March 6, 2014

Ms. Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4159-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Re: AHCA Response to Proposed Rule, Medicare Program; Contract Year 2015  
Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (RIN 0938-AR37)

Dear Ms. Tavenner,

The American Health Care Association and the National Center for Assisted Living (AHCA/NCAL) represents over 12,245 skilled nursing facilities (SNFs), or 1.012 million beds, and 157,584 assisted living residence (ALR) beds. The Association represents the vast majority of SNFs and a rapidly growing number of ALRs. Thus, we play a critical role in all Medicare-financed post-acute care (PAC) and Medicaid-finance long term services and supports service delivery policy and programmatic development, both fee-for-service (FFS) and managed care.

We appreciate the Centers for Medicare and Medicaid Services (CMS) efforts to provide additional guidance on Part C, which governs Medicare Advantage (MA) Plans but we have a number of ongoing MA and MA-PD concerns which are discussed, below. Additionally, regarding Part D, the framing authority for the Medicare drug benefit delivered by Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs) we are deeply concerned about the proposed changes and must oppose several proposals and offer alternative approaches were possible.
Our comments are structured as follows: a) context for our comments (page 1); b) overarching comment themes and specific requests of CMS as the Agency finalizes the proposed regulations (page 2); and c) detailed comments section by section which articulate in detail our concerns and recommendations (page 7).

**Context for AHCA/NCAL Comments**

AHCA/NCAL analysis shows that in 2012, 36 percent of Medicare discharges from acute care hospitals were referred to post-acute care (PAC) settings. Of the 36 percent, 52 percent of all people referred to PAC received such services in SNFs, making SNFs the dominant PAC resource.¹

AHCA/NCAL research also indicates that, nationally, MA plan enrollment likely will climb to over 33 percent nationally by 2019. The Office of Management and Budget as well as the Congressional Budget Office also project continued enrollment growth despite MA payment reductions contained in the Affordable Care Act². Already, eleven states (AZ, CA, FL, HI, ID, MN, OH, PA, NY, RI, WI) have over 30 percent of Medicare beneficiaries enrolled in MA plans. In fact, close to 50 percent of Medicare beneficiaries in three states, HI, MN, and OR, are enrolled in MA plans today.

Based on the facts, above, the Association is deeply concerned about MA reimbursement for PAC services and related impacts on people and their families. The vast majority of MA plans pay less than Medicare Resource Utilization Group (RUG) levels for care delivered to a population with increasing complex medical care needs. As has been well documented in FFS, Medicare cross-subsidization of Medicaid has historically played an important role in sustaining SNF care. However, with recent Medicare rate reductions, this program no longer fully subsidizes increasing Medicaid shortfalls.

Expressed as a shortfall in reimbursement per Medicaid patient day, the estimated average 2013 Medicaid shortfall is projected to be $24.26, which is 8.6 percent higher than the preceding year’s projected shortfall of $22.34. Combined 2013 Medicare-Medicaid margins are projected to be negative 3.5 percent.³ In its analysis, the MedPAC Medicare and Medicaid margin projection shows an average national margin of 1.8 percent; MedPAC analysis also includes private pay.⁴ The end result is that FFS rates are producing dangerously thin margins and places access to critical SNF services in a highly unstable position as both Medicare and Medicaid managed care expand bringing with them even tighter margins and additional administrative overhead costs.⁵ ⁶

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⁵ Saucier, P. et al. The Growth of Managed Long-Term Services and Supports (MLTSS) Programs: A 2012 Update. Prepared for the Centers for Medicare and Medicaid Services. July 2012. Additionally, since this report was issued four more states have announced statewide MLTSS efforts.
Because of such enrollment growth and AHCA/NCAL membership’s critical role in the delivery of PAC services, the Association strongly believes that additional guidance as well as increased CMS engagement in plan oversight. Such oversight is critical to protecting Medicare beneficiaries and ensuring an adequate base of high quality providers to support them and their families as well as ensuring these individuals have adequate access to needed medications. We also believe that a serious consideration must be given to the reimbursement impacts on people and critical PAC services which are key to CMS’ preventable re-hospitalization efforts.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added a new Part D to the Medicare statute entitled the Medicare Prescription Drug Benefit Program (PDP), and made significant changes to the existing Part C program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, regulations for the MA program. Generally, the MMA provisions took effect January 1, 2006. Today, according to MedPAC, nearly 30 million Medicare beneficiaries were enrolled in Part D in 2012 with 63 percent in stand-alone prescription drug plans (PDPs) and the remaining 37 percent in MA-PDs.

Since the inception of both Parts C and D, CMS has periodically revised its regulations either to implement statutory directives or to incorporate knowledge obtained through experience with both programs. Thus, CMS issued interim and final rules in 2008, 2009, 2010, and in the April 2011 final rule, revised regulations on a variety of issues based on the Affordable Care Act.

AHCA heralded the addition of Part D for filling a painful gap in health care coverage for older adults and persons with disabilities who are Medicare eligible. The Association worked diligently with CMS to preserve the vital role of the long-term care pharmacy, a much needed institution in providing drugs to people in Medicare-financed PAC SNF stays, as well as for people who are Medicare-Medicaid eligible in Medicaid-financed long-stay nursing center in a safe, effective and timely manner. Since 2006, AHCA has weighed in with comments in response to CMS’ ongoing issuance of regulations vital to implementing legislation and continuing improvement of the Part D benefit.

We continue our participation in improving and protecting Part D with the comments in this letter on CMS’ Part D proposals and, when appropriate, with specific reference to the needs of nursing center residents who also use Part D.

**Overarching Comment Themes**

Below are our overarching themes on the proposed rule. These observations were gleaned from a careful review of the proposed regulations and based on a synthesis of our more detailed comments (see below).

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• **Increased MA oversight is positive as long as such efforts do not increase provider administrative burden.** With such large numbers of Medicare beneficiaries enrolled in MA plans, particularly the health maintenance organization (HMO) model, it is critical that past problems with the HMO model are prevented. However, such oversight efforts should not impose additional administrative burden on SNF providers already struggling with cumbersome and often duplicative MA-related business processes as well as the long-standing SNF multilayered regulatory requirements.

• **AHCA is deeply concerned about CMS’ proposed Part D approach.** It is feasible that some proposed concepts will aid AHCA/NCAL in achieving its goal of reducing use of antipsychotics and foster appropriate medication management for patients. And, while AHCA agrees that some of these medications may be overprescribed as well as their being overall equivalency in effectiveness, we disagree that with the strategy to limit their use by restricting their inclusion on the formulary. This is a relatively blunt strategy and does not take into consideration differences in side effect profile, drug-drug interactions, and differences in individual metabolism of medications. We believe there are more effective strategies that will not limit access to medications and can help assure more appropriate use of medication and less expensive medication when overall equivalency is found in the literature.

• **New plan costs associated with complying with new requirements should not be passed on to providers in the form of further rate reductions.** The Association recognizes CMS’ position on non-interference in plan-provider contractual negotiations and the proposed regulation pertains to Part D. However, we urge CMS to consider that in Part C, plans typically already pay less than Medicare Resource Utilization Group (RUG) rates and that the administrative costs of delivering critical PAC services under MA plans are higher. In addition to higher administrative cost, prior authorized lengths of stay are typically quite a bit shorter under MA plans, and since many costs are “front loaded” during a patient’s stay, providers’ ability to cover cost to care for MA participants is already difficult. Furthermore, some MA enrollees have copays, which if unpaid, providers have to absorb since they are not allowable as Medicare bad debts. As MA enrollment grows and provider exposure to unavailable Medicare bad debt grows. This must be considered in tandem with decreasing levels of Medicare bad debt allowed in fee-for-service due to changes included in the Middle Class Tax Relief and Job Creation Act of 2012. Such combined reductions will have negative impacts on access as providers face more complex operating and financially challenging environments.

Thus, SNFs increasingly will be paid less to deliver services that come with additional administrative burden and costs. Therefore, CMS must provide some form of guidance to plans on the Agency’s expectations that plan operating costs and related reductions in MA plan reimbursement should not be passed on to any
providers, including SNFs, in order to ensure adequate access to services to a
-growing population

- **Fiscal impacts of the rule coupled with MA payment reductions could result in
the survival of only large plans.** In its comments on non-interference, CMS
makes clear its intent of fostering market forces. The goal of such a competitive
marketplace is to offer beneficiaries choice of plan, a variety of plan types, and
value. However, the Association is concerned that the new requirements might
negatively impact the variety of plans available because of new plan operating
expenses coupled with Affordable Care Act (ACA) related payment reductions,
Sequester reductions and potential reductions laid out in the 2015 Call Letter and
Advance Notice. Specifically, only larger plans may be able to weather such
changes leaving beneficiaries and providers with only large health plans with
whom to enroll or contract with, respectively.

- **Beneficiary protections are helpful and should be further strengthened.** The
Association applauds the array of beneficiary protections including the addition of
new quality requirements for both Parts C and D and termination of poor
performing plans. As the portion of Medicare beneficiaries enrolled in MA plans
continue to rise, we strongly encourage that CMS work with beneficiary advocacy
groups and health care provider associations to further strengthen such
protections.

**Requests of CMS as the Regulation is Finalized**

Based upon our review of the proposed rule and existing MA and Part D requirements,
we strongly urge CMS to consider the following Association requests as the Agency
finalizes this rule and considers future Parts C and D refinements:

- **CMS should fully enforce its MA oversight authority and responsibilities
located at Section 1857(e)(i) --** Plan responsibilities that are critical to ensuring
people have access to restorative and life sustaining PAC services include prompt
pay, timely adjudication of grievances and appeals, timely prior authorization, and
payment levels that are sufficient to attract and retain an adequate network of high
quality providers as stipulated at Section 422.112(a)(1). Regarding payment
levels, we respect CMS’ current position on noninterference located at Section
1860D-11(i) of the Medicare Modernization Act (MMA) but believe CMS could
institute guardrails to aid providers struggling with challenging plan business
practices and low payment rates (see discussion, below).

- **CMS should not expand passive enrollment of full Medicare-Medicaid eligibles
into D-SNP or only do so with clear timeframes.** Full Medicare-Medicaid
eligible individuals have low health literacy levels and complex health care needs.
CMS characterizes passive enrollment as a “process by which a beneficiary is
informed that he or she will be considered to have made a request to enroll in a
new MA plan by taking no action.” The provisions found at Section 422.60(g) are inadequate to ensure such individuals have sufficient information and time to make educated decisions about what they consider to be “substantially similar” coverage and to determine whether their current providers are in or out of network (OON). If the latter, transfers to in-network providers could prove harmful to the recovery of individuals in a PAC stay or for full duals in a long stay. Finally, if an individual is a current long-stay resident, their current home skilled nursing facility (Section 422.133) should automatically be offered a contract or paid “substantially similar payment under the same terms and conditions that apply to similar nursing facilities that contract with the MA organization” as is stated in the current code of federal regulations (CFR). Finally, as an additional protection we urge CMS to modify its current requirement found at 422.101(f), Basic Benefits, Special Needs Plan Model of Care that potentially covering plans offer the beneficiary a “comprehensive initial health risk assessment … such that the assessment is conducted as part of the pre-enrollment activities to ensure the D-SNP can deliver needed services.

- **CMS should reconsider its position on noninterference and explore signaling language.** In the Medicare Modernization Act (MMA), one word—“noninterference”—is the headnote and first word of Section 1860D-11(i) applying to both Parts C and D. The MMA conference report explains that the Secretary is prohibited from taking certain actions for the purpose of promoting the market to decide the outcome of competition. However, AHCA/NCAL strongly believes that a less conservative view of the provision is needed to address critical issues in the MA marketplace and in a rapidly expanding Medicare and Medicaid managed marketplace. We do not believe the drafters anticipated the serious, negative implications of combined Medicare and Medicaid managed care and the downstream impacts on provider capacity to deliver critical services to people in such a challenging environment. Of key importance are challenges with adequate reimbursement to deliver high quality services in Medicare and Medicaid negotiated rate environments which include no guardrails for such negotiations. Other examples of MA plan challenges which should be addressed using its authority located at Section 1857(e)(i) include issues with prompt pay in Medicare and Medicaid managed care, unnecessarily long periods of time to receive prior authorizations, and ill-defined utilization review processes which disrupt care and services. We understand that our comments on Part C, presented below, are not germane to CMS’ Part D specific comments contained herein but we do believe that CMS has created an opening for a discussion on the underlying noninterference statutory provision by offering clarifying guidance on Part D. Further, separate commentary will be transmitted to CMS on this point. For now, we respectfully request that CMS consider the payments to providers “signaling”

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language approach used by the CMS Medicare-Medicaid Coordination Office for demonstration participating plans.  

**CMS should ensure that information collection from plan providers does not result in additional provider burden and that such information collection only is used for the purpose of evaluating plan compliance with CMS requirements.** In a number of places, (442.504(i)(2)(i) and 423.505(i)(2)(i)), CMS indicates its intent to establish authority to collect information directly from plan first tier, downstream and related entities (FDRs). CMS should approach such information collection and review activities from the perspective of assessing only plan operations and performance in accordance with its authority found at Section 1857(e)(i). Additionally, such reviews should adhere to assessment of existing MA plan related materials and documentation and not to add to the already extensive array of current SNF oversight activities. In addition, related to Part D, use of prescription drug event (PDE) data alone to evaluate appropriate prescribing trends will have the effect of restricting prescribers. We would oppose the following example: Prescribers with a disproportionate number of patients in skilled nursing centers or assisted living centers specialized in certain diagnoses or patient types such as pain or behavior problems will be triggered for possible exclusion when using PDE data only. Without recognizing the location of service or coordination of PDE data with other clinical data, this proposed rule change may discourage physicians from practicing in long term care (LTC) or settings that have high proportion of patient’s requiring medications that are under close scrutiny by CMS or the Part D plans.

**Providers should be held harmless in overpayment or inappropriate payment scenarios.** Specifically, SNFs that deliver services in good faith based on plan organization determinations authorizing such services should not be penalized in part of CMS recovery effort or related plan recovery efforts in overpayment scenarios or for incarcerated individuals.

**The Association strongly supports all beneficiary protections.** Despite CMS efforts to ensure clarity and accuracy of marketing materials and other plan information issuances, the membership continues to report challenges with plan practice alignment with CMS requirements and plans’ own policies. We strongly support the provisions in the proposed rule to further refine and define plan communication with potential and current enrollees.

Additionally, while continuity of care is not included in the Part C portion of the regulation, many AHCA/NCAL members are receiving prior authorizations for less than what members believe are appropriate lengths of stay in a PAC setting.

Association members have expressed serious concerns about the implications of premature discharge including negative health impacts on people and avoidable

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rehospitalizations. Such plan decisions would appear to be incongruent with CMS’ requirements at 422.206, Interference with Health Care Professionals Advice to Enrollees, and CMS requirements that plans deliver medically necessary services. Under separate cover, AHCA/NCAL will provide more detail on this serious challenge.

**Detailed Section-By-Section Comments**

In the following section, AHCA/NCAL provides detailed comments on proposed Parts C and D regulatory changes.

A. Clarifications

- **Two Year Limitation on Submitting a New Bid in an Area Where an MA Has Been Required to Terminate a Low Enrollment MA Plan (422.504(a)(19).** AHCA/NCAL supports this provision. We further recommend that CMS employ heightened scrutiny of bids submitted by MAs that have been subject to such terminations for the same area when/if they submit a bid after the two year period to ensure viability of such an offering prevent further disruption of beneficiary services.

- **Authority to Impose Intermediate Sanctions and Civil Monetary Penalties (422.752, 423.752, 422.760, 423.760).** SNFs are the most heavily regulated health care providers and have long been subject to a wide array of oversight requirements and related sanctions at the state and federal level. CMS proposes two changes to its intermediate sanctions and civil monetary penalties (CMPs) authority.

  First, pursuant to section 6408 of Affordable Care Act (ACA), CMS proposes to provide for sanctions or CMPs if an Medicare Advantage or Part D sponsor (i) enrolls an individual without prior consent (except in certain limited circumstances) or transfers an individual to a new plan without prior consent, or (ii) violates the Part C and D marketing requirements. Second, existing regulations designate HHS, OIG, as the sole government agency with the authority to impose CMPs for the violations contained in § 422.752 and § 423.752.

  CMS proposes revisions to clarify that either CMS or the OIG may impose CMPs for the violations listed at § 422.752(a) and § 423.752(a), except that only the OIG may impose CMPs for violations under § 422.752(a)(5) regarding misrepresentation and/or falsification of information furnished to CMS, an individual, or other entity. AHCA has no issue with these proposed changes; but would ask that States be able to use the Federal CMP funds (collected by CMS) to contract with, or grant funds to, any entity permitted under State law, provided that the funds are used for CMS approved projects to protect or improve SNF services for residents, as described in CMS S&C: 11-42-NH at [https://www.pionernetwork.net/Data/Documents/Use%20of%20Civil%20Money%20Penalty%20Fund%20Funds%20by%20States.pdf](https://www.pionernetwork.net/Data/Documents/Use%20of%20Civil%20Money%20Penalty%20Fund%20Funds%20by%20States.pdf).

- **Contract Termination Notification Requirements and Contract Termination Basis (422.510, 423.509).** AHCA/NCAL supports the three revisions to the existing
regulation which clarify grounds for termination. Furthermore, AHCA/NCAL strongly suggests, based on the authority at Section 1857(e)(i) that grounds for termination should include a clear and persistent pattern of plan non-compliance with CMS requirements including consistent issues with prompt payment which could interfere with service access, clear and persistent pattern of response time that do not comply with terms for adjudicating grievances and appeals as described in Section 422.564, and other issues that impact the timely and efficient delivery of services to enrollees such as prior authorizations. In terms of termination, AHCA/NCAL strongly recommends that 90 day notice be provided to all PAC providers as well as to people using PAC. The 45 day standard for notice may be sufficient for non-post-acute care users but not for people in a short stay setting. For MA plans that are serving full duals and that also hold a Medicaid contract under which they are delivering Medicaid-financed services to duals should be required to provide 180 day notice to individuals and providers.

- **Reducing the Burden of the Compliance Plan Training Requirements (422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)).** Standardized training on communication, particularly among plans and their FDRs is helpful and AHCA/NCAL appreciates CMS’ recognition of duplicative plan trainings as well as critical recognition of the administrative burden that comes with delivering services under MA plan contracts. However, CMS should include requirements that plans with additional FDR training requirements beyond the CMS standardized trainings are not duplicative and will not result in an unintended increased administrative burden (e.g., CMS standardized training plus any plan-specific training). Regarding CMS’ request for comment on how plans should be required to continue to communicate information about compliance officers, the Association strongly recommends that plans be required to include such information in contract language with their provider networks and be contractually required to update such information when changes occur.

- **Changes to Audit and Inspection Authority (422.503(d)(2), 423.504(d)(2).** In general, AHCA/NCAL supports the notion of an independent plan audit requirement. We believe that triggers for such audits should include a clear and persistent pattern of late payment which could interfere with service access, clear and persistent pattern of response time that do not comply with terms for adjudicating grievances and appeals, and additional items which could impact the timely delivery of critical PAC services such as prior authorizations. The Association requests that CMS clarify the language offered on page 1927, “(2) inspect or otherwise evaluate the facilities of the organization where there is evidence of some need for such inspection; and (3) audit and inspect any books, contracts, and records of the organization ....” The language goes on to note that audited entities could include plan FDRs. Already, SNFs are the most heavily regulated and overseen Medicare providers via Medicare and Medicaid survey and certification and Medicare cost reporting. The Association believes that existing SNF oversight information should be used for such audits if FDRs include SNFs and other direct care providers. CMS should not require any additional reporting or add administrative burden to SNFs. Already, CMS has indicated its
intention to reduce provider burden in this proposed rule. CMS should adhere to this notion and not inadvertently introduce new burden.

- **Procedures for Imposing Intermediate Sanctions and Civil Monetary Penalties under Parts C and D (422.756, 423.757).** AHCA/NCAL applauds CMS’ efforts to strengthen beneficiary protections via extension of the test periods. The Association also believes that in addition to the prohibition on auto-enrollment for low-income subsidy (LIS) eligible beneficiaries, the freeze should also apply to passive enrollment of persons who are dually eligible. Specifically, the Association believes that Medicare-Medicaid eligible individuals should not be passively enrolled into an MA or an MA Special Needs Plan (SNP) that is under sanction or in a test period as part of a demonstration or a state developed integrated plan product.

- **Timely Access to Mail Order Services (423.120).** As the Association understands the proposed changes, CMS seeks to ensure timely delivery of Part D benefits using mail order pharmacies. Specifically, CMS proposes moving from an industry standard of 7 to 10 business days, the rule proposes fulfillment within 5 business days when intervention is required (illegibility, need for coordination, etc.) and 3 business days when intervention is not required. AHCA/NCAL strongly supports this change particularly for Assisted Living Residences. The use of mail order medications is more prevalent in assisted living but also is used by some beneficiaries in long term care nursing centers. Given the complexity of beneficiaries’ medication regimes and the prevalence of multiple chronic disease coupled with the limited assets of many beneficiaries requiring assisted living or long term care in a nursing center, timely access to medication refills and new medications is critical. We do not want this to supersede state laws and other regulations requiring the timely delivery of medications for beneficiaries residing in skilled nursing facilities or assisted living facilities. In addition, providing unrestricted authority to plan sponsors could shift the current timely and efficient delivery of medications through LTC pharmacies to a mail order requirement for maintenance medications in SNF settings. Required mail order, even if packaging and delivery requirements could be made to comply with CMS SNF guidelines for medication storage and delivery, would be an untenable operational issue resulting in higher nursing costs and potentially making errors more likely. In addition, mail-order often provides large quantities of medications which can cause not just storage issues but increases the likelihood of wastage as well as medication errors, especially when packaging is different. We recommend that CMS not allow plans to require Medicare beneficiaries in a SNF or Assisted living use mail order delivery.

Additionally, CMS proposes to relax Part D access requirements in emergencies at Section 423.126. We offer comment later in this document, but would suggest that CMS further modify this provision as well as include a reflexive change in 423.120. We suggest such changes allow enrollees who have enrolled in mail order pharmacy programs to use local retail or hospital pharmacies during emergencies which interfere with mail order delivery.
- Not Lawfully Present in the U.S. (417.2, 417.420, 417.422, 417.60, 422.1, 422.50, 422.74, 423.1, 423.30, 423.44). AHCA/NCAL believes that providers which have delivered services under MA organization determinations in good faith should be held harmless. That is, such providers should be paid in a timely fashion for services and should not be subject to retrospective denials, or post-utilization reviews for delivery of services to such individuals for whom the plan issued organization determinations authorizing the delivery of such services (e.g., eligibility verification, prior authorizations, etc.).

- Part D Notice of Changes (423.128(g)). This proposed provision is intended to harmonize the requirements applicable to MA and Part D plans by requiring Part D plans to submit to CMS and distribute to beneficiaries the Annual Notice of Changes (“ANOC”) for formularies and cost sharing. AHCA/NCAL supports any CMS or plan effort to better inform Medicare beneficiaries about their coverage options. The Association also requests that plans be required to share such general information with providers such as SNFs and assisted living residence included in plan networks. Greater transparency is critical for both the beneficiary as well as the LTC provider to better coordinate and support the beneficiary in making an informed decision. In addition, a majority of SNF residents are “dual eligible,” for which plan selection is limited. There has been over a 50 percent decrease in sponsors from 2006 to 2013. Plan sponsors continue to consolidate, which leaves fewer options and no efficient way to notify the LTC provider of a beneficiaries’ ANOC. Without LTC provider’s access to ANOCs, the only source of plan change are the family members since many beneficiaries in SNFs or assisted living suffer from dementia limiting their ability to effectively communicate information contained in ANOCs.

- Separating EOC from ANOC (422.111(a)(3), 423.128(a)(3)). The proposed provision requires separate mailings of plan Evidence of Coverage and ANOC to improve consumer review of these materials. Again, AHCA/NCAL supports any CMS or plan effort to better inform Medicare beneficiaries about their coverage options. The Association also requests that such general information be shared with providers included in plan networks.

- Agent/Broker Compensation Requirements (422.2274, 423.2274). AHCA/NCAL believes that this change will reduce a perverse incentive for brokers to unnecessarily prompt beneficiaries to change coverage and interrupt services while driving up costs. The Association also believes that reduced coverage changes will also provide some relief from the administrative burden associated with enrollees changing plans due to such perverse broker incentives.

- Drug categories/Classes of Clinical Concern (423.120(b)(2)(v) and (vi). AHCA/NCAL opposes the changes in protected classes. While the Association agrees that some of these medications may be overprescribed as well as their being overall equivalency in effectiveness, we disagree with the strategy to limit their use by restricting their inclusion on formularies. This is a relatively crude strategy and does not take into consideration differences in side effect profile, drug-drug
interactions and differences in individual metabolism of medications. We believe there are more effective strategies that will not limit access to medications, but that can help assure more appropriate use of medication and less expensive medication when overall equivalency is found in the literature. The Association would welcome the opportunity to provide more detail as requested by CMS.

Additionally, the removal of the antidepressant and antipsychotic’s class protection will adversely impact low income and dual-eligible beneficiaries. The majority of long-stay SNF patients are low-income, dual eligible beneficiaries. The antipsychotic and antidepressant formulary selection controlled by plan sponsors will trigger unnecessary changes in therapy that will adversely impact well managed patients with these medications and could endanger their stability. An example is when an annual plan auto-enrollment will require mandatory changes in drug therapy without consideration of patient clinical status. Low income dual-eligible beneficiaries do not have the resources to select and/or purchase higher cost plans with broader coverage. Many LTC SNF patients do not have a patient advocate and LTC operators are prohibited from directing patients to specific plans even if it provides better coverage than the auto assigned plan. This proposed change will result in increased cost to SNF operators for non-covered medication previously covered.

- **Medication Therapy Management Program Under Part D (423.153(d)).** AHCA supports the proposed change but strongly believes that plans must coordinate and share information with the primary care providers as well as the PAC or long term services and supports providers (e.g. SNF and ALF) since these providers are delivering restorative or life-sustaining supports and managing the patient/residents’ diseases and medications. This proposed change will increase the percentage of participants in Medication Therapy Management Program services and could potentially increase positive patient outcomes for these individuals. It would also decrease the amount spent on healthcare, but will require effort on all parties responsible for providing healthcare to the patient. CMS also should allow opportunities to re-evaluate the “selection criteria” on an annual basis to help ensure that those that would benefit most from the program are enrolled.

- **Business Continuity for MA and Part D plans (422.504(o), 423.505(p)).** As we understand the proposed change, CMS would requires MA plans, Part D sponsor and PACE programs to develop and maintain business contingency plans in response to natural disasters and emergencies. Considering the nature of PAC and long term services and supports (e.g., people are short term or long term stay are residing in SNFs and/or ALRs), AHCA/NCAL urges CMS to require plans to have policies and procedures targeted to PAC and long term services and supports providers. Additionally, regarding PAC and long term services and supported delivered in disaster unaffected areas but which could be impacted because of plan operation center disaster issues, we request that SNFs and ALRs be specifically noted in the list of providers for “which essential functions … must be operational within 24 hours.”
• **Efficient Dispensing in Long Term Care Facilities and Other Changes (423.154).** AHCA/NCAL’s interpretation of this provision is that it is intended to better protect long term care (LTC) pharmacies from payment arrangements with Pharmacy Benefit Managers that penalize them for more efficient dispensing techniques by adding a clause prohibiting such arrangements. CMS proposed to eliminate a section that had been misinterpreted in a manner that caused LTC pharmacy dispensing fees to be prorated. This would add an additional waiver for short-cycle dispensing requirement for LTC pharmacies using restock and reuse methodologies under certain conditions. In general, AHCA/NCAL supports this proposal but points out that in SNFs this would lead to nursing staff having to re-order short cycle dispensing which could reduce medication availability due to failure in the re-ordering process.

AHCA/NCAL supports the prohibition of payment arrangements that penalize the offering and adoption of new and more efficient LTC dispensing techniques. The development of dispensing technologies increases time for nurses and pharmacists to offer direct patient counseling and other patient MTM services. Allowing Part D plans to introduce payment structures that discourage the use of technology to replace pharmacist pick, pack and ship duties will negatively impact the pharmacy and nursing practice. Since 2007 there has been nearly a 50 percent reduction in the number of Part D sponsors. As plan sponsors continue to consolidate and allowed to place barriers to technology, SNFs will lose operating efficiency and incur higher pharmacy costs which will affect access to needed services by Medicare beneficiaries.

• **Interpreting the Non-Interference Provision (423.10).** AHCA/NCAL understands that in this proposed provision CMS seeks to clarify the limits of the non-interference provision in Part D programs. Specifically, the Agency seeks to clearly limit CMS involvement in the competitive market to only those actions that promote competition such as facilitating transparency and information to beneficiaries. It also seeks to clarify that CMS’s role in price negotiations is limited to that which it regulates, such as access to network pharmacies and negotiated prices. However, the provision seeks to further limit CMS involvement as to disputes between manufacturers and distribution channel customers over price negotiations but not over negotiations between Part D plans and pharmacies.

In the latter context, CMS would only be involved in those business relationships that it is required to enforce such as, among other things, access to negotiated prices and a host of other topics. As to price structure interference, CMS believes that it may not require that Part D prices be based on any particular published or unpublished pricing standard or that there be price concessions using such standards. However, CMS is of the view that it can establish rules for consistent treatment of drug costs in the program. Thus, it proposes to establish definitions for what constitutes a pricing standard, a price concession and how drug costs are to be treated under Part D, including disclosure, bidding availability and reporting, etc. Finally, based on the above, the proposed rule includes a provision that specifies that CMS does not establish drug product pricing standards or the dollar level of price concessions at any stage of the drug distribution channel.
More broadly, one word—“noninterference”—is the headnote and first word of section 1860D-11(i) of the Medicare Modernization Act (MMA) applying to both Parts C and D. The MMA conference report explains that the Secretary is prohibited from taking certain actions for the purpose of promoting the market to decide the outcome of competition. However, AHCA/NCAL strongly believes that a less conservative view of the provision is needed to address critical issues in the MA marketplace. We do not believe the drafters anticipated the serious, negative implications of combined Medicare and Medicaid managed care and the downstream impacts on provider capacity to deliver critical services in such a challenging environment. Of key importance are challenges with adequate reimbursement to deliver high quality services in Medicare and Medicaid negotiated rate environments which include no guardrails for such negotiations. We understand that our comments on Part C, presented below, are not germane to CMS’ Part D specific comments contained herein, but we do believe that CMS has created an opening for a discussion on the underlying noninterference statutory provision by offering clarifying guidance on Part D. Further, separate commentary will be transmitted to CMS on this point. We understand that our comments on Part C are not germane to CMS’ Part D specific comments but we do believe that CMS has opened a dialogue on the underlying statutory provision by offering clarifying guidance on Part D. For now, we respectfully request that CMS consider the payments to providers “signaling” language approach used by the CMS Medicare-Medicaid Coordination Office for demonstration participating plans. Further commentary will be transmitted to CMS on this point at a later date.

- **Pharmacy Price Concessions in Negotiated Prices (423.100).** AHCA/NCAL understands that CMS is revising the definition of negotiated prices to require that all price concessions from pharmacies are reflected in those prices. This is based on the belief that there has been inconsistent reporting of costs and price concessions by Part D sponsors. We believe that this will positively impacts transparency. AHCA/NCAL supports the notion and would request a similar construction for services delivered under Part C.

- **Any Willing Pharmacy Standard Terms & Conditions (423.120(a)(8)).** AHCA/NCAL understands that this section is in response to concerns about barriers to preferred cost sharing not being offered to any willing pharmacies in the Part D sponsors’ standard terms and conditions. Here, CMS would make preferred cost sharing for all beneficiaries (if offered by Part D sponsors) in order to ensure fairness to average wholesale price (AWP) pharmacies as well as to expand such structures reach to the long term care, specialty and pharmacy settings. Such changes seek to better clarify cost sharing in the areas of "extended days' supply" and "mail order." AHCA/NCAL believes this is a positive proposed change for community retail pharmacies. This may actually reduce the use of mail order pharmacy in the community which may improve the response rates for prescription fills/refills for

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home patients, improving prescription compliance in that setting. This proposed rule will help eliminate the Part D plan practice of creating favorable pricing relationships with preferred pharmacies leading to the exclusion of smaller or rural pharmacy operators; many of whom service beneficiaries residing in SNFs. This could drive smaller pharmacies out of business creating an access problem for beneficiaries residing in SNFs. Similarly, dispensing technologies to improve nursing efficiency and reduce waste are driven by the smaller innovator pharmacies not the large national providers.

However, AHCA/NCAL is concerned that having mail order in the SNF setting would be very problematic. The days’ supply and ordering process can become more complicated, increase errors and decrease availability making the situation worse than the current situation. The urgent needs of medications would require both mail order and non-mail order resulting in dealing with two different pharmacies with different packaging and different formularies. In addition, providing unrestricted authority to plan sponsors could shift the current timely and efficient delivery of medications through LTC pharmacies to a mail order requirement for maintenance medications in SNF settings. Required mail order even if packaging and delivery requirements could be made to comply with CMS SNF guidelines for medication storage and delivery would be an untenable management scenario resulting in higher nursing costs and increasing the probability of errors. We recommend that CMS not allow plans to require Medicare beneficiaries in a SNF use mail order delivery.

- **Enrollment Requirements for Part D drug prescribers (423.120(c)(5)).** Here, CMS would require physicians to be enrolled in Medicare by January 1, 2015 in order to prescribe prescription drugs covered by Part D. The provision is designed to ensure safety and program integrity by requiring enrollment rather than relying on qualifications to prescribe under state law. It also recognizes that residents and interns can enroll and dispense as well as seeks to recognize the "opt out" provisions in a Parts A and B so that enrollment is only for prescribing purposes. AHCA/NCAL supports this proposed change. This would help ensure that more qualified practitioners are prescribing medications for beneficiaries. The six month window of notification to the prescribers to initiate and complete the enrollment process may be too stringent. A more lengthy notification would increase the likelihood that as many prescribers would complete enrollment as possible. It would also allow the pharmacies to update their records on who is qualified to prescribe Part D drugs. Finally, the provision would also allow the patient more time to seek out a new practitioner if need be.

AHCA/NCAL requests clarification on this section. Is CMS proposing a new provider enrollment and approval process for Part D, in addition to the current enrollment for obtaining a Medicare provider number? In addition, how will plan sponsors and pharmacist identify revoked or limited provider status? Without effective and timely notification to pharmacists and LTC providers, retrospective audits could result in payment recovery from pharmacies for providers revoked or without proper enrollment credentials. This will then be billed to providers creating
additional cost. How would Part D revocation impact Part B billing by the same practitioner? Consideration also should be given regulatory redundancy. It appears CMS will use prescribing trends (PDE DATA) to determine inappropriate patterns or prescribing are already covered by other state and federal regulations. CMS should default to state and federal rules. We are concerned that this proposal as written could give CMS the right to deny a prescriber authorization based on unpublished rules that CMS alone determines appropriate.

- **Improper Prescribing Practices (424.535).** In this proposal, CMS would alter its authority to deny (or revoke) Medicare enrollment based on suspension or revocation of DEA certificates and suspension or revocation of ability to prescribe by state authorities. Also, CMS proposes enrollment/revocation power based on objective as well as more subjective grounds relating to patterns or practices of prescribing that are "abusive and a threat to the health and safety of Medicare beneficiaries." AHCA/NCAL supports the concept, but the rule does not provide enough guidance as to what constitutes a pattern of prescribing that is abusive and represents a threat to health and safety. For example, the use of PDE data to identify prescriber trends alone is not sufficient to determine abusive practices. There is no way to distinguish legitimate high dose and frequency of prescriptions from illegitimate prescribing from PDE data. Prescribers may avoid LTC practice for fear of benign revoked from Medicare.

- **Establish Authority to Collect Information Directly from MA and Part D plan FDRs (422.504(i)(2)(i), 423.505(i)(2)(i).** In this provision, CMS seeks to permit HHS, Comptroller General and designees to have the right to directly collect, audit, evaluate and inspect any records of FDRs rather than having to go through the plans to gain access to such information. This provision would alter current process of using plans as gatekeepers. CMS should approach such information collection and review activities from the perspective of assessing plan operations and performance only in accordance with its authority found at Section 1857(e)(i). Additionally, such reviews should adhere to assessment of existing MA plan related materials and documentation and not to add to the already extensive array of current SNF oversight activities. Finally, CMS should issue a transmittal to all Medicare providers explaining how such information collection processes will be conducted.

- **Eligibility changes of enrollment of incarcerated individuals (417.1, 417.60, 422.74, 423.44).** In this provision, CMS seeks to require MA plans, PDPs and cost plans to dis-enroll individuals incarcerated for 30 days or more upon notification of such status by CMS. Federal health care benefits are generally allowable when furnished to a beneficiary who is either a U.S. citizen or a U.S. national or to an alien who is lawfully present in the United States. Federal health care benefits are not allowable for services provided to unlawfully present beneficiaries. CMS has specifically implemented a policy that bars Federal payments for health care services provided to unlawfully present beneficiaries in Medicare Parts A and B. Furthermore, an individual is eligible for Part D benefits if he or she is entitled to Medicare benefits under Part A or enrolled in
Part B and lives in the service area of a Part D plan. Thus, Federal law prohibits Part D payments for prescription drugs provided to unlawfully present beneficiaries.

There are many instances, however, where a provider admits a new resident in good faith -- having checked with the State, SSA, and obtained a social security number and or card, as well as checked the CMS Common Working File (CWF) (i.e., CMS tool to determine eligibility of patients and to monitor the appropriate usage of Medicare benefits) to query for Medicare eligibility, and later finds out that the individual is illegally in the US. In 2012, CMS published MLN Matters transmittal, SE1249, which discusses the replacement of the CWF with the Health Insurance Portability and Accountability Act (HIPAA) Eligibility Transaction System (HETS) and encourages providers to transition to the HETs; but does not make this transition mandatory. Because the transition is not mandatory; SNFs are making this transition slowing, and inappropriately getting caught up with inaccurate information from the CWF. If it is inappropriate to use the CWF tool any longer, the Federal government must make this clear. At no time has CMS ever indicated that the information in the CWF is incorrect or incomplete.

We agree that individuals illegally present in the US, should not receive Medicare benefits, as outlined in the federal law. However, if a SNF provider has queried the CWF and the information shows that the individual has Medicare coverage, there should be some “without fault” or comparable basis for challenging the denial, until at such time the Federal government mandates the use of the HETS. Providers should be held harmless including no retrospective denials.

- **Rewards and incentive plans for Part C enrollees (422.134).** CMS would permits health-driven rewards and incentives to MA plan enrollees under certain circumstances. And, CMS would implement this provision in such way as to not discriminate in favor of healthy beneficiaries and against higher acuity individuals. AHCA/NCAL supports delivery of services that foster health and wellness but that also do not permit discrimination on the basis of health conditions including those that require institutional services. Related to institutional services, AHCA/NCAL recommends that CMS craft language that makes clear that plans may in no way create incentives for use of services that are not sufficient to meet beneficiaries’ health care needs in an effort to contain costs. Additionally, AHCA/NCAL recommends that CMS require plans to provide information on such programs to all enrolled providers.

- **Authority to Expand Auto-assignment and Passive Enrollment (422.60).** CMS would increase authority to auto-assign/passively enroll people who are full Medicare-Medicaid eligible from one duals special needs plan (D-SNP) to another D-SNP if the current plan does not renew its contract with CMS or if the current D-SNP. Furthermore, it would permit auto-assignment to another D-SNP if the enrollee is enrolled in a Medicaid MCO that offers a D-SNP with a substantially similar network.
AHCA/NCAL appreciates CMS’ efforts to align benefits and services for persons who are eligible for Medicare and Medicaid. Integration of financing and services is essential to the improvement of services and supports for people who are dually eligible as well as for the fiscal integrity of Medicare and Medicaid. However, AHCA/NCAL has serious concerns about the notion of any expansion of passive enrollment particularly for a population that by definition has complex medical needs and minimal health literacy. We strongly recommend that CMS not adopt this proposal.

However, should CMS move forward, AHCA/NCAL urges CMS to provide critical information to beneficiaries and their families and to allow time for decision-making. Specifically, in keeping with timelines in some of CMS’ Financial Alignment Demonstration Memoranda of Understanding, beneficiaries should be given 90 day notice by their current D-SNP of termination or non-renewal to allow time for the individual or decision-maker to choose a new D-SNP or other vehicle for Medicare coverage. The beneficiary or decision-maker should be given information about the Medicaid MCO’s D-SNP offering as well as other Medicare coverage options. Section 422.60(g)(2) currently offers no such information sharing requirements, timelines or education about choice.

In addition to use of only CMS approved D-SNP materials and information on other Medicare options, beneficiaries should be provided information about resources to aid in decision making such as LTC Ombudsman, Managed Care Ombudsman and State Health Insurance Programs (SHIPs). Should the individual make no decision, AHCA/NCAL strongly recommends that passive enrollment only move forward once the individual or decision maker has been presented with a CMS approved document displaying the “substantially similar” offerings of the current D-SNP and the potential D-SNP and after the individual or decision-maker signs the document acknowledging their agreement that the new plan will meet their needs.

B. Improving Payment Accuracy

- **Overpayments (422.326, 423.360).** In this section, CMS seeks to establish 60-day rules for Parts C and D. Utilizes a six-year look-back, which is different from proposed rule as to Parts A and B (10 years). Also, CMS would establish that the timing is subject to specific plan reconciliations unique to each of the two programs and the identification/repayment is data disclosure. There is also a discussion about MA and Part D plans not being responsible for the accuracy and data controlled and submitted to CMS by other entities and an example associated with the “date of death.” AHCA/NCAL believes that providers should be held harmless in overpayment or inappropriate payment scenarios. Specifically, SNFs that deliver services in good faith based on plan organization determinations authorizing such services should not be penalized as part of CMS plan recovery effort in overpayment scenarios or for incarcerated individuals.

- **Risk Adjustment Data Requirements (422.310).** In this provision, CMS seeks to require MA plans to conduct risk adjustment data validation (i.e. medical record
reviews) that focuses on the accuracy of diagnoses to determine both underpayments and overpayments. AHCA/NCAL supports any efforts to improve plan oversight and more accurate risk adjustment. However, the Association is concerned about the potential administrative burden and costs associated with such data validation efforts. Plans should be required to disclose any such data validation efforts in their provider agreements and should also incur the cost of producing needed materials. Finally, providers should be held harmless. Specifically, no post-utilization review recoveries may be made for services delivered in good faith based on plan operation determinations authorizing such services. Payment alterations may only be made prospectively based on such reviews.

- **Rate Adjustment Validation Audit Appeals (422.2, 422.311).** In this section, CMS seeks to amend definitions associated with appeal of RADV audits, simplify the appeals process, narrow the presentation of evidence on appeal available to an MA plan, requires the presentation of certain types of evidence by the MA plan, establishes a 30-day appeal requirement and documentation requirements, specifies processes at each level of appeal, establishes the burden of proof on the MA plan in medical record review appeals, alters the compliance date for RADV audits and expands the scope of RADV audits. AHCA/NCAL supports this provision and analogous provisions that improve risk adjustment processes and related appeals processes.

- **RAC appeals (Parts 422 and 423).** Here, CMS seeks to establish a process that would require a validation contractor to confirm a RAC finding before a demand for repayment is made. The agency further seeks to thereafter establish a three-part appeals process of reconsideration, hearing official determination and administrator review but limit the scope of such appeals. None of these processes utilize the OMHA process. AHCA/NCAL supports an appeals process that uses a validation contractor to confirm the Recovery Auditor (RA) findings before a demand for repayment is made. Currently, with the increase in RA audits, providers are experiencing a high percentage of unfavorable results in the first 2-levels of the Medicare appeals process, eventually being overturned at the 3rd-level by the Administrative Law Judges (ALJ). This has resulted in a two-plus year backlog at the ALJ level. If a validation contractor looked more closely at the RA results early on, this problem may be improved. After the Medicare Administrative Contractors (MAC) initial determination there is a 5-level Medicare appeals process with different HHS agencies involved in the management of the appeal:

  - **Level 1 – MAC Redetermination (CMS)**
  - **Level 2 – Qualified Independent Contractor (CMS)**
  - **Level 3 – Administrative Law Judge (ALJ) Hearing (Office of Medicare Hearings and Appeals (OMHA))**
  - **Level 4 – Medicare Appeals Council (DAB)**
  - **Level 5 – Federal Court**
Overall, from the provider perspective, there is a substantial amount of time and money wasted in the first two Medicare appeal levels (Redetermination and Qualified Independent Contractor) b/c many of these appeals are denied at the lower levels and then overturned at the third level of appeal (ALJ). If there were a validation contractor to confirm the RA findings up front, there may not be such a high percentage of denials being overturned at the ALJ level, and the current system’s backlog would be markedly improved.

D. Strengthening the Ability to Distinguish Between Stronger Applicants and Remove Poor Performers

- **Two-year Prohibition for Organizations That Terminate (422.502, 422.503, 422.506, 422.508, 422.512).** CMS seeks to apply a two-year ban to re-enter the MA program from non-renewals or mutual terminations regardless of product type or service area. CMS would retain discretion as to applying the ban where there are special circumstances warranting special consideration. The provision specifies different rules for different situations. To ensure protections for the increasing number of beneficiaries enrolling in MA, AHCA/NCAL supports this provision and would suggest that at the end of the two year waiting period such plans would undergo heighten bid scrutiny by CMS.

- **Termination of Contracts of MA-PDs for Failure to Achieve Three-Stars In Same Year for Three-Consecutive Years (422.510).** This provision would extend existing regulatory authority to terminate MA-PDs if there were three consecutive years in which the plan was below three stars in Part C and Part D quality scores. Existing authority permits termination based on MA plans and Stand-Alone PDPs not achieving three-star score in three consecutive years. However, CMS allowed a three-year transition period before the ratings-based termination authority was used to begin issuing termination notices to plans whose performance met the criteria in late 2014 with an effective date of January 1, 2015. This would further clarify that MA-only contracts are subject to CMS termination when the plans fail for three consecutive years to achieve a Part C star rating of at least three stars. AHCA/NCAL supports this provision.

D. Implementing Other Technical Changes

- **Skilled Nursing Facility Stays (422.101, 422.102).** This provision would revise accounting rules regarding ensuring Medicare-financed SNF coverage when an enrolled moves from an MA plan to FFS and the application of the 3-day stay hospital rule. It would further define the requirements allowing people who entered a SNF while enrolled in an MA plan under the 3-day waiver and then dis-enroll into Medicare FFS to continue Medicare financed PAC services. This provision clarifies administrative process and should improve transitions from MA to Medicare FFS. AHCA/NCAL supports this provision.

- **Deemed Approval of Marketing Materials (422.2266, 423.2266).** Here, CMS seeks to reorganize existing regulations which indicate that if CMS has not disapproved
marketing materials and forms with respect to a plan in a given area, except for materials specific to that area, CMS is deemed to not have disapproved materials in all areas covered by the organization. Furthermore, CMS seeks to simplify language that provides that if CMS does not approve or disapprove materials within the specified timeframe, the materials are deemed approved. As noted in the introduction, MA is expanding rapidly with more offerings and higher penetration rates depending upon counties and regions. The Association believes that CMS has a responsibility to ensure that marketing practices and materials are carefully monitored. Therefore, we oppose this proposed provision and recommend that CMS review all marketing materials. Deeming should not be permitted.

- **Definition of a Part D Drug (423.100).** In this provision, CMS seeks to clarify when a “combination product” is appropriately classified as a Part D drug. It appears that CMS is attempting to avoid situations where a combination of items is packaged or bundled for convenience. The provision also would clarify that a combination product containing at least one constituent product that would, if dispensed separately, meet the definition of a Part D drug and is eligible for Part D coverage only if it has received FDA approval in its combined form. CMS would not require all constituent ingredients of a combination product be FDA-approved prescription drugs (i.e. a FDA-approved prescription drug that is combined with a non-Part D covered vitamin). However, a product combining a Part D drug with a medical food, dietary supplement or another Part D drug, where the combined product has not received FDA approval as a prescription drug, vaccine or biologic would not be eligible for Part D coverage. Also, this provision seeks to remove the exclusion of barbiturates and benzodiazepines from Part D coverage for all medically accepted indications, as required by ACA. Finally, CMS seeks to include language that would specify that medical foods are not Part D drugs. However, would not affect current policies surrounding Part D coverage of parenteral nutrition. AHCA/NCAL would support this change. Having the FDA approval for the combination should be all that is required. At this time these combination products are not being covered. We anticipate this would open coverage to a number of combo products that may benefit beneficiaries in SNFs patients. This would also prevent SNF providers from having to get these products separately and allow combination products to be used, improving compliance and reducing the risk of medication errors from administration of increased numbers of tablets/capsules.

- **Special Part D Access Rules During Disasters or Emergencies (423.126).** CMS seeks to relax PDP sponsor edits for refill too soon (RTS) in the event of any imminent or occurring disaster or emergency that would hinder an enrollee’s access to covered Part D drugs. Specifically, CMS references LTC residents receiving refills from LTC pharmacies in the location to which they are being evacuated. The proposed requirement would apply to one refill for each drug the beneficiary is taking for refills sought within 30 days of the date the plan sponsor began relaxing RTS edits. AHCA/NCAL members have experienced a wide array of serious situations in recent years ranging from hurricanes to successive snow storms in early 2014. AHCA/NCAL asks that CMS automatically grant special Part D access rules when a
state of emergency is declared in a state or a region of a state. Furthermore, special waivers should be provided for highly specific and serious local challenges that do not rise to a state of emergency. Special access should allow mail order pharmacy users to fill prescriptions at retail pharmacies or hospitals as noted above.

- **MA Organizations Responsibilities in Disasters and Emergencies (422.100).** Here, CMS seeks to codify sub regulatory guidance requiring that beneficiaries continue to receive access to services when normal business operations are disrupted due to public health emergencies, disasters and warnings of imminent disasters. The provision would require MA plans to ensure access through non-contracted facilities and charge no more cost sharing than would be the case for in-network providers. This also would provide guidance on determining the beginning and end of an emergency and requires posting on the plan website and transmittal of an annual notice to enrollees on plan disaster and emergency policies. AHCA/NCAL supports this provisions and further recommends that MA plans be required to have specialized protocols in place for PAC and long term services and supports providers. Such specialized protocols should recognize that people are residing, short term or long term, in SNFs or ALRs as well as recognize transitions issues associated with moving PAC and long term services and supports patients/residents to new settings. These protocols also should recognize the medically fragile condition of the vast majority of this population.

Finally, while continuity of care is not included in the Part C portion of the regulation, many AHCA/NCAL members are receiving prior authorizations for less than what members believe are appropriate lengths of stay in a PAC setting. Association members have expressed serious concerns about the implications of premature discharge including negative health impacts on people and avoidable hospitalizations. Such plan decisions would appear to be incongruent with CMS’ requirements at 422.206, Interference with Health Care Professionals Advice to Enrollees, and CMS requirements that plans deliver services in accordance with National Coverage Decisions or local Medicare Administrative Contractors. Under separate cover, AHCA/NCAL will provide more detail on this issue.

AHCA/NCAL appreciates the opportunity to comment on the proposed regulation and would welcome the opportunity to speak with CMS on these and other MA-related points. Please contact Mike Cheek at mcheek@ahca.org or 202-454-1294 with questions or requests to discuss our comments.

Sincerely,

Michael W. Cheek
Vice President, Medicaid & Long Term Care Policy