Submitted electronically via: PARTDPOLICY@cms.hhs.gov

December 2, 2016

Centers for Medicare and Medicaid Services
Attn: Chad Buskirk, Mail Stop C1-24-23
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CARA Sec. 704 Comments

Dear Sir or Madam:

Thank you for the opportunity to submit our comments regarding Sec. 704 of the Comprehensive Addiction& Recovery Act of 2016 (CARA) and to participate in the CARA Teleconference hosted by CMS on November 14, 2016. As CMS considers public comments received pertaining to Sec. 704, and promulgates regulations to implement the program, the National Community Pharmacists Association (NCPA) is committed to working with CMS and other interested stakeholders on this issue.

NCPA represents America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Independent community pharmacies dispense approximately 40% of the nation's retail prescription drugs.

Overall, NCPA has several concerns with the establishment by Prescription Drug Plan (PDP) sponsors of a drug management program for at-risk beneficiaries (aka "lock-in" program) and the impact it will have on access to medications and pharmacy services offered by small business community pharmacies. NCPA, on behalf of our membership and the vital pharmacy services they provide, will expand on our concerns below.

I. Frequently abused drug definition: Per the statute, a frequently abused drug is a drug that is a controlled substance that the HHS Secretary determines to be frequently abused or diverted. Besides opioids, NCPA strongly recommends that no other scheduled drugs be considered for the program at its inception. NCPA has been supportive of improved drug utilization controls to prevent overutilization of medications in Part D. NCPA appreciates the success of these efforts and that CMS has historically required plans take a step-wise approach to prevent overutilization. In this same manner we would ask the agency take a step-wise approach when developing the Part D lock-in program, especially in regards to drugs impacted. We understand and support the work that CMS has undertaken to quantify the concurrent use of opioids and benzodiazepines among Medicare Part D enrollees. We encourage the agency to support efforts by plans/PBMs to utilize current tools to address vs. adding benzodiazepines to the list of frequently abused drug for lock-in purposes. We also continue to encourage CMS to collaborate with the Pharmacy Quality Alliance related

to measures that include criteria to monitor opioid and benzodiazepine overutilization. It is important to note that these are health plan level measures. We also think that it is wise to limit the application of PDP sponsor drug management programs to opioids for the time being to give such sponsors time to fine-tune such programs and identify operational difficulties before expanding the scope of the program to encompass additional drugs.

II. Exempted individuals: In addition to the exempted individuals outlined in the statute (is one who receives hospice care, is a resident of a long-term care facility, ICF-MR, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy) NCPA strongly urges the agency to include residents residing in assisted living facilities (ALFs). Our members who provide pharmacy services to those residing in long-term facilities provide services to ALFs in a very similar, if not identical, fashion. This is due to the need ALFs have because many patients are being admitted who would most likely qualify for a LTC facility if it were not for cost containment measures. To require a resident of an ALF to receive pharmacy services from a provider outside of normal ALF operations is not feasible and leads to disconnects in care. NCPA also agrees with other stakeholders that patients under a doctor's care for treatment of cancer or related conditions should be considered for a possible exemption under this section.

III. The information to be included in the first and second notices that are sent to lock-in patients and the standardization of such notices: In addition to the requirements that the initial notice must include (make beneficiaries aware of potential at-risk status, provide resources addressing prescription drug abuse, appeal rights and a request for the beneficiary to submit preferences for prescribers and pharmacies), NCPA strongly recommends that the initial notice make abundantly clear the lock-in program only applies to opioid medications. While the law only requires the lock-in to prescriber and pharmacy apply to frequently abused drugs, NCPA is very concerned that the plans/PBMs will effectively cause all of the patient's scripts to be filled at the lock-in pharmacy.

NCPA is also concerned that once patients are notified of their lock-in status, our members will have no way to know if one of their patients is impacted. We recommend there be a process in place to inform the current prescriber/pharmacy that a patient has been locked into a specific prescriber/pharmacy and for what medications and for what duration.

IV. Assessing the impact of drug management programs on cost-sharing and accessibility to drugs: Per the statue, a plan sponsor must ensure the beneficiary continues to have reasonable access to frequently abused drugs by taking into account geographic location, beneficiary preference, impact on cost sharing, and reasonable travel time. The sponsor must also ensure access for beneficiaries with multiple residences, in the case of natural disasters and similar situations, and in the case of emergency services. Our members have experience with lock-in programs, primarily at the state Medicaid level, and have told us the ultimate impact of many of these programs is that the lock-in only applies to *coverage* and not *access*.

Our members have relayed that while those who require opioids and other potentially abused drugs for chronic therapy are the ones most impacted by lock-ins, those who utilize opioids in an abusive manner are unfortunately many times not impacted by these programs.

NCPA is concerned that legitimate patient access and therefore adherence and compliance will be negatively impacted by the Part D lock-in program. In virtually all of the Medicaid lock-in programs, it is the beneficiary that has the clear ability to choose both the in-network prescriber and pharmacy. Since preference only is to be considered by plans/PBMs when delegating prescriber/pharmacy for purposes of the Part D lock-in program, there must be protections in place for continual access. Our members have relayed to us that a very common scenario with lock-in programs is when the lock-in pharmacy is closed and the patient has no alternative to obtain their medication. In these instances we have learned of unfortunate hospital admissions. NCPA therefore recommends that there be a back-up plan in place for a beneficiary to obtain medications when their lock-in pharmacy is closed.

In addition, the agency must address potential plan/PBM "conflicts of interest." As NCPA has articulated in the past, there are multiple PDP sponsors that have existing commercial relationships with large retail pharmacy chains. In no way should plans/PBMs be able to assign patients to those pharmacies in which they have a financial stake.

The CARA Act provides that an "at-risk" patient may be "locked-in" to a pharmacy chain or group of pharmacies under common ownership and control. Also, if a PDP sponsor determines that a beneficiary's choice of pharmacy is determined to be a contributing factor in that beneficiary's "at-risk" status, the PDP sponsor may re-assign the beneficiary to another pharmacy. We feel strongly that if a PDP sponsor determines that a beneficiary's choice of pharmacy is contributing to his or her "at-risk" status and that pharmacy is part of a group of pharmacies under common ownership or control, the PDP sponsor may not simply assign that beneficiary to another location of that pharmacy chain.

We urge CMS remain vigilant in ensuring appropriate patient access. We strongly recommend that CMS require plans/PBMs report percentage of times when beneficiary preference is/is not taken into account and also to track which pharmacy the plan/PBM utilizes to override patient preference.

We greatly appreciate your consideration of our comments.

Sincerely,

Susan Pilch, J.D.
Vice President, Policy and Regulatory Affairs