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OF THE UNITED STATES

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program; Medicare Prescription Drug Benefit -CMS-4068-P

I. Introduction

The Catholic Health Association of the United States (CHA) is pleased to submit comments in response to the August 3, 2004 Federal Register notice "Medicare Prescription Drug Benefit" (42 CFR Parts 403, 411, 417 and 423). CHA is the national leadership organization of the Catholic health ministry. By pursuing the strategic directions of mission, ethics, and advocacy, CHA is engaged in strengthening the health ministry for the future and creating health care that works for all. CHA represents more than 2,000 sponsors, systems, facilities, and related organizations that form the nation's largest group of not-for-profit health care. Founded in 1915, CHA unites the ministry engaged to advance selected strategic issues that are best addressed together rather than as individual organizations. CHA applauds Congress for passing the Medicare Modernization Act of 2003 (MMA), Public Law 108-73, mandating the creation of a Medicare Part D prescription drug benefit. CHA appreciates the efforts of the Centers for Medicare & Medicaid Services (CMS) to gather input from the public to meet the intentions of the lawmakers to design a reasonable and comprehensive benefit that ensures access to a prescription drug benefit for all Medicare-eligible individuals. However, after careful review, CHA believes there are fundamental flaws and omissions in the proposed regulations. CHA believes these problems will pose challenges for persons who are dually eligible for Medicare and Medicaid and for health care entities, including long-term care (LTC) settings; the Medicare beneficiaries who reside in these facilities; and the health care professionals who render care to this frail population.

II. General Implications of Medicare Drug Benefit on LTC Settings and the Residents Served CHA believes the regulation, in its current form, could have a negative impact on long-term care facilities and the residents they serve unless special attention is granted to this unique population. CMS needs to take into consideration the complexity of long-term care residents and their distinct pharmaceutical needs before implementing a complicated and imposing prescription drug benefit. Recent studies have shown that a large number of LTC residents have eight or more chronic conditions ranging from chronic physical ailments to devastating cognitive impairments. To treat these conditions, most LTC residents receive seven or more medications in a given day. The stability of their health is dependent on medication regimen. CHA believes that the uniqueness of this population should be reflected in the final regulation. If this is not done, the Medicare drug benefit will be unsuccessful in long-term care facilities and could present great harm to residents' welfare. For example, long-term care residents may face the following challenges: Inability to research the new drug benefit and its many options; Poor comprehension of Part D program due to cognitive impairments; Inability to comprehend the many complex processes and variations in premiums, benefit design, formularies, and preferred drug lists each year; Potential negative consequences of a bad decision such as the "annual lock in." These challenges were not understood when the MMA was drafted. Legislators considered this new Medicare program to be an "outpatient" benefit -- primarily applicable to the ambulatory. However, Congress asked for a study to examine services needed for a LTC facility population. CMS Administrator Dr. Mark McClellan, Administrator recently acknowledged the need to for this study

when he testified: "It will be very important to make sure that the Part D drug benefit works seamlessly for beneficiaries as they move in and out of nursing homes, especially now that the dual eligibles will get their drug benefits under Medicare rather than Medicaid. That's why the MMA called for CMS to undertake a study within 18 months of enactment to look at the question of how best to coordinate the drug benefit with the needs of nursing homes…" Recommendation:CHA is very supportive of this mandated study and urges CMS to commission an entity to initiate a comprehensive and geriatric driven study. We are concerned that while the study has been mandated, no movement on it has taken place. We believe that the results of the study are needed to present placing long term care residents at risk for increased morbidity and mortality.

III. Specific CHA Comments Implications of Medicare Part D Drug Benefit on Persons Who are Dually Eligible and Persons Who Qualify for Low-Income Assistance On January 1, 2006, more than 6 million dually eligible individuals will lose their Medicaid drug benefit and transfer their drug coverage to Medicare Part D. These individuals, therefore, must be enrolled in a Medicare Part D plan prior to the end of 2005. CMS plans to permit dually eligible individuals to choose a Prescription Drug Plan or Medicare Advantage plan within their region beginning November 15, 2005. Individuals who do not choose a plan voluntarily will be automatically enrolled through random assignment to a plan in their region. This causes CHA, and other patient advocacy groups, serious reservations. As a result of random assignment, many individuals will no longer be able to get prescriptions filled at their customary pharmacy, and will need assistance locating a participating pharmacy near their homes. They are likely to discover that one or more of their medications that had been covered by Medicaid are not covered by their new drug program. They will then have to contact their physicians to obtain a prescription for a different medication or seek assistance to apply for permission to continue their current medication. We are concerned that persons enrolled in both Medicare and Medicaid will not be able to navigate the complex challenges imposed by the drug benefit. These individuals are elderly and economically poor. Most have serious chronic and disabling conditions. They are likely to be confused by these new policies and may to too frail or disabled to get the medications they need. Recommendation:CHA believes it is critical that the transition of dually eligible persons from Medicaid to Medicare be extended until January 1, 2007. This extra time will permit more time for creation of the new drug benefit and transitioning individuals into this new program. CHA also recommends that dually eligible residents of long-term care facilities should only be auto-enrolled into prescription drug plans if there is a long-term care pharmacy serving the facility within the network. Expanded Definition of Long-Term Care Facilities is Needed Within the text of the proposed rules, CMS suggests that the drug benefit will include all Medicare beneficiaries, even those who reside in long-term care facilities. As written, the proposed rules define long-term care facilities as: Medicare-certified skilled nursing facility (SNFs) Medicaid-certified nursing facility (NFs) Recommendation:CHA believes the definition of long-term care facilities in the proposed regulation is too narrow and needs to be broader in its scope, including venues where chronically ill and frail Medicare beneficiaries are served. CHA strongly urges CMS to expand the definition to include residents in: Assisted living ICFs/MR Adult day care Group homes Formularies for Persons Residing in Long-Term Care Facilities Should Not Limit Access to Needed Medications Seniors in institutional settings are at greater risk for medication related problems because they represent the most frail and ill of all seniors in this country. Medication therapy decisions for all seniors, particularly residents of long-term care facilities, must be carefully considered. Not only do residents need access to the medication appropriate for their conditions, but they must also have access to special dosage forms, such as sustained-release dosage forms, crushable tablets, and liquid products. The current proposed formulary

structure permits pharmacy and therapeutics committees to make determinations based on pharmaceutical data and clinical outcomes. Often the available data do not reflect outcomes associated with a very ill senior population; therefore, CHA cautions that more weight be given to clinical outcomes for a senior population. CHA believes that the MMA gives too much latitude and flexibility to prescription drug plans to create their own formularies. Broad and economically driven formularies may be appropriate for a "healthy" senior population, but pose a great threat to the health and safety of frail beneficiaries residing in long-term care facilities. Therefore, CHA suggests that CMS use their oversight authority and monitor and assist in the creation of responsible formulary processes Recommendation: CHA recommends that any formulary applied to the long-term care population should Contain a broad range of drug dosage forms, including liquids, and crushable tablets; Be developed within the broad context of practice guidelines and disease management protocols; Be developed and frequently reviewed by a multidisciplinary committee; Discourage the use of medications which are considered inappropriate for use in the elderly. Proposed Regulations Do Not Include Necessary Coverage of IVs and other Critical Medications Including Benzodiazepines and Barbiturates Used by Long-Term Care Residents The proposal excludes coverage of intravenous medications and other drugs known to be therapeutic for many long-term care residents. CHA is very concerned by the selection of excluded agents listed in the proposed drug benefit regulations. Many of the excluded drugs are widely used in the long-term care population, and if not available to the residents could jeopardize their health status. Recommendation: CHA believes that drugs covered under the Medicare Part D program need to be expanded to include forms of medications currently covered under state Medicaid programs and commonly used in long-term care facilities. These include: Liquid, chewable, transdermal and other special dosage forms to accommodate swallowing limitations; Individually compounded medications or combinations of medications; Intravenous medications, such as antibiotics; Total parenteral nutrition therapy (i.e., hyperalimentation). In addition, CHA recommends that CMS use its authority to permit coverage of benzodiazepines and barbiturates under the Medicare prescription drug benefit. IV. Comment Conclusion CHA appreciates the opportunity to comment on this long-awaited Medicare prescription drug benefit. We conclude that while the Medicare prescription drug benefit offers America's seniors discounts to needed and appropriate medications, the proposed rule needs considerable revision to ensure the health and welfare to millions of seniors who reside in long-term care facilities.

Thank you for your consideration of these comments. If you need further clarification or assistance regarding these comments, please contact Julie Trocchio by phone at 202-721-6320 or by e-mail at jtrocchio@chausa.org.