arnstein & Herr, in press). Increased vulnerability to side effects and drug interactions exist in older persons due to differences in drug distribution, metabolism and elimination (Gupta & Avram, 2012; Milton et al., 2008), as well as the challenges of multiple comorbid conditions and polypharmacy (Evans et al., 2012). Analgesics are integral to treatment of moderate to severe pain, yet most drugs contain some element of concern in older adults (Brandt, Hanna & Walters, 2013). Thus clinicians need an armamentarium of options that can be considered based on the unique circumstances of each older person. With appropriate precautions (AGS, 2009), analgesics can be part of a comprehensive treatment plan in older adults that is based on a careful evaluation of risk/benefit, includes planned reassessment and monitoring of outcomes, and incorporates nonpharmacological and alternative interventions along with analgesic treatment.

Impaired cardiovascular, renal, and liver disease, along with increased risk of gastrointestinal bleeding, impact safe choices of analgesics in this population. Nonopiods can be effective in managing mild and some moderate pain, but for those with greater discomfort stronger treatment options are often necessary. Non-Steroidal Anti-inflammatory Drugs (NSAIDs) can damage these end-organs, and thus in the recently published Beers Criteria (AGS, 2012) it is strongly recommended that NSAIDs be avoided in patients with heart failure, chronic renal diseases, and in patients with a history of peptic ulcer disease. Opioids are recommended as an option for consideration in moderate to severe persistent pain not responding to other approaches, following a careful risk/benefit analysis of pain and its impact, pain goals, and risks of treatment (AGS, 2009). A comprehensive assessment and individualized treatment plan should include careful consideration of available treatment options, both drug and nondrug, and is determined in conjunction with patient preferences and values. Opioids can be used safely with careful patient selection, monitoring and use of risk reduction strategies (Arnstein & Herr, in press). Further, concerns regarding drug diversion and opioid abuse have not been established in the older population without a prior history of substance abuse, and certain studies show a significant association between older age and lower risk for opioid misuse and abuse (AGS, 2009; Ives, Chelminski, Hammett-Stabler, et al., 2006; Reid, Engles-Horton,Weber, et al., 2002). Although there is limited evidence of risk of aberrant behavior, the possibility of such a risk can be addressed through careful treatment planning and monitoring—risk evaluation and mitigation. In addition, strategies for managing opioid use are available including CMS Medication Therapy Management Program (CMS, 2010), the FDA Risk Evaluation Mitigation Strategies (REMS) for ER/LA opioids, and other opioid monitoring programs such as instituted by the states (Deyo et al., 2013).
Consequences of Potential Limits on Prescribing Practices
All drugs should be used with caution and with appropriate determination of medical necessity. Decisions about appropriate analgesic use should be tailored to the individual’s pain type, risk factors, personal preferences, ability to adhere to treatment and should be determined by the health care provider in conjunction with personal preferences and values. Studies have documented functional impact from moderate pain, not just severe, that can seriously affect the quality of life of our elders. Because of unique responses to pain, people experience pain differently, but similar levels of pain can have dramatically different impacts depending on the individual’s experiences, personal characteristics, coping ability, attitudes and beliefs. Establishing an indication for opioid use for severe pain only, or a maximum dose and/or duration for opioid use, discounts the older person’s unique experience of pain, response to pain and response to treatment. Pain treatment is not cookie-cutter and one treatment approach, therefore it cannot be blindly applied across all people experiencing a certain chronic disease or level of pain severity. Treatment must be tailored to the older adult and health care providers need an armamentarium of potential treatment options that can be used depending on the comorbidities and risks of the older person. Opioid medications are also important in managing chronic and acute symptoms of breathlessness (shortness of breath/dyspnea) experienced by many individuals with chronic cardiopulmonary diseases including congestive heart failure, chronic obstructive pulmonary disease, and pulmonary fibrosis. Approval of the proposed rule could have profound consequences for older adults leading to greater suffering and adverse consequences. If these stricter limitations are imposed on prescribing practices, especially based on consideration of factors that are vague and subject to wide variation depending on type of illness and analgesic needs, it is likely that the fear of opioids that already exists among providers and older persons will be heightened and access to strong treatments will be difficult to obtain by those who need them.

Ethical Issues: Person-Centered and Humanistic Care
GSA does wish to draw particular attention to the risks inherent in any approach to regulation that involves forms of implicit or explicit biological reductionism and does not take account of the health and well-being of older adults as human persons who are fully engaged until the end of their lives in processes of human development and resilience. Evaluation of pain that is based solely on biology, identification of disease etiology, and measurement of pain intensity will exclude large domains of pain and suffering experience and analgesic needs in the older adult population. The paradigmatic case of a frail elderly patient with advanced dementia who has multiple chronic conditions and contractures, has lost the capacity to communicate, and moans and groans persistently, demonstrates the challenges of relieving pain for the suffering older adult for whom there may not be a well-established causal explanation. Although evidence-based tools are available for assessing pain in such nonverbal cases, in light of the challenges identified in the assessment, evaluation, and treatment of pain in older adults, GSA calls for more humanistic responses to the pain experiences of older adults that will be sensitive to older adults’ social ecological contexts and person-centered care needs (Morrissey, 2011), and effective in enabling access to comprehensive assessment and multimodal treatment.

Recommendations: Interdisciplinary Research, Education and Training
The health and well-being of older adults call for interdisciplinary approaches (Berkman, 2011; IOM, 2011; Mayday Fund, 2009) to pain management in meeting their complex health care and palliative needs. The primary goals of improved and effective pain management for older adults who are living through experiences of pain and serious illness are to protect their dignity, maintain or improve function, optimize quality of life, reduce pain levels and prevent and relieve suffering, and give voice to their
values and preferences. Pain management is recognized as one of the major and essential pillars of a palliative care approach to person-centered and geriatric care (National Consensus Project, 2009). Both the American Geriatrics Society (AGS, 2009) and the Institute of Medicine (IOM, 2011) have been instrumental in bringing national attention to this critical issue affecting the public health. Among the recommendations of the IOM that are critically important to the care of older adults are enabling self-management of pain, eliminating barriers to adequate pain care, and promoting interdisciplinary research and training for those who are conducting research on pain.

The call in the IOM Report (IOM, 2011) for improvements in pain care are timely and appropriate given the urgent and oftentimes neglected needs of vulnerable older adults. This transformation extends to the interdisciplinary professional community. Specialists in pain and palliative medicine as well as generalists need to receive ongoing training in principles of pain assessment and pain management, and spend time educating the older adults they serve about the complexities of pain. The hallmark of palliative care is the concept of interdisciplinary collaboration. Hospice has provided an example of successful implementation of the interdisciplinary team model. Best practice today across all health care settings is an interdisciplinary and collaborative approach to pain management and pain care involving physicians, nurses, psychologists, social workers, pharmacists, and chaplains among a number of other disciplines. Even in primary care settings, it is incumbent upon health care practitioners to maintain dialogues with members of the other professions and seek support and counsel when appropriate in the assessment and treatment of pain, and the promotion of health literacy among older adult patients about prevention and access to care.

Conclusion
In conclusion, GSA expresses its strong opposition to broad-based provisions of the proposed rule that would have a detrimental and disproportionate impact on older adults’ access to effective pain management. In light of the strong evidence base supporting comprehensive assessment of older adults’ unique needs for appropriate medical and palliative interventions, and pain and symptom management, GSA favors a public health approach to the issue of non-medical use of prescription medications including opioids that is fully integrated into health and social systems at all levels of society, identification of the multiple vectors and social contexts in which drug diversion, abuse and misuse occur, and substantial investments in training and education for all health care practitioners and members of the public.

Sincerely,

James C. Appleby, RPh, MPH
Executive Director & CEO
References


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