

**Submitted Via E-mail**

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July 1, 2021

Department of Social Services  
Legal Services Division-Rulemaking  
PO Box 1527  
Jefferson City, MO 65102-1527

**RE: Emergency Rule Adoption, 13 CSR 70-20.070 – Drug Reimbursement Methodology**

To Whom It May Concern:

On behalf of the 907 chain pharmacies operating in the state of Missouri, the National Association of Chain Drug Stores (“NACDS”) is writing to urge the Department of Social Services (“DSS”) to remove the newly added definition of “usual and customary” in part (D) of 13 CSR 70-20.070 (the “Emergency Rule”).

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. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit [nacds.org](http://nacds.org).

As written, it appears that the added definition of usual and customary (“U&C”) fails to consider the impact on pharmacies and the patients they serve and is inconsistent with federal law, including current Centers for Medicare & Medicaid Services (“CMS”) standards. The Emergency Rules newly defines U&C for purposes of reimbursement for covered drugs under the state’s Medicaid program as:

U&C is defined as the provider's charge to the general public that reflects all advertised savings, discounts, special promotions, or other programs including membership-based discounts initiated to reduce prices for product costs available to the general public, a special population, or an inclusive category of customers.

Under federal regulations, payments for drugs must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of (1) actual acquisition cost (AAC) plus a professional dispensing fee established by the agency; or (2) the providers' usual and customary charges to the general public<sup>1</sup> not on rates paid by different payers with different programs. For the reasons stated below, NACDS urges DSS to remove the new definition of “usual and customary” from the Emergency Rule.

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<sup>1</sup> 42 C.F.R. § 447.512

## **I. The Emergency Rule language fails to consider the impact on pharmacies and the patients they serve**

Pharmacies, employers, associations, and other groups offer “savings, discounts, special promotions or other programs” as a way to lower the cost of prescription of drugs, especially for people who are uninsured or underinsured. These programs can help ensure access to medication and promote medication adherence for various communities in need. Thus, as a matter of public policy, promoting the widespread usage of such programs at pharmacies yields immense benefits for public health. Yet, the inclusion of these kinds of savings, discounts, special promotions, or other programs in the definition of U&C may negatively impact a pharmacy’s reimbursement under the Medicaid program. Such inclusion could then force some pharmacies to consider not participating or offering such programs, undermining the positive benefits of the programs for American patients.

Additionally, in the instances where savings, discounts, special promotions or other programs are operated by third-parties (also known as “third-party programs”), a reimbursement schedule with the pharmacy has been contractually negotiated with the program operator. Thus, the inclusion of “savings, discounts, special promotions or other programs” in the U&C assumes that pharmacies control such prices when these programs are provided to patients when that is not the case. To be clear, pharmacies do not control the terms and conditions for, the pricing under, or what persons can participate in a program. Although individuals certainly pay pharmacies the amounts made available by such programs, the price returned to the pharmacy by the third-party operator during adjudication is not the price the provider charges the general public. Stated differently, it is not the pharmacy that is providing a discount in a third-party program transaction. The pharmacy is merely facilitating the savings, discount, or special promotion being made available by a third-party. The pharmacy stands in the exact same position in relation to providing savings, discounts, and special promotions for persons with third-party programs as it does with beneficiaries of other third-party payors, such as health insurers and governmental entities. Because a pharmacy is merely facilitating the third-party program, NACDS has specific concerns that the inclusion of such programs in the U&C may lead some pharmacies to choose to not participate in such programs, which could raise unintended consequences for those patients who benefit from the programs as described above.

## **II. The Emergency Rule language is inconsistent with federal law, including current CMS standards regarding fair and adequate reimbursement**

Federal policymakers have long recognized the high prices of prescription drugs as a significant problem. To combat this issue, CMS has distinguished between savings, discounts, special promotions, or other programs prices from U&C prices to help promote the usage of such programs to help lower patient costs. In fact, before the creation of Medicare Part D, CMS encouraged pharmacies to offer discount programs to Medicare beneficiaries and distinguished between discounted program prices and U&C prices, and ensured the beneficiary could receive the lower of the two prices. This policy continued under Part D, and the federal Health and Human Services Office of Inspector General issued enforcement guidance confirming that a provider’s “usual” charges do not need to consider “free or substantially reduced charges to...patients who are self-paying[.]”<sup>2</sup>

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<sup>2</sup> Office of Inspector General, Hospital Discounts Offered to Patients Who Cannot Afford to Pay Their Hospital Bills, Feb. 2, 2004, available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/fa021904hospitaldiscounts.pdf>.

With respect to Medicaid, we are specifically concerned that the inclusion of savings, discounts, special promotions, or other programs in the U&C price is contrary to the spirit of CMS' 2016 Covered Outpatient Drugs Final Rule (the "Final Rule") wherein CMS has outlined its intent for pharmacies to receive fair and adequate Medicaid reimbursement that covers both the cost of the product and the cost of dispensing. Specifically, in calculating total reimbursement, the Final Rule methodology does not include reimbursement amounts set by other third parties. Any inclusion of third-party programs into Medicaid reimbursement rates effectively incorporates a most favored nation ("MFN") clause into the payment methodology, which would require pharmacies to pass on the lowest payment rate they accept from other payers. NACDS has serious concerns about the imposition of this kind of reimbursement in Medicaid and the impact it would have on pharmacy reimbursement.

Community pharmacies choose to accept various reimbursement rates from different third-party plans because each plan represents a different book of business generally involving different overall contributions to total business, different costs of doing business, clientele, program rules, and administrative requirements. However, community pharmacies strongly oppose MFN reimbursement methodologies because the Medicaid program's use of an MFN approach to ingredient cost reimbursement could result in pharmacies being reimbursed less than the cost of acquiring and dispensing prescription medications. This sort of reimbursement appears contradictory to the intent of the Final Rule to ensure fair and adequate pharmacy reimbursement.

While MFN rates may have been appropriate for setting reimbursement rates for other reimbursement methodologies, its use in cost-based reimbursement structures is inappropriate and poses a significant financial burden on participating pharmacies. Therefore, to remain compliant with the Final Rule, NACDS urges DSS not to use MFN rates to set Medicaid reimbursement rates.

### **III. The Emergency Rule language requires DSS to comply with current CMS standards regarding material changes to state Medicaid plans**

It is well-established that states must obtain federal approval for an "amendment of a Medicaid state plan for any '[m]aterial changes in State law, organization, or policy, or in the States operation of the Medicaid program . . . [s]o that CMS can determine whether the plan continues to meet the requirements for approval[.]'."<sup>3</sup>

NACDS highlights this requirement because the definition in the Emergency Rule may be a material change to the state's policy regarding its definition of U&C as compared to the definition provided in the state's Medicaid plan. We urge the DSS to determine whether the Emergency Rule complies with 42 C.F.R. § 430.12(c) pending enforcement of the new definition and also determine whether the Emergency Rule is in compliance with the currently approved definition of U&C as reflected in the most recent approved state plan amendment related to reimbursement for covered outpatient drugs.<sup>4</sup> Such a material change would be disruptive to and challenging for DSS, but also the Missouri pharmacies serving the state's Medicaid beneficiaries and possibly the beneficiaries themselves. Consequently, if DSS decides to proceed with this improper and questionable Emergency Rule, it should only do so after it has submitted and had approved a SPA.

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<sup>3</sup> See 42 C.F.R. § 430.12(c).

<sup>4</sup> See CMS, State Plan Amendments, Missouri, available at <https://www.medicaid.gov/medicaid/spa/downloads/MO-18-0020.pdf> Missouri State Plan Amendment 18-0020; Approved by CMS 01/19/2021; Section 4.19B; Page 3a.

## **CONCLUSION**

Discount healthcare programs can provide value to consumers who do not have health insurance by helping to reduce the out-of-pocket cost of health care. However, NACDS remains concerned that if DSS continues to include savings, discounts, special promotions or other programs in the definition of U&C, the inclusion could discourage affected pharmacies from continuing to participate in or offer such programs.

Furthermore, retail pharmacies are committed to preserving Medicaid beneficiaries' access to their needed medications and the ability of our members to provide services to this important population. NACDS supports retail community pharmacies receiving fair and adequate reimbursement that is based on the cost of acquiring and dispensing prescription drugs in the Medicaid program. In order to do this and based on the concerns outlined above, we strongly urge DSS to reconsider the adoption of this Emergency Rule and to comply with standards of pharmacy reimbursement based on "usual and customary charges to the general public" as required under federal regulations and the currently approved state plan.

Thank you for the opportunity to share our concerns. Should you have any questions, please reach out to NACDS' Christie Boutte, Senior Vice President of Reimbursement, Innovation and Advocacy at [CBoutte@NACDS.org](mailto:CBoutte@NACDS.org) or 703-837-4211.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Steven C. Anderson, FASAE, CAE, IOM  
President & Chief Executive Officer