November 24, 2014

Ms. Patrice Drew
Office of Inspector General
Department of Health and Human Services
Attention: OIG–403–P, Room 5269
Cohen Building, Room 5269
330 Independence Avenue SW
Washington, DC 20201

Re: File Code OIG-403-P3: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing

Dear Ms. Drew:

The National Association of Chain Drug Stores (NACDS) is pleased to submit the following comments on the above-referenced proposed rule recently issued by the HHS Office of Inspector General. See 79 Fed. Reg. 59717 (Oct. 3, 2014). The proposed rule, if properly finalized, will allow government program beneficiaries to enjoy access to programs voluntarily implemented by pharmacies which reduce healthcare costs, improve quality, and promote patient health.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 800 supplier partners and nearly 40 international members representing 13 countries. For more information, visit www.NACDS.org.

I. Pharmacy Programs Offer Substantial Benefits To Patients And Government Programs

NACDS supports the statutory exemptions to the Anti-kickback statute (AKS) and Civil Monetary Penalty (CMP) law that the proposed rule is designed to implement. See 42 U.S.C. § § 1320a-7a(i)(6), 1320a-7b(b)(3). These statutory exemptions offer beneficiaries in government programs such as Medicare and Medicaid the ability to access pharmacy programs that have provided meaningful benefits to many other patients. As OIG notes, the AKS and CMP laws are broad statutes with major penalties for violations. 79 Fed. Reg. at 59718, 59719. Therefore, it is important to implement these new statutory exemptions to the AKS and CMP law in a manner that protects and encourages pharmacy programs that promote patient outcomes and lower healthcare costs.

As discussed below, pharmacy programs affected by the proposed rule reduce healthcare costs, both for individual patients and for the healthcare system as a whole. At the same time, these pharmacy programs promote access to prescribed medications that are essential to maintaining patient health and wellness. Failure to take medications as prescribed leads to major healthcare complications for patients and $290 billion in increased healthcare costs as a result of preventable physician visits and hospitalizations.[1] Incentives to participate in medication adherence programs and other beneficial pharmacy programs have a demonstrated track record of increasing patient health while simultaneously decreasing overall healthcare costs.[2]

NACDS understands OIG's concern that inducements or rewards may lead to overutilization of covered items or services, which is a central rationale for the AKS and CMP law. See 79 Fed. Reg. at 59718. However, the risk of overutilization is greatly reduced in the pharmacy context, because pharmacies dispense medications based on prescription orders that are typically written by physicians or other prescribers, so a pharmacy patient does not normally utilize a covered prescription drug unless a prescriber has already determined that the drug is medically necessary and has issued a prescription order for the patient to utilize that drug.[3] Likewise, concerns about incentivizing the use of low-quality covered items is also inapplicable in the pharmacy context, because the U.S. Food and Drug Administration ensures that all prescription medications satisfy the highest quality standards in the world. Non-governmental payers and patients have utilized the pharmacy programs discussed below for many years, because they know the pharmacy programs significantly reduce health care costs and enhance patient outcomes without promoting overutilization of care.

II. Part D Cost-Sharing Waivers By Pharmacies – Proposed 42 C.F.R. § 1001.952(k)(3)

NACDS supports the statutory exemption to the AKS for voluntary pharmacy waivers or reductions of cost-sharing. See 42 U.S.C. § 1320a-7b(b)(3)(G). NACDS appreciates OIG's efforts to implement this AKS exemption. Pharmacies should not be forced to waive or reduce

[1] Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease, New England Institute of Health (August 2009).

[2] A 2013 study performed for CMS found that Medicare Part D Medication Therapy Management (MTM) programs consistently and substantially improved medication adherence and quality of prescribing for beneficiaries with congestive heart failure, COPD, and diabetes. The study also found significant reductions in hospital costs, particularly when a comprehensive medication review was utilized. This included savings of nearly $400 to $525 in lower overall hospitalization costs for beneficiaries with diabetes and congestive heart failure. The report also found that MTM can lead to reduced costs in the Part D program as well, showing that the best performing plan reduced Part D costs for diabetes patients by an average of $45 per patient. Additionally, a study published in the January 2012 edition of Health Affairs identified the key role retail pharmacies play in providing MTM services. The study found that a pharmacy-based intervention program increased patient adherence for patients with diabetes and that the benefits were greater for those who received counseling in a retail, face-to-face setting, as opposed to a phone call from a mail order pharmacist. The study suggested that interventions such as in-person, face-to-face interaction between the retail pharmacist and the patient contributed to improved behavior with a return on investment of 3 to 1.

[3] In other limited instances, pharmacies dispense medications pursuant to Collaborative Practice Agreements (CPAs) with physicians, and/or in accordance with evidenced based clinical protocols. The prescriber's independence from the pharmacy is ensured by the Stark Law and the limitation on payment for referrals established by the AKS. See 42 U.S.C. §1395nn (Stark Law), 42 U.S.C. §1320a-7b(b) (AKS).

cost-sharing, but pharmacies that wish to implement copay waiver or reduction programs are allowed to do so by the statute.

Voluntary waiver or reduction of cost-sharing by pharmacies is entirely consistent with the criteria for establishing AKS safe harbors identified by OIG. See 79 Fed. Reg. at 59718. Reducing the burden of cost-sharing has been proven to increase patient access to prescribed medications, which promotes medication adherence, and thus patient health.[4] Therefore, there is no reason to believe that waiving or reducing cost-sharing by pharmacies would harm the quality of care received by patients, especially in light of the fact that the quality of prescription drugs is ensured by FDA standards. There is no evidence that these pharmacy programs reduce patient freedom of choice, and in fact they may lead to increased competition among providers. Far from increasing the government's healthcare costs, helping patients obtain prescribed medications decreases overall healthcare costs. Finally, OIG's concerns regarding overutilization and provider benefits are not a concern in the pharmacy context because, as discussed above, prescription drugs are only dispensed based upon a prescriber's assessment of medical need or in accordance with evidence-based clinical protocols.

A. Establish A Broad Safe Harbor

As OIG notes, the statute creates "exceptions" to the AKS for pharmacies that voluntarily waive or reduce cost-sharing for beneficiaries of government programs. See 79 Fed. Reg. at 59717. It appears that the AKS safe harbor proposed by OIG is more restrictive than the AKS exemption created by the statute. We understand OIG's desire to "strike an appropriate balance" in creating a safe harbor (79 Fed. Reg. at 59719), but that balance has already been struck by Congress when it created the AKS exemption, and it is now incumbent upon OIG to implement Congress' decision. As discussed below, therefore, NACDS asks OIG to broaden the safe harbor to implement Congressional intent. NACDS also asks OIG to confirm that a pharmacy may still satisfy the statute's AKS exemption even if a cost-sharing waiver program does not fit squarely within the proposed rule's AKS safe harbor.

Proposed section 1001.952(k) limits the safe harbor to pharmacy cost-sharing in Medicare Part D. OIG requests comments on expanding the safe harbor beyond Medicare Part D to other government programs. *Id.* at 59720. NACDS supports expanding the safe harbor. Limiting the cost-sharing safe harbor to Medicare Part D would severely restrict patient access to these cost-saving pharmacy programs, especially for beneficiaries in Part C Medicare Advantage Programs. It is anticipated that thirty-three (33%) of Medicare enrollees will opt for a Medicare Advantage plan in 2015 as a result of new coordinated care initiatives, disease management programs, and lower out-of-pocket expenses for beneficiaries. It would also create unnecessary compliance problems for pharmacies, as they attempt to establish mechanisms and work processes for allowing Medicare Part D patients – but not other Medicare patients and other government program beneficiaries – to participate in copay waiver programs.

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[4] Eaddy MT, et al., How Patient Cost-Sharing Trends Affect Adherence and Outcomes. A Literature Review. Pharmacy and Therapeutics. January 2012; 37(1):45-55. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/; Chernew ME, et al., Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment. Health Affairs. 2008; Volume 27(1): 103-11; http://content.healthaffairs.org/content/27/1/103.abstract

Although the statutory language creating the AKS exemption refers to Medicare Part D, OIG may employ its separate statutory authority to apply the safe harbor to other government programs.[5] A parallel exemption under the CMP law applies to more broadly to the entire Medicare program as well as state healthcare programs. See 42 U.S.C. § 1320a-7a(i)(6); 42 C.F.R. § 1003.101. Therefore, there is no rational basis not to expand the parallel AKS safe harbor to the entire Medicare program, as well as to Medicaid and other government healthcare programs.

At the very least, OIG should expand the safe harbor to Medicare Part B (pharmacy cost-sharing for covered supplies) and Medicare Part C (pharmacy cost-sharing for items and services covered by Medicare Advantage plans). Limiting the safe harbor to Prescription Drug Plans in Medicare Part D could inadvertently create a competitive disadvantage for Medicare Advantage Plans in Part C, and would establish unnecessary barriers to the cost-saving pharmacy programs.

B. Restrictions on Advertising And Solicitation Are Unconstitutional

Proposed section 1001.952(k)(3)(i) provides that a pharmacy must not offer to waive or reduce cost-sharing "as part of an advertisement or solicitation." NACDS understands this restriction is established by the statute. However, this provision should not be included in the final rule because it is an unconstitutional restriction on pharmacies' First Amendment right to free speech. *See Thompson v. Western States Medical Center,* 535 U.S. 357 (2002) (federal statute providing that pharmacies may "not advertise or promote" drug compounding was unconstitutional restriction on commercial speech). *See also Sorrell v. IMS Health Inc.,* 131 S.Ct. 2653, 2659 (2011) (striking down statute that restricted use of pharmacy data for marketing purposes because "[s]peech in aid of pharmaceutical marketing … is a form of expression protected by … the First Amendment"); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748 (1975) (statutory ban on pharmacists advertising prescription drug prices violated First Amendment). Moreover, there is no rational basis for prohibiting pharmacies from informing the public about programs that reduce healthcare costs and promote access to prescribed medical care. OIG should recognize pharmacies' First Amendment rights and eliminate this restriction.

If OIG does not eliminate this restriction, OIG should impose no more than the least restrictive limits on pharmacies' free speech that are absolutely necessary to directly advance a substantial governmental interest. For example, a pharmacy should be able to publicly announce the availability and nature of a copay waiver program, and announce that interested individuals may access a website or phone number for details. Allowing pharmacies to announce the availability of cost savings to the general public will help patients, and will allow pharmacies to centralize and harmonize the copay waiver determination process. Any restrictions must not apply to advertising or solicitation that does not directly and specifically target government program beneficiaries.

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[5] AKS safe harbors are created pursuant to separate statutory authority that allows OIG "to limit the reach of the statute somewhat." *Id.* at 59718-19, *citing* Social Security Act § 1128B(b)(3)(E).

C. "Routine" Waivers And Determinations Of "Financial Need"

Proposed section 1001.952(k)(3)(ii)(A) provides that a pharmacy must not "routinely" waive copayments, coinsurance or deductibles. Proposed section 1001.952(k)(3)(ii)(B) provides that a pharmacy may waive cost-sharing only after determining in "good faith" that the "individual" is in "financial need," and may fail to collect a cost-sharing only after "reasonable collection efforts."[6] These provisions of the proposed safe harbor are based on parallel provisions of the statute.

OIG should clarify that a pharmacy does not "routinely" waive cost-sharing so long as the pharmacy does not automatically waive cost sharing amounts for beneficiaries of government programs. In calculating whether a pharmacy routinely waives cost-sharing amounts, OIG should only consider waivers for government program beneficiaries covered by the safe harbor, not waivers offered to private-pay patients or waivers offered to "subsidy-eligible individuals" who are exempt from these requirements. In addition, OIG should provide pharmacies flexibility to establish protocols to guide employees when they are deciding whether to waive cost-sharing amounts.

Pharmacies also would appreciate constructive guidance regarding the requirement to assess beneficiaries' "financial need." In light of the fact that pharmacies dispense billions of prescriptions every year, an individualized assessment of financial need for each patient is not practical. Many copays can be quite small, especially for common generic drugs, so it could easily cost a pharmacy more to conduct an individualized needs assessment than the copay is worth.

CMS has approved State Medicaid plans that require pharmacies to accept as true a patient's statement that the patient is financially unable to pay a drug copay, even when the copay is less than a dollar. See State Medicaid Plans approved by CMS pursuant to 42 C.F.R. § 447.52(e)(2). Because CMS has already concluded that beneficiaries' assertions are a legitimate basis for determining financial need, pharmacies should be allowed to accept beneficiaries' statements of financial need as a good faith assessment of financial need in compliance with the proposed safe harbor.

Likewise, the requirement to conduct "reasonable collection efforts" should be considered in light of the fact that many copays are quite small. Collection efforts will easily cost the pharmacy more than the copay amount in many instances, so it would not be reasonable to require collection efforts in those circumstances. Pharmacies should be allowed to forego collection efforts for smaller than average cost-sharing amounts, and in situations where past collection efforts indicate that the cost of collection efforts outweigh projected recovery amounts.

Finally, as a technical matter NACDS recommends that the introductory language in proposed section 1001.952(k) should be revised to say "copayment, coinsurance, or deductible…" rather than just "coinsurance or deductible…." That will make the introductory

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[6] NACDS appreciates and supports OIG's recognition that these requirements do not apply to "subsidy-eligible individuals" as defined by federal law.

language consistent with the pharmacy cost-sharing safe harbor, which repeatedly uses the phrase "copayment, coinsurance, or deductible…." In addition, OIG should clarify in proposed section 1001.952(k)(3) that the safe harbor applies to "reductions" of cost-sharing, not just full "waivers."

III. CMP Exemptions And Application of the AKS

The remainder of NACDS' comments concern OIG's implementation of statutory exemptions from the CMP law. NACDS understands that OIG interprets the law to mean that an exemption to the CMP law does not necessarily constitute an exemption to the AKS. See 79 Fed. Reg. at 59724. However, strict application of AKS to the programs discussed below could entirely frustrate the intent of Congress when it created the new CMP exemptions. For example, if OIG concludes that coupon and rewards programs remain illegal under the AKS, then such programs will most likely not be extended to beneficiaries of government programs, even though Congress enacted a CMP exemption to encourage beneficiary participation in these pharmacy programs.

Therefore, OIG should adopt AKS safe harbors that track each of the CMP exemptions addressed in the proposed rule. OIG has authority to adopt new AKS safe harbors pursuant to section 1128B(b)(3)(E) of the Social Security Act. Adopting AKS safe harbors that track the new CMP exemptions will ensure that Congressional intent is implemented, allowing government program beneficiaries to participate in pharmacy programs that reduce healthcare costs and promote patient health and wellness.

Alternatively, we ask OIG to adopt an enforcement discretion policy. OIG should expressly state that it has no plans to bring AKS enforcement actions against pharmacy programs that satisfy the CMP exemptions discussed in the proposed rule. OIG has already exercised this enforcement discretion in specific situations involving programs that satisfy the CMP exemption for pharmacy rewards programs. See OIG Advisory Opinions 12-05, 12-14. We ask OIG to extend that individualized enforcement discretion to a more generalized policy applicable to pharmacies that satisfy the CMP exemptions.

IV. Remuneration That "Promotes Access To Care" – 79 Fed. Reg. at 59725-26

In the Affordable Care Act, Congress enacted an exemption to the CMP law to protect "any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs…." 42 U.S.C. § 1320a-7a(i)(6)(F). NACDS supports implementation of this CMP exemption, which allows pharmacies greater freedom to help improve patient access to beneficial pharmacy care. NACDS appreciates OIG's recognition of this important CMP exemption in the preamble to the proposed rule, but we urge OIG to adopt specific regulatory language that implements this CMP exemption in the final rule.

A. "Promotes Access To Care"

NACDS agrees with OIG that the phrase "promotes access to care" includes remuneration to patients as part of a program that "improves a particular beneficiary's ability to

obtain medically necessary health care items and services." 79 Fed. Reg. at 59725. However, NACDS believes this phrase should also be interpreted more broadly, beyond items and services that are "medically necessary." As OIG suggests, a broader definition is justified in light of the movement toward innovative coordinated or integrated care arrangements that depend on patient engagement. NACDS supports interpreting "promotes access to care" to include encouraging patients to access healthcare, supporting or helping patients to access healthcare, or making access to healthcare more convenient for patients than it would otherwise be. Likewise, NACDS supports the inclusion of programs that encourage enhanced consumer engagement through fiscal and other incentives to promote better health and preventive care.[7]

NACDS also supports broadening the scope of the proposed rule to include pharmacy programs that promote access to care at the population level, as opposed to protecting only programs that promote access for particular beneficiaries. We encourage OIG to implement its suggestion that the proposed rule could be broadened to apply to "remuneration that promotes access to care for a defined beneficiary population generally, such as, by way of example, beneficiaries in a designated care network or beneficiaries being treated under a designated care protocol." *Id.*

NACDS strongly supports OIG's belief that this CMP exemption is intended to protect provider programs that "offer beneficiaries incentives to engage in their wellness or treatment regimens or that improve or increase beneficiary access to care, including better care coordination." *Id.* We also support protection of pharmacy programs that "include care that is nonclinical but reasonably related to the patient's medical care…." *Id.*

We also appreciate OIG's recognition that "patients might be offered incentives to encourage them to engage in arrangements that lower health care costs (without compromising quality) or that promote their own wellness and health care, for example, by participating fully in appropriate prescribed treatment, achieving appropriate treatment milestones, or following up with medically necessary appointments." *Id.* at 59726. It is important to ensure that pharmacy programs promoting proper adherence to medication regimens and other programs are covered by the final rule.

OIG seeks comments on broader CMP exemptions for providers that participate in government programs involving "accountable care organizations, medical homes, bundled payments, coordinated care programs, and other initiatives to improve the quality of care and reduce costs." *Id.* NACDS supports broad exemptions from both the CMP law and the AKS for pharmacies that participate in these and other government-sponsored programs. Enforcement of the AKS and CMP law should not stand in the way of participation in government programs, or frustrate the accomplishment of government program goals.

In response to OIG's request for specific examples, NACDS suggests that this CMP exemption should be sufficiently broad to cover any program that encourages patients to participate in activities that can maintain or improve their health, such as free or reduced price health screenings, free or reduced price blood pressure screenings, free or reduced price diabetes

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[7] CMMI, PCORI and others are considering behavioral science tools to increase consumer engagement to promote medication adherence, beneficial life style changes, and other methods of promoting patient health.

education programs, rewards for participating in medication synchronization programs and other programs that promote medication adherence, as well as rewards for engaging in routine exercise or other healthy activities.

NACDS agrees with OIG that providing resources to patients to help them record and report health data (e.g., blood pressure cuffs) does promote access to care, because the recording and reporting of health data increase their ability to obtain medically necessary care. 79 Fed. Reg. at 59725. With the promise of innovations in health care technology, NACDS also urges OIG to include technology resources and tools, such as health apps, which assist patients in maintaining and improving their health. Therefore, NACDS supports protecting such programs under this CMP exemption.

OIG seeks specific comments on whether certain "limitations or safeguards" should be imposed on "incentives for compliance with treatment regimens." 79 Fed. Reg. at 59726. The statute that creates the CMP exemption does not establish additional limits on patient incentives associated with medication adherence programs or other programs that promote compliance with treatment regimens, and NACDS does not support the imposition of new limits that are not authorized by the statute. In particular, OIG seeks comments on whether it should impose specific dollar limits or documentation requirements related to such incentives. Dollar limits and documentation requirements are not practical for pharmacies. As discussed below regarding pharmacy coupons, tracking aggregate dollar limits is simply not feasible in the pharmacy context, where billions of prescriptions are filled each year for millions of patients. OIG also seeks comments on whether "the form of the incentive" should be required to bear a reasonable connection to "medical care." Under the statutory CMP exemption, the "form" of the incentive is irrelevant, so long as the incentive promotes access to care. These and the other potential limitations mentioned by OIG are not authorized by the statutory exemption to the CMP law, and NACDS does not support the imposition of these limitations on pharmacy programs that help patients adhere to prescribed medication regimens. Studies have repeatedly demonstrated that medication adherence programs both improve patient health and reduce healthcare costs.[8] OIG should not impose barriers to these beneficial programs that are not contained in the statutory CMP exemption.

B. "Low Risk of Harm"

OIG proposes to interpret the phrase "low risk of harm" as including an incentive or other remuneration provided to beneficiaries that "(1) Is unlikely to interfere with, or skew, clinical decision-making; (2) is unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) does not raise patient-safety or quality-of-care concerns." *Id.* at 59725. We understand OIG's concern that in some situations remuneration might be abused to induce beneficiaries "to obtain items or services billable to Medicare or Medicaid that may be unnecessary, too expensive, or of poor quality." *Id.*

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[8] Eaddy MT, et al., How Patient Cost-Sharing Trends Affect Adherence and Outcomes. A Literature Review. Pharmacy and Therapeutics. January 2012; 37(1):45-55. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/; Chernew ME, et al., Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment. Health Affairs. 2008; Volume 27(1): 103-11; http://content.healthaffairs.org/content/27/1/103.abstract

As discussed in section I above, however, OIG should keep in mind that these concerns are greatly reduced in the pharmacy context. The risk of interfering with clinical decision-making or obtaining "unnecessary" covered items is low because pharmacies ordinarily cannot dispense a prescription drug to a beneficiary unless a prescriber has determined that the drug is medically necessary and issued a prescription order. The risk of increasing costs is also extremely low in the pharmacy context because (a) pharmacy programs that promote medication adherence and access to pharmacy care have been demonstrated to lower overall healthcare costs, and (b) the vast majority of the relevant pharmacy reimbursement rates are established by highly competitive PDP plans, MA plans and Medicaid Managed care plans, or are capped by federal and state reimbursement limits. Pharmacies do not set the rates charged for prescription medications and supplies provided to government program beneficiaries. Likewise, patient safety and quality of care issues are much less of a concern in the pharmacy context, because the Food and Drug Administration ensures that medications dispensed by pharmacies satisfy stringent quality control requirements. For these reasons, a strict interpretation of "low risk of harm" is not necessary for pharmacy programs that promote access to care.

C. Proposed Regulatory Language

OIG does not propose regulatory language to implement this CMP exemption. Instead, OIG solicits proposals for regulatory language. 79 Fed. Reg. at 59726. NACDS supports the inclusion of language in the final rule to implement this CMP exemption. It is important to provide regulatory guidance to pharmacies about OIG's expectations as pharmacies implement programs that promote access to care. Without clear regulatory guidance, pharmacies are less likely to offer such programs to beneficiaries of government programs, and as a result beneficiaries will not be able to benefit from increased access to care.

We recognize that it may be a challenge to craft regulatory language that covers all such programs. At the very least, however, NACDS suggests that OIG should incorporate the statutory language into the regulation. The statutory language could be inserted as paragraph (6) of the definition of "remuneration," which OIG has proposed to mark as "[Reserved]." See proposed 42 C.F.R. § 1003.101.

V. Retailer Rewards Programs – Paragraph (7) of Definition of "Remuneration" in Proposed Section 1003.101

The Affordable Care Act includes an exemption from the CMP law for "coupons, rebates, or other rewards" offered by a "retailer," so long as certain conditions discussed below are met. See 42 U.S.C. § 1320a-7a(i)(6)(G). NACDS strongly supports implementation of this statutory exemption, which allows pharmacies to extend coupons and rewards programs to government program beneficiaries.

A. Beneficiaries Should Gain Access To Helpful Pharmacy Rewards Programs

For years, retail community pharmacies have offered coupons and discount programs that help reduce the cost of both healthcare and non-healthcare items and services. We are not aware

of any non-governmental health plans or payers that object to these pharmacy programs, because they know these programs help pharmacy patients without harming plans or payers.

Unfortunately, in the past the government has not always allowed beneficiaries covered by Medicare, Medicaid and other government programs to participate in these cost-saving pharmacy programs to the extent they involve covered items and services. Even today, almost five years after Congress enacted the exemption for retailer rewards programs, the vast majority of government program beneficiaries remain excluded from participating in these beneficial pharmacy programs due to regulatory uncertainty and OIG's restrictive interpretation of the law. As a result, government program beneficiaries are unable to access benefits routinely available to all other pharmacy patients.

Pharmacies recognize OIG's policy of allowing pharmacies to provide discounts to government program beneficiaries of no more than $10 individually and no more than $50 in the aggregate annually per patient. See 79 fed. Reg. at 59726. However, with millions of patients filling billions of prescriptions each year, it is exceedingly difficult to ensure that government program beneficiaries do not inadvertently exceed the $50 annual limitation. The result is that the vast majority of pharmacies have to carve out government program beneficiaries from the healthcare aspects of their coupon, discount and rewards programs, in what OIG refers to as a "blanket exclusion." *Id.* NACDS hopes that OIG will implement the CMP exemption for retailer rewards programs in a manner that allows government program beneficiaries to enjoy the benefits that have long been enjoyed by other patients and accepted by other plans and payers. OIG should also clarify that this statutory CMP exemption preempts analogous state restrictions on retailer coupons, rebates and rewards programs, at least to the extent they involve federal programs such as Medicare.

B. "Coupons, Rebates, And Other Rewards From A Retailer"

Paragraph (7)(i) of the proposed definition of "remuneration" would apply the CMP exemption to coupons, rebates and other rewards offered by retailers. This language is consistent with the language of the statute.

NACDS submits that OIG's interpretation of "other rewards" as "primarily as describing free items or services, such as store merchandise, gasoline, frequent flyer miles, etc." (79 Fed. Reg. at 59727) is too limited. Rewards may include not just "free" but also reduced price items and services.

Most importantly, under the statute "rewards" may include free or discounted *healthcare* items and services, not just non-healthcare items and services. As discussed below in section VI(D), the statute provides that coupons, rebates and other rewards may be offered for covered items and services, so long as they are not "tied" to the provision of "other" covered items or services.[9]

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[9] NACDS appreciates OIG's favorable recognition of a coupon for $10 off the purchase of a prescription, although OIG subsequently questioned the propriety of other prescription coupons. *Id.* We seek confirmation that coupons and rewards may take the form of discounts off covered healthcare services.

NACDS asks OIG to expressly state that all retail community pharmacies - including traditional drug stores, grocery stores with pharmacies and mass merchandisers with pharmacies - qualify as "retailers." Congress has determined that all of these types of pharmacies constitute "retail" community pharmacies. See 42 U.S.C. § 1396r-8(k)(10) (definition of "retail community pharmacy").

We appreciate OIG's recognition of "drug stores" as retailers. 79 Fed. Reg. at 59726. However, OIG subsequently solicits comments on whether "entities that primarily sell items that require a prescription" should not be considered "retailers." *Id.* at 59727. There is no statutory basis for disqualifying retail pharmacies that "primarily" sell items that require a prescription. Some traditional retail pharmacies generate a majority of their revenues from sales of prescription medications, whereas other retail pharmacies generate less than fifty percent of their revenues from prescriptions. OIG should not create a competitive advantage for some types of retail pharmacies over others.

Likewise, there is no statutory basis for excluding from the definition of "retailer" entities that "primarily provide services." *Id.* Retail pharmacies provide both items and services, and there is no need or basis for applying the CMP exemption to some retail pharmacies but not others. Moreover, the statute clearly and expressly includes service providers as retailers, because it repeatedly refers to the provision of "services" by the "retailers" covered by the statutory exemption. See 42 U.S.C. § 1320a-7a(i)(6)(G).

C. "Equal Terms"

Paragraph (7)(ii) of the proposed definition of "remuneration" provides that the discounted items or services must be offered on "equal terms available to the general public, regardless of health insurance status." This provision tracks the language of the statute.

We ask OIG to clarify that it is appropriate for pharmacies to continue their longstanding practice of having participants in discount card and rewards programs complete an enrollment process, so long as enrollment is offered on equal terms to the general public. Enrollment is often a necessary component of rewards programs, because pharmacies and other retailers must be able to track whether and when individuals earn rewards, and then notify individuals about the rewards they have earned.

As an example of satisfying the "equal terms" criterion, OIG describes a retailer that mails a coupon to every resident of a surrounding zip code. See 79 Fed. Reg. at 59727. The "equal terms" requirement should not be interpreted this narrowly. Pharmacies will not always have access to the names and addresses of all residents of a particular area. Pharmacies should be able to mail or email coupons and other rewards to their existing customers, so long as they do not specifically target government program beneficiaries. Similarly, pharmacies must have flexibility to send rewards offers and notices to enrollees in their rewards programs, so long as enrollment in the program is offered on equal terms to the general public and government program beneficiaries are not specifically targeted to receive the rewards.

Overall, NACDS requests clarification regarding OIG's understanding of what constitutes inappropriate "targeting" of government program beneficiaries. It is a common business practice of retailers to send marketing and offers to subsets of their customer population, as it can be expensive and ineffective to distribute the same offer to every potential customer. We believe the "equal terms" requirement can be satisfied as long as (i) the redemption terms for the offer do not require any particular health insurance status, and (ii) the offer is not intentionally disseminated to individuals based on their status as government program beneficiaries.

D. "Tied" To "Other" Covered Items And Services

Paragraph (7)(iii) of the proposed definition of "remuneration" provides that the offer of transfer of discounted items or services must not be "tied to the provision of other items or services reimbursed in whole or in part by" government programs. Statements in the preamble to the proposed rule leave NACDS concerned that OIG appears to have misinterpreted the statute. The statute clearly allows retailers to offer coupons, discounts and other rewards for healthcare items or services, so long as the offer is not "tied" to the purchase of "other" covered items or services. See 42 U.S.C. § 1320a-7a(i)(6)(G)(iii). For example, a coupon for $15 off a prescription drug qualifies for protection under the statute, so long as it is offered on equal terms to the general public and is not "tied" to the purchase of an "other" covered item or service. In contrast, a "buy one get one free" prescription coupon may not qualify, because the offer of a discount off the first prescription would be "tied" to purchase of a second ("other") covered prescription.

OIG appears to assert that a retailer reward may not be earned by purchasing a prescription unless the same reward can also be earned by purchasing *non*-prescription items or services - even if the reward is not tied to the utilization of an "other" covered item or service.[10] Likewise, OIG appears to assert that no retailer reward may be redeemed toward the purchase of a prescription unless the same reward may also be redeemed toward the purchase of *non*-prescription items or services – even if the reward is not tied to the utilization of an "other" covered item or service.[11] This is a misinterpretation of the statute. The statute does not require retailer rewards to be equally applicable to healthcare and non-healthcare items or services. The statute limits a reward connected to a healthcare item or service only if that reward is "tied" to the provision of a second ("other") covered healthcare item or service.

OIG's interpretation would improperly prohibit retailers from offering coupons and rewards that focus on healthcare items and services they offer, and also effectively eliminates the statutory requirement that the offer should not be tied to the purchase of "other" reimbursable items or services. We urge OIG to give effect to the word "other" in the statute and allow coupons and rewards that focus on prescription drugs and other healthcare items and services. In addition to being contrary to the statute, requiring that a reward must be earned or redeemed on equal terms for reimbursable as well as non-reimbursable items or services could place retail

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[10] 79 Fed. Reg. at 59727, OIG's discussion of "earning" rewards.
[11] *Id.*, OIG's discussion of "redeeming" rewards: OIG interprets the statute "to exclude from protection rewards programs in which the rewards themselves are items or services reimbursed in whole or in part by a Federal health care program."

pharmacies in a difficult position of needing to choose between compliance with the retailer rewards exception or compliance with Medicare rules, state laws and third-party payer contract terms which prohibit discounting or waiving copayment or co-insurance amounts.

In the CMP exemption for individuals in financial need (discussed below), the statute uses the same language prohibiting remuneration that is “tied” to the provision of “other” covered items or services. However, for the financial need exemption OIG interprets this identical language in a very different manner than it does for the retailer rewards exemption. The financial need exemption requires that remuneration provided to the patient must have a connection to the patient’s “medical care,” so Congress clearly did not intend the “tied” language to prohibit coupons or other remuneration that focus on prescription drugs or other healthcare items or services. Instead, in the context of the financial need exemption OIG correctly interprets the “tied” language as prohibiting remuneration that focuses on healthcare items and services only when a discount on one covered healthcare item or service is tied to the purchase of a second, “other” covered item or service. *Id.* (“a provider’s conditioning the offer or transfer of items or services on the patient’s use of other services from the provider that would be reimbursed by Medicare or Medicaid would violate this requirement.”) OIG should apply this same interpretation of the phrase “tied to the provision of other” covered items and services in the retailer rewards program exemption, not just in the financial needs exemption.

VI. Financial-Need-Based Exemption - Paragraph (8) of Definition of “Remuneration” in Proposed Section 1003.101

NACDS supports efforts by OIG to implement the CMP exemption allowing pharmacies to help low income beneficiaries. This CMP exemption would protect pharmacies and other providers that offer free or reduced cost items or services to beneficiaries in “financial need,” so long as certain requirements discussed below are satisfied. See 42 U.S.C. § 1320a-7a(i)(6)(H). If implemented wisely, this CMP exemption has the potential to allow pharmacies to assist the neediest government program beneficiaries.

A. Restrictions On Advertising And Solicitation Are Unconstitutional

Paragraph (8)(i) of the proposed definition of “remuneration” would require that free or reduced cost items or services must not be “offered as part of any advertisement or solicitation.” See proposed 42 C.F.R. § 1003.101. NACDS understands this restriction is established by the statute. However, this provision should not be included in the final rule because it is an unconstitutional restriction on pharmacies’ First Amendment right to free speech. *See Thompson v. Western States Medical Center,* 535 U.S. 357 (2002) (holding that federal statute providing that pharmacies may “not advertise or promote” drug compounding was unconstitutional restriction on commercial speech). *See also Sorrell v. IMS Health Inc.,* 131 S.Ct. 2653, 2659 (2011) (striking down statute that restricted use of pharmacy data for marketing purposes because “[s]peech in aid of pharmaceutical marketing … is a form of expression protected by … the First Amendment”); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748 (1975) (statutory ban on pharmacists advertising prescription drug prices violated First Amendment). Moreover, there is no legitimate rationale for prohibiting pharmacies from informing the public about programs that reduce healthcare costs for financially

needy individuals. OIG should recognize pharmacies' First Amendment rights and eliminate this restriction.

If OIG does not eliminate this restriction, OIG should impose no more than the least restrictive limits on pharmacies' free speech that are absolutely necessary to directly advance a substantial governmental interest. For example, a pharmacy should be able to publicly announce the availability and nature of assistance for low income individuals, and announce that interested individuals may access a website or phone number to determine whether they qualify. Allowing pharmacies to announce the availability of cost savings to the general public will help financially needy and medically underserved patients, and will help pharmacies centralize and harmonize the determination of whether individuals qualify for assistance. Any restrictions must not apply to advertising or solicitation that does not directly and specifically target government program beneficiaries.

B. "Tied" to "Other" Covered Items Or Services

Paragraph (8)(ii) of the proposed definition of "remuneration" would prohibit an offer or transfer of remuneration that is "tied" to the provision of "other" covered items or services. As discussed above regarding the CMP exemption for retailer rewards programs, this language should be interpreted to allow remuneration connected to a healthcare item and service, so long as the remuneration is not conditioned on the purchase or utilization of a second ("other") covered item of service. It appears that OIG has adopted that interpretation of the "tied" and "other" language in the financial need exemption. See 79 Fed. Reg. at 59727. OIG should adopt that same interpretation of the same language in the retailer rewards exemption.

C. "Reasonable Connection" to "Medical Care"

Paragraph (8)(iii) of the proposed definition of "remuneration" would require a "reasonable connection" between the free or reduced cost items or services provided to a beneficiary and the "medical care of the individual." NACDS appreciates OIG's recognition that care provided by pharmacies qualifies under this provision. See 79 Fed. Reg. at 59728. We also support OIG's recognition that "medical care" can include "the treatment and management of illness or injury and the preservation of health" *Id.*

However, NACDS supports a broader interpretation of "medical care" that focuses on an individual's overall "medical condition, not just the care the individual has received in the past. Rather than limit "medical care" to "treatment and management" of existing illness or injury, medical care should also be interpreted to incorporate preventive measures taken prior to the onset of illness or injury, or other medical conditions. "Medical care" should also be interpreted to include items and services that support the structure and function of the body, not just care provided after injuries and illnesses occur. For example, flu shots and immunizations, services recommended by the U.S. prevention task force, CLIA-waived laboratory tests, administration of injectable medication, assessment and treatment of minor ailments, and nutrition and motivational counseling provided by pharmacies should be considered "medical care" under this CMP exemption. NACDS also supports examples offered by OIG such as "distribution of

pagers to alert patients with chronic medical conditions to take their drugs" and "provision of free blood pressure checks to hypertensive patients." *Id.*

We understand OIG's belief that the existence of a "reasonable connection" to a patient's medical care may depend on a patient's specific circumstances. However, NACDS believes additional guidance can be provided in some circumstances. For example, NACDS urges OIG to confirm that items or services provided by pharmacies pursuant to a prescription, or based on a pharmacist's professional judgment, are by definition reasonably connected to a patient's medical care. In general, the determination of whether the statute's "reasonable connection" requirement has been satisfied should be made with reference to generally accepted professional practice, or as indicated in published medical literature.

OIG also proposes to interpret the "reasonable connection" requirement from a "financial perspective." *Id.* This "financial perspective" standard that does not exist in the statute, and NACDS does not believe it is an appropriate basis for interpreting the "reasonable connection" requirement. Instead, financial perspectives should be considered with respect to making a good faith determination of financial need, which is discussed below.

D. "Good Faith" Determination of "Financial Need"

Paragraph (8)(iv) of the proposed definition of "remuneration" would require a provider to make a good faith determination that an individual is in financial need. OIG states that a good faith determination of financial need should involve an "individualized assessment" of each patient's financial need, which "requires the use of a reasonable set of income guidelines" that vary by "locality." 79 Fed. Reg. 59728.

In light of the fact that pharmacies dispense billions of prescriptions every year, an individualized assessment of financial need for each patient is not practical. Similarly, it is not practical to expect pharmacies to establish income guidelines that vary by locality, and then ask pharmacy personnel to conduct income assessments of each individual patient before assisting them. The cost of conducting individualized needs assessments for millions of patients would easily exceed the value of remuneration provided to qualifying beneficiaries.

In the Medicaid program, CMS has approved State Medicaid plans that require pharmacies to accept as true a patient's statement that the patient is financially unable to pay small drug copayments. See State Medicaid Plans approved by CMS pursuant to 42 C.F.R. § 447.52(e)(2). Because CMS has already determined that patient statements are a legitimate basis for determining financial need, pharmacies should be allowed to accept beneficiaries' statements of financial need as a good faith assessment of financial need.

VII. Waiver Of Medicare Cost-Sharing For "First Fill" Generics - Paragraph (9) of Definition of "Remuneration" in Proposed Section 1003.101

NACDS supports efforts to encourage greater utilization of generic prescription drug products. Generic drug products are equivalent to brand name drug products and satisfy the same stringent quality standards as brand name drug products, but generics offer substantial cost

savings. When pharmacies dispense generics, government healthcare programs and beneficiaries receive high-quality medications at reduced cost.

As discussed throughout our comments above, NACDS supports voluntary pharmacy programs that offer cost-sharing waivers and other cost reductions for beneficiaries. Each pharmacy should be allowed to decide whether it wishes to offer such programs to beneficiaries. An important difference with the CMP exemption for waivers of "first fill" generics, however, is that the decision to waive the copayment for a first fill generic is made by Medicare PDP and MA plans, not by the pharmacies.

As this CMP exemption for Medicare cost-sharing is implemented, OIG should remind PDP Plans and MA plans that pharmacy reimbursement must remain sufficient to provide Medicare beneficiaries adequate access to care. Drug copayments are part of the reimbursement paid to pharmacies for dispensing prescription drugs, so when a plan waives beneficiaries' copayments it reduces the amount of reimbursement received by pharmacies. Pharmacies are understandably concerned that plans may simply waive copayment amounts at no cost to the plan but at potentially great cumulative cost to pharmacies. That could create a financial incentive for pharmacies to *not* dispense generic drugs to Medicare beneficiaries. It is important to ensure that financial incentives for pharmacies remain aligned with the financial incentives for the Medicare program and Medicare beneficiaries to utilize low-cost generic drugs.

Therefore, NACDS asks OIG to caution PDP and MA plans not to reduce pharmacy reimbursement when implementing copayment waiver programs, to ensure that pharmacies continue to dispense low-cost generic drugs whenever possible. NACDS also supports advanced disclosure of any copayment waiver programs in Medicare plan benefit packages, as well as transparent and early disclosure of such programs to pharmacies, in order to allow pharmacies sufficient notice to decide whether (and on what terms) pharmacies may agree to participate in a plan's provider network and copayment waiver program.

VIII. Conclusion

NACDS appreciates the opportunity to offer these comments as OIG implements AKS and CMP exemptions. If properly implemented, these exemptions will help improve patient access to high quality pharmacy care and reduce costs for government programs and beneficiaries. If you have any questions regarding these comments, please feel free to contact NACDS General Counsel Don Bell at (703) 837-4231 or dbell@nacds.org.

Sincerely,

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