NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

August 12, 2020

Mr. Calder Lynch
Deputy Administrator and Director
Centers for Medicare & Medicaid Services
Center for Medicaid and CHIP Services
7500 Security Boulevard
Baltimore, MD 21244

RE: State Definitions Of "Usual and Customary" Pharmacy Charges

Dear Mr. Lynch:

On behalf of the nation's chain pharmacies, the National Association of Chain Drug Stores (NACDS) writes to express our concerns with state definitions of usual and customary (U&C) pharmacy charges that are inconsistent with federal policy and law. To ensure that state definitions of U&C comport with federal standards that promote access to affordable prescription medications, NACDS asks the Centers for Medicare & Medicaid Services (CMS) to issue guidance that states' U&C definitions should not include prices available through third-party discount cards.

I. Background

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly and help patients use medicines correctly and safely while offering innovative services that improve patient health and healthcare affordability.

To help consumers access affordable medication in the absence of adequate insurance coverage, several companies operate – and almost all pharmacies participate in – third-party discount programs that enable customers to obtain better pricing for prescription drugs than the pharmacies' usual retail prices. A number of independent companies, such as GoodRx and Blink Health, market discount cards to consumers, either directly or through employers, community associations, or other groups, such as AARP. These third-party discount cards play a pivotal role in reducing the out-of-pocket costs of healthcare for consumers without insurance, or with limited insurance benefits.

Although consumers pay out of pocket when using third-party discount cards, the price returned to the pharmacy by the third-party discount-card operator during adjudication is not the price that the pharmacy usually charges the general public. The pharmacy only facilitates the lower prices made available by the third-party card operator to customers who present

the card. Indeed, the pharmacy stands operationally and financially in the exact same position as it does with beneficiaries of other third-party payors, such as health insurers and governmental entities. [1]

Certain state Medicaid programs have attempted to include these third-party discount cards in their U&C definitions. For the reasons set forth below, these definitions are inconsistent with federal policy and law.

II. Federal Policy and Law Distinguish Discount-Card Prices from U&C Prices

The federal government has long recognized the high prices of prescription drugs as a significant societal problem, and lowering prescription-drug prices has been a clear and consistent policy of this Administration. As one example of a federal policy seeking to lower drug prices, President Trump signed into law the "Know The Lowest Price Act," making it explicit federal policy that American citizens should have access to lower-cost prescriptions at their pharmacies, whether or not they are using their insurance benefits to obtain prescription drugs. *See* 42 U.S.C. § 1395w–104(m). Likewise, the American Patients First Blueprint[2] states that "One of [President Trump's] greatest priorities is to reduce the price of prescription drugs. . . . Prices **will** come down." (emphasis in original).

Even before the creation of Medicare Part D, CMS encouraged pharmacies to offer discount programs to Medicare beneficiaries. In doing so, CMS distinguished between discounted prices and "usual and customary" prices and ensured that Medicare beneficiaries could receive the lower of the two, without ever suggesting that offering a discount necessarily resulted in a lowering of the "usual and customary" price. *See* 66 Fed. Reg. 37564, 37567 (July 18, 2001); 67 Fed. Reg. 56618, 56636 (Sept. 4, 2002); 68 Fed. Reg. 69840, 69918 (Dec. 15, 2003). After Medicare Part D was adopted, CMS guidance continued to distinguish between pharmacies' discount prices and their "usual and customary" prices. For example, CMS reiterated that if a beneficiary "is using a discount card" and "is able to receive a better cash price . . . he or she may purchase that covered Part D drug without using his or her Part D benefit." *See* Medicare Prescription Drug Benefit Manual, Ch. 14.

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[1] The lower price accepted by many pharmacies when a member presents a third-party discount card for a covered drug, which may be less than the pharmacies' retail price, is negotiated by a third party and is subject to the terms of contractual arrangements with that third party. Such terms may be narrower than those of other third-party payors, excluding things like claw backs, audits, processing fees, third-party adjudication fees, and the like. However, third-party discount cards are much more analogous to third-party insurance cards than to unrepresented cash-paying customers due to the advance negotiated pricing.

[2] https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf (May 2018)(addressing the issue of attempts to prohibit pharmacies from informing Medicare beneficiaries that they can save money by paying cash for their Medicare-covered drugs).

Likewise, the Department of Health and Human Services – Office of Inspector General (OIG) issued enforcement guidance confirming that a provider's "usual" charges do not need to consider "free or substantially reduced charges to (i) uninsured patients or (ii) underinsured patients who are self-paying[.]"[3] OIG re-affirmed this policy after it affirmatively decided to *not* issue a final regulation defining "usual" charges, confirming that "[t]he decision to forgo publishing a final regulation will not change the OIG policy" that providers do not need to include free or substantially reduced charges to uninsured or under-insured patients in their "usual" charges.[4] OIG has also said that: "We have also stated that 'a provider need not even worry about section 1128(b)(6)(A), unless it is discounting close to half of its non-Medicare or non-Medicaid business.'"[5]

Any attempt to include third-party discount cards in state Medicaid U&C definitions is also contrary to the spirit of the 2016 Covered Outpatient Drugs Final Rule (Final Rule), in which CMS outlined its intent for fair and adequate Medicaid reimbursement that covers both the cost of the product and the cost of dispensing. In calculating total reimbursement, the Final Rule does not include reimbursement amounts set by third parties. Including third-party discount cards in Medicaid reimbursement rates would effectively incorporate a most favored nation (MFN) clause into the Medicaid reimbursement methodology, which would require pharmacies to pass on the lowest payment rate they accept from any other payor. The imposition of this kind of reimbursement in Medicaid would have a significant and detrimental effect on pharmacy reimbursement.

Critically, if state Medicaid programs include third-party discount cards in calculations of U&C, pharmacies may be financially unable to continue to accept third-party discount cards. For consumers on tight budgets who rely on third-party discount cards to pay for their medications, the potential loss of access to these discounted medications would be devastating. Elimination of an option that provides lower-priced medication to the underinsured and uninsured would directly contravene the Administration's policy to promote affordable access to prescription drugs. Accordingly, attempts by state Medicaid programs to include in U&C calculations the prices available through third-party discount cards is inconsistent with both federal policy and law.

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[3] Department of Health and Human Services – Office of Inspector General, "Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills" (Feb. 2004), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospitaldiscounts.pdf.

[4] Department of Health and Human Services – Office of Inspector General, "Addendum to 'Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills (02/02/2004)" (June 2007), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2007/revised%20addendum%20to%20uninsured%20gui dance%20_4_%20_2_%20_2_.pdf.

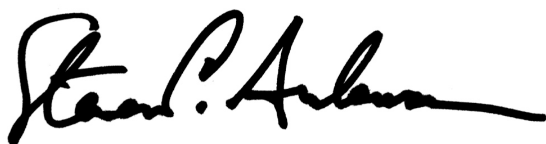
[5] Department of Health and Human Services – Office of Inspector General, Advisory Opinion 15-04 (Mar. 2015).

III. Conclusion

For these reasons, NACDS strongly urges CMS to issue guidance to state Medicaid programs that including third-party discount cards in U&C is inconsistent with federal law and policy.

We appreciate your attention to this matter, and are happy to set up a meeting to discuss.

Sincerely,



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