February 25, 2015

The Honorable Paul Ryan
1233 Longworth HOB
Washington, D.C. 20515

Re: NCPA Comments on H.R. 1021, "Protecting the Integrity of Medicare Act of 2015"

Dear Chairman Ryan:

On behalf of the National Community Pharmacists Association (NCPA), I am pleased to provide comments on the "Protecting the Integrity of Medicare Act of 2015. NCPA represents the owners and operators of approximately 23,000 small business independent community pharmacies in the United States. Our pharmacies provide about 41 percent of all outpatient prescriptions dispensed in the U.S. and would be directly impacted by several provisions in this bill. NCPA would like to provide comments/recommendations on the following section of the bill.

Section 12—Programs to Prevent Prescription Drug Abuse Under Medicare Part D

This section would limit beneficiaries that are determined to be at "high risk" of prescription drug abuse to a single prescriber and pharmacy that are authorized to prescribe and dispense a "frequently abused drug." Historically NCPA has had serious concerns with proposed "lock-in" programs primarily due to the fact that without detailed beneficiary protections, some patients may experience delays in accessing much needed pain medications. Our secondary, yet substantially significant issue from a market fairness perspective is that currently Medicare Part D plan sponsors in many cases have existing commercial relationships with certain large chain pharmacy providers; raising serious conflict of interest concerns.

Any Medicare Part D Patient "Lock-In" Program Must Include Both Prescriber and Pharmacy

NCPA is pleased to note that the program outlined in H.R. 1021 would require the "lock-In" of **both a prescriber and a pharmacy**. The prescription drug abuse epidemic is complex and wide-ranging in nature and at the forefront of prevention efforts must be a focus on reducing the inappropriate prescribing or the overprescribing of controlled substances, as well as the prohibition of "doctor shopping." After all, without a physician-issued prescription, a drug abuser cannot obtain these substances through a pharmacy. It should be noted that similar initiatives in existing state Medicaid programs virtually always include the "lock-in" of both prescriber and pharmacy in recognition of the fact that a coordinated approach to patient care is essential to the success of any such program.

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Patient—Not Plan Sponsor—Must Have Ability to Choose In-Network Prescriber and Pharmacy; Legislation Must Ward Off Potential PDP "Conflicts of Interest"

It should be noted that in virtually all of the forty-six state Medicaid "lock-in" programs, **it is the beneficiary that has the ability to choose both the in-network prescriber and pharmacy**. However, the current language of H.R. 1021 would only allow the beneficiary the ability to indicate "preferences for which in-network prescribers and pharmacies the beneficiary would prefer the PDP sponsor select." This language is not clear enough and ultimately vests the PDP sponsor with the authority to select the prescriber and pharmacy. As NCPA has noted in response to other Part D "lock-in" proposals, there are multiple PDP sponsors that have commercial relationships with large retail pharmacy chains (i.e., Humana-Walmart). Our concern is that by only allowing the patient to indicate preferences, the plan sponsor would still retain the authority to effectively "assign" these types of beneficiaries to pharmacies in which they have a commercial or financial interest in, including mail-order pharmacies they own. In addition, it should be noted that H.R. 1021 already includes language—that is similar to language that appears in many state Medicaid programs-- that would allow the PDP sponsor to change the prescriber or pharmacy if it is determined that either entity is somehow contributing to the potential abuse or diversion. As long as this "fail safe" provision is in place, that would allow the PDP to override patient choice in the event of suspected abuse, the beneficiary should be able to choose where and from whom they receive their in-network health care services.

Greater Specificity Needed to Identify Exempted Individuals

The current language of H.R. 1021 would specifically exempt those patients receiving hospice care. Patients also in long-term care settings would also need to be exempted as these patients receive their medications at bed-side—and usually receive their medications automatically from the pharmacy that holds the contract with the care facility. In addition, certain language should also be added to take into account other patients with a terminal diagnosis—who are not in hospice. This is an area in which policymakers need to err on the side of caution to ensure that patients in intractable pain are not forced to forego their needed medications altogether or suffer long delays in receiving them.

Caution Needed In Application of Additional Utilization Management Tools at Pharmacy Level

H.R. 1021 would allow the PDP application of certain utilization management tools to identify patterns of abuse or overutilization at the patient and pharmacy level. While this is an admirable goal and certainly various types of utilization management tools are currently used, past experience warns against dispositive reliance on these tools. In the past, supply chain partners have used certain "quotas" or the ordering patterns of certain substances to justify "cutting off" certain pharmacies or restrict the medications that they may order. However, it is critical to look at a number of different factors in addition to ordering patterns or quotas. For example, a pharmacy may be located next door to a pain care clinic or large oncology practice or perhaps several pharmacies in the area may have closed within recent months; these factors may explain a larger percentage of controlled substances being dispensed through one particular pharmacy.

Recently Released CMS 2016 Call Letter Provides Direction to Part D Plan Sponsors on the Use of Existing Front–Line Tools to Combat Opioid Overutilization

NCPA would also like to highlight the most recent CMS 2016 Call Letter includes some direction from CMS to plan sponsors encouraging them to make use of the some of the tools that they currently have at their disposal to combat opioid overutilization. It is our belief that these tools that plans currently have at their disposal should be a front-line strategy to be employed before the imposition of any "lock-in" proposal. "Although the use of improved drug utilization review, case management, and beneficiary-level POS edits have reduced overutilization of opioids in the Part D program, CMS believes that Part D sponsors should implement soft formulary-level POS edits based on cumulative daily morphine equivalent dose (MED) to further reduce opioid overutilization, especially before it develops, as described in prior Call Letters. For CY 2016, we expect sponsors' Pharmacy and Therapeutics (P&T) committees to develop the specifications for a cumulative MED soft POS edit to prevent opioid overutilization while minimizing false positives. Sponsors can minimize false positives by accounting for known exceptions, such as hospice care, certain cancer diagnoses, reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary such as through prior authorization, case management or appeals processes."

Role of MEDICs and Lack of Corresponding Responsibility of PDP Sponsors to Report Findings to CMS

The current legislation would require the HHS Secretary to authorize the Medicare Drug Integrity Contractors (MEDICs) to directly request prescription and medical records from entities such as pharmacies, physicians and PDP sponsors. However, as reported in the January 2013 OIG report on MEDICs, CMS itself does not support this provision for the very reason that CMS directly contracts only with plan sponsors. The OIG report also identifies the greater problem as the fact that there does not currently exist a requirement for Part D plan sponsors to refer incidents of potential fraud and abuse to CMS. In addition, the current bill language seems to imply that MEDICs would be used to evaluate patient, pharmacy and prescriber information in order to even identify any of these entities as "high risk." NCPA has serious concerns about the proposed expansion of the role of these private contractors into territory in which CMS itself does not have jurisdiction.

Conclusion

NCPA appreciates the opportunity to provide our comments on and suggestions for possible revisions to H.R. 1021 and stands ready to assist in the examination of these factors. In addition, NCPA recommends that any larger stakeholder discussion include other interested federal agencies including CMS, ONDCP and FDA.

Sincerely,

Steve Pfister, Sr. Vice President, Govt. Affairs