January 25, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P.
7500 Security Boulevard
Baltimore, MD 21224-1850

Re: [CMS-4180-P] Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses RIN 0938-AT92

Via Electronic Submission to: http://www.regulations.gov

Dear Administrator:

The undersigned organizations represent America's senior care pharmacists and long-term care pharmacies. Unique among pharmacy specialties, our members focus on effectively managing the complex diseases of the frail and elderly residing in skilled nursing facilities (SNFs), assisted living facilities (ALFs) and an increasing number of seniors living in the community.

We are grateful for the opportunity to comment on this proposed rule and will restrict our observations and recommendations to those issues most reflective of the communities we serve.

Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vi))

CMS proposes to expand Part D sponsor ability to impose drug utilization management tools for medicines included within the six protected classes. These tools include expanded prior authorization, exclusion of new drug formulations of existing drugs and drugs whose price increases exceed the Consumer Price Index-Urban (CPI-U).

Our organizations are deeply concerned with the proposed rule due to the nature of the resident population we serve. As you are aware, the institutionalized senior population is characterized by increased age, the presence of multiple co-morbidities and the need for higher levels of specialized care. We note that these conditions are the same conditions CMS referenced in its final rule on Skilled Nursing Facility Prospective Payment for FY 2019[1] that predict increased use of non-therapy ancillary (NTA) services in SNFs. NTA consists largely of prescription drug costs.

We believe this argues against introducing new drug utilization management techniques in this population. Broadening prior authorization and step therapy policies within the protected classes, particularly for patients who are already stabilized on treatment regimes, will create barriers to prescription medications for Medicare patients with chronic conditions. As a result, this could undermine adherence to highly effective medication regimens, drive up medical costs for patients and the Medicare program, and create unnecessary administrative hurdles for patients, their caretakers and providers. The proposed policies have a singular focus on lowering costs to the program and enrollees

[1] Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF) Final Rule for FY 2019, SNF Value-Based Purchasing Program, and SNF Quality Reporting Program

and are not supported by scientific evidence, clinical best practices, or analysis, particularly the policy allowing broader use of prior authorization and other utilization management tools.

Drugs included within the protected classes are, by their nature, both vital and potentially dangerous when prescribed and withheld. The risk is higher when any one of these drugs is co-prescribed with one or more other medications. While the adverse events related to a single drug may be easily detectable, the effects may be exponentially more difficult to observe in the presence of several other medications.

As CMS is aware, adverse events related to medication use in the Medicare population is a serious concern, both medically and financially. It takes only a few instances of adverse events to overwhelm any potential savings that result from the use of management tools such as prior authorization or financially-driven drug exclusions. We urge CMS to consider the countervailing costs associated with destabilizing patient care.

Our organizations believe that CMS is over reliant upon largely informal expectations for how Part D plans would design their formularies and the extent to which they would engage in negotiations with manufacturers of therapies within the protected classes. Further, the agency has not added specificity around the clinical criteria that will be applied to its revised formulary review or any additional oversight and monitoring that would be appropriate to ensure the well-being of Part D enrollees with chronic conditions.

We understand and agree with CMS that the unchecked cost of prescription drugs is a serious public health concern and finding an effective solution is vital to the ongoing health of the Medicare program. However, we believe CMS has the experience, knowledge and creativity to arrive at a solution that is driven by patient-centered solutions and best medical practices.

We point to our collective collaboration with CMS on the issue of inappropriate use of antipsychotic drugs in nursing homes. Rather than issue mandates and empower health plans with restrictive tools, CMS chose to engage pharmacists, SNFs and pharmacies through the Partnership to Improve Dementia Care in Nursing Homes. This effort proved to be exceptionally successful, dramatically reducing the inappropriate use of atypical antipsychotics in residents diagnosed with dementia.

We believe CMS should build on this success by creating similar collaborations that target the behavior the agency finds inappropriate. This rule may create unintended barriers to patient care and impede access for Medicare beneficiaries.

Recommendation:

We encourage CMS to replicate its success with appropriate management of dementia in nursing homes by bringing stakeholders together for a more targeted approach that is supported by substantial scientific evidence and does not put patients at risk. We believe CMS should, at the very least, exempt long term care facility (LTCF) residents from enhanced drug utilization management techniques.

Pharmacy Price Concessions in the Negotiated Price (§ 423.100)

We applaud CMS' attempt to redefine negotiated price to include the lowest reimbursable price to pharmacies for drugs prescribed under the Part D program. We are also pleased that CMS, in the

proposal related to "Pharmacy Price Concessions in the Negotiated Price (§ 423.100)," is “considering an option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements.” If CMS decides to establish a standard set of metrics, we urge CMS to use metrics developed by an established measure developer.

Part D sponsors operate under the misunderstanding that pharmacies are able to earn additional compensation by conforming to the plan standards for appropriate dispensing and drug management. The practice, as CMS notes, is that pharmacies seldom achieve the standards established by the plans. For example, many plans create quality metrics related to dispensing 90-day supplies. However, given the unique impairments of nursing home patients, long-term care pharmacies limit dispensing to 30-day supplies, except in the case of oral solid single-source drugs, where CMS rules require dispensing in 14-day supplies.

This has been noted to ensure quality, as adherence amongst nursing home patients actually decreases as the duration of medication prescriptions increase. Enforcing 90-day supplies of prescription medication will not improve quality among this population and will restrict long-term care pharmacies from qualifying for quality incentives under this metric. This is but one example of why our organizations believe it is important for CMS to require plans, if they use incentive-based reimbursement systems, to create incentives that are based on providing relevant, patient-centered clinical services to residents in LTC facilities.

Objective standards are far more likely to produce clinically-relevant performance standards. Medicare is a public program, financed by tax dollars and beneficiary premiums, and should serve first the interest of its participants residing in LTC facilities.

Recommendation:

We encourage CMS to work together with pharmacy stakeholders to develop objective, clinically-based standards for use by plans in providing network pharmacy incentives.

Thank you for your attention to our concerns. We stand ready to work with CMS and other agencies to improve the quality and efficiency of the Medicare drug benefit.

Sincerely,

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