



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

VIA Electronic Submission at: <http://www.regulations.gov>

January 12, 2018

Seema Verma
Administrator of the Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013.

Re: Proposed Rule for Contract Year 2019, Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P).

Dear Administrator Verma:

The National Association of Chain Drugs Stores (NACDS) appreciates the opportunity to submit the following comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule for Contract Year 2019, Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P).

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' more than 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3 million individuals, including 152,000 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 20 countries. Please visit nacds.org.

NACDS offers comments on the following proposals and looks forward to working with CMS on these important policy changes.

Medicare Part D Lock-in Program

Definition of Pharmacy

NACDS shares the goals of policymakers to curb the incidence of abuse and diversion, and believes that any potential programs aimed at "locking in" a beneficiary to a certain pharmacy or pharmacies must ensure that legitimate beneficiary access to needed

medications is not impeded. Policies to reduce overutilization must maintain access to prescription medications by the beneficiaries who need them most. Because of this, NACDS strongly supports the CMS proposal “that where a pharmacy has multiple locations that share real-time electronic data, all locations of the pharmacy collectively be treated as one pharmacy under the clinical guidelines.”

Defining a “pharmacy” in this manner does not require a beneficiary to use such a pharmacy, but would provide them with the option if doing so would best meet their healthcare needs. The ability to utilize multiple store locations also protects access by allowing a beneficiary to obtain needed medication when they cannot use their usual pharmacy location due to situations such as an emergency or extended travel or when their usual pharmacy location is unable to supply the medication. The proposed definition of “pharmacy” will help ensure legitimate beneficiary access to needed prescriptions without compromising the integrity of the program and its goal to combat abuse and diversion.

Clinical Guidelines for Identifying At-Risk Beneficiaries

NACDS supports CMS in their effort to apply new policy to minimize the effects of the opioid crisis, and we ask CMS to continue working with standards development organizations, such as NCPDP, to standardize a methodology for exchanging clinical information between healthcare partners (e.g., prescribers, pharmacies, plans) to ensure beneficiaries have appropriate and timely access to medications.

Point of Sale Edits

In addition to the lock-in program, CMS is proposing that plan sponsors also have the option to enact a beneficiary-specific point-of-sale claim edit. NACDS requests clarification as to whether the beneficiary Notice of Appeal Rights (reject 569) should accompany any point-of-sale claim rejection regarding prescriber or pharmacy lock-in, or any additional beneficiary-specific point-of-sale edits recommended by CMS.

We ask that CMS be mindful of any changes that may require modifications to the NCPDP standards such as the proposed point-of-sale claim edits. Standards modifications timelines are controlled both by NCPDP *Standing Operating Procedures* and, for those standards named in other federal legislation (e.g., HIPAA), the associated rule-making process. These timelines need to be taken into consideration during rulemaking.

Request for Information Regarding the Application of Pharmacy Price Concessions to Drug Prices at the Point of Sale

NACDS appreciates the efforts of HHS in investigating ways to keep healthcare affordable for beneficiaries while at the same time maintaining access and health. The increasing use of fees in the Part D program has been a growing burden for retail pharmacies. Retail pharmacies must conduct business in an environment where they are

unsure if a reimbursement they received is the final reimbursement or if a fee will be applied to them at some future point. The unpredictable variability in the use of fees provides little visibility to retail pharmacy, particularly for performance-based fees and the goals necessary to achieve specified targets to “earn back” fee amounts. We believe restructuring pharmacy price concessions could lower out-of-pockets costs for beneficiaries and make medicine more accessible, leading to greater adherence and better health outcomes.

We agree with CMS that there is a need for greater transparency among Part D plans and pharmacies in the use of DIR fees, post-adjudication fees, and quality and performance-based network fees by prescription drug plans in the Medicare program. One way we believe this could be accomplished is to require the inclusion of all potential pharmacy price concessions in the point-of-sale negotiated price. However, NACDS requests clarification from CMS as to whether it would expect the negotiated price, including all pharmacy price concessions, to be used for determining pharmacy reimbursement for prescription drugs at point of sale, or if CMS would expect such a negotiated price to be used solely for determining beneficiary payment at the point-of-sale.

While we support the inclusion of all potential pharmacy price concessions in the negotiated price, under this scenario we would urge CMS to consider that the negotiated price be used solely for determining beneficiary payment at the point of sale and not for determining pharmacy reimbursement at point-of-sale. We also believe performance-based payments should not be incorporated into the negotiated price. In addition, we ask CMS to clarify that the negotiated price would still be determined on a contractual basis and not be the same negotiated price among all pharmacies within a network.

NACDS agrees with the general concept of using the “lowest possible reimbursement” at the point-of-sale for ensuring reduced cost-sharing amounts for beneficiaries, and believe that this would provide retail pharmacies with greater transparency into the total concessions to be provided during the plan year. Moreover, we urge CMS to couple this with a meaningful and consistent pharmacy-specific performance-based incentive program that would be calculated separate and apart from the negotiated price to ensure such incentives do not increase costs for beneficiaries. A pharmacy-specific program can be accomplished by requiring plans to determine performance-based payments on achievable and proven criteria that actually measure pharmacy performance, such as the medication related measures used in the STAR Ratings program, as opposed to criteria that focus on measuring plan performance and for which pharmacies may have little to no opportunity to influence.

We believe that CMS should also ensure that the pharmacy-specific measures are standardized across and among plans. Currently, many plans have “performance programs” based on measures designated by the plans themselves. This leads to each retail pharmacy being subject to a varying number of potentially inconsistent and confusing performance measures.

We further believe CMS should place a cap on performance-based fees on a per script basis, limiting the amount of performance fees that can be collected related to a specific drug. Such a cap would facilitate greater transparency and predictability for pharmacies with fee amounts and ultimately reimbursement. Patients would benefit because cost variability would be minimized from drug to drug, as only a limited amount of fees could be subject to performance and outside of the negotiated price. A cap would also minimize the occurrence of DIR fees exceeding projected DIR in plan bids.

CMS should also explore ways to ensure any potential actions to modify pharmacy price concessions do not result in increased government or beneficiary spending at the expense of decreases in manufacturer spending.

In addition to requiring the lowest possible price at the point-of-sale, NACDS recommends CMS also issue guidance that would create even greater transparency and consistency in the use of fees and incentives. Such guidance should address the need for:

- consistency in terminology applied to pharmacy reimbursement in the Medicare program for Part D plans and downstream entities, and
- consistency in disclosures to pharmacies, including:
 - how fees and incentives are defined,
 - how fees and incentives are calculated,
 - the timing for fee collection and incentive payments, and
 - how fees and incentives will be reported to pharmacies at the claim level, thus allowing reconciliation of reimbursement.

Increased transparency in the Medicare program will benefit HHS, participating pharmacies, and beneficiaries alike.

Pharmacy Networks

CMS is clarifying that although Part D sponsors may continue to tailor their standard terms and conditions to various types of pharmacies, Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network based on not fitting in the correct pharmacy type classification. NACDS appreciates the clarification from CMS on this issue and agrees that “where there are barriers to a pharmacy’s ability to participate in the network at all, it raises the question of whether the standard (that is, entry-level) terms and conditions are reasonable and relevant.”

Timing of Contracting Requirements

In the proposed rule, CMS states it has received complaints over the years from pharmacies that have sought to participate in a Part D plan sponsor’s contracted network but have been told by the Part D plan sponsor that its standard terms are not available

until the sponsor has completed all other network contracting.

NACDS agrees with CMS that changes should be made to establish deadlines by which Part D plan sponsors must furnish their standard terms and conditions to requesting pharmacies. However, NACDS requests CMS revise the proposed date by which Part D plans must have the standard terms and conditions available. We believe greater transparency and improved communication between Part D plans and community pharmacies can be achieved by revising the proposed date to September 1 of each year for the succeeding benefit year. This will give all parties sufficient time to adequately review the terms and conditions, leading to a more transparent and efficient contracting process.

In addition to improving the timing of contract requirements, NACDS urges CMS to require Part D plans to provide advance notice regarding changes in plan design, as well as the status of the pharmacy in terms of whether it has been selected to participate in a standard, preferred, or limited network. Pharmacies report not finding out about the existence of a preferred or limited network, and the pharmacy's resulting exclusion, until after the fact. Because of this, the pharmacy has no ability to work with beneficiaries to inform them of upcoming changes in their plan structure and their ability to continue filling prescriptions at the pharmacy.

Our members report being in very good relationships with plan sponsors and being in negotiations towards completion of a contract, but they never hear anything from the plan until they are told just before enrollment they are not included in the network, long after the decision had been made. Such tactics and poor communication impact all involved with the Part D program. CMS should take steps to improve and ensure transparency throughout the contracting and enrollment process.

Retail Pharmacy and Mail Order Pharmacy Definitions

NACDS agrees generally with the CMS proposal to revise the definition of retail pharmacy, however, we believe the proposed definition should be revised in a manner that ensures retail pharmacies are not prevented from being able to mail prescriptions to their patients. Similarly, we believe the proposed definition of mail-order pharmacy should be revised to ensure it doesn't inadvertently include retail pharmacies. Without these changes, the unintended consequences of the proposed definitions may be to limit patient access and, ultimately, adversely affect patient health. NACDS suggests CMS revise the definitions to clarify that pharmacies will be defined by the primary function they serve. We offer the following revision:

- ***Retail pharmacy** means any licensed pharmacy that primarily dispenses prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.*

- *Mail-order pharmacy means a licensed pharmacy that **primarily** dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.*

We believe the suggested changes will help prevent the inappropriate defining of retail and mail-order pharmacies that could impact patient care.

Specialty Pharmacy

While we acknowledge that CMS is proposing not to define specialty pharmacy at this moment, NACDS recommends that CMS, when it does begin to explore a specialty pharmacy definition, consider a specialty pharmacy as one that is a state licensed pharmacy that dispenses specialty prescriptions for people with serious health conditions requiring complex therapies.

In addition to being state licensed and regulated, CMS should consider and recognize the role specialty pharmacies play in facilitating education and coordination with prescribers and payers, implementing clinical review and drug utilization protocols, providing patient care services and comprehensive patient management programs, and offering support programs for patients facing reimbursement challenges.

Pharmacy Accreditation

NACDS appreciates clarification from CMS that it does not support the use of Part D plan sponsor or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations, apart from drug-specific limited dispensing criteria such as FDA-mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy. The accreditation process is costly and time consuming. The current policy that leads to the need for multiple accreditations only adds more costs and burdens on the pharmacy and into the healthcare system without providing any real additional benefit or security.

NACDS also agrees with CMS that Part D plan sponsors should not limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, REMS processes) or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so.

NCPDP SCRIPT

NACDS strongly supports the proposal to adopt NCPDP SCRIPT Standard Version 2017071. The use of technology to electronically transmit prescription information between prescribers and pharmacists benefits both patients and health care providers. Use of e-prescribing technology increases operational efficiencies and enhances the level of accuracy of prescriptions that are transmitted in this manner. Through e-prescribing practices, pharmacies have worked to improve the quality of patient care and to deliver efficient and cost-effective care to patients. E-prescribing can also be a powerful tool in combatting prescription drug abuse as the electronic transmission of prescriptions for controlled substances helps reduce the incidence of drug diversion.

Notwithstanding our support for CMS's proposal, we believe the proposed effective date of January 1, 2019 is too aggressive for both pharmacies and software vendors. A fewer than twelve-month implementation timeframe does not afford enough time to adequately assess, plan, develop, program, certify, test, and deploy the new system. We are concerned that such an aggressive effective date could potentially delay a patient's ability to receive their prescriptions in a timely manner, thus ultimately impacting patient care.

NACDS supports the comments of NCPDP in requesting that a transition period be added to the implementation timeline. The implementation should include a voluntary use date to be the effective date of the Final Rule and the sunset date for SCRIPT Version 10.6 should be 24 months later. Having the transition period would decrease the risk of healthcare delivery delays and interruption. The transition from SCRIPT Version 8.1 to SCRIPT Version 10.6 took approximately three years and provided an opportunity for early adopters to identify any possible issues with documentation or the standard itself. Additionally, as NCPDP notes, there are many actions that must happen prior to the mandated use of SCRIPT Version 2017071, including design, development, testing by vendors which include prescribing/EHR vendors, pharmacy software vendors, prescribers, pharmacies, payers, and intermediaries who route transactions. Also required will be release and end user testing, software certification, EPCS auditing, and training.

Finally, we urge that the regulatory compliance date for the NCPDP SCRIPT Standard Version 2017071 not fall on the first of January as it would compound the risk of healthcare delivery delays and interruption associated with the processing and administrative changes occurring with the new plan year.

Medication Therapy Management in Medical Loss Ratio

NACDS supports policies that encourage greater utilization of medication therapy management (MTM) services. NACDS has previously urged that CMS should clarify that all MTM activities, including efforts to expand such activities beyond the regulatory minimum, are a ‘quality improving activity’ (QIA) for the purpose of calculating the Medical Loss Ratio (MLR) and bidding for Part D plans. NACDS believes that lack of clarity in this area has been a contributing factor to the lack of expansion and innovation by Part D plans.

Therefore, we support the proposal to revise the MLR requirements to clarify that Part D MTM programs will be counted as QIA and agree that allowing Part D sponsors to include compliant MTM programs as QIA in the calculation of the Medicare MLR would encourage sponsors to ensure that MTM is better utilized, particularly among standalone PDPs that may currently lack strong incentives to promote MTM.

Rescinding Prescriber Enrollment Requirements and Use of Preclusion List

NACDS supports CMS’ proposal to rescind the enrollment requirements for physician and eligible professionals for Part D or Medicare Advantage prescription coverage. Basing prescription coverage on Medicare enrollment only added duplicative, burdensome requirements on physicians and providers leading to more waste and cost in the system.

NACDS supports the replacement proposal that states a Part D plan sponsor, or Medicare Advantage plan must reject, or must require its pharmacy benefit manager to reject, a pharmacy claim for a Part D drug, or an item or service furnished to a Medicare Advantage enrollee, if the provider is included on the “preclusion list.”

In implementing this proposal, CMS must ensure that the preclusion list is updated frequently and on a regular basis to minimize the lag time between when a provider is excluded to the time that information is available to health plans and other providers such as pharmacies. The greater the lag time between exclusion and disclosure, the greater the potential of unknowingly filling a prescription written by an excluded provider.

CMS must also ensure the preclusion list contains the vital information needed to properly identify a precluded prescriber, such as National Provider Identifier (NPI) and the current practice address of the provider. Lack of a current address increases the difficulty in finding an excluded provider, especially when a provider has a common name which yields many search results.

NACDS requests CMS to consider the comments and recommendation outlined in the detailed NCPDP comments that support the need for an effective date that is no earlier than Jan. 1, 2020 and a minimum of 18 months after CMS publishes the necessary technical guidance and confirmed file layouts.

Reducing the Burden of the Compliance Program Training Requirements

NACDS supports CMS' proposal not to require first-tier, downstream, and related entities (FDRs) to complete compliance training requirements. The retail pharmacy community has long supported efforts aimed at curbing fraud, waste, and abuse. However, the current requirements for compliance training have been inefficient and unnecessarily burdensome.

NACDS asks CMS to clarify that if a plan sponsor does choose to require a FDR, such as a retail pharmacy, to complete compliance training, that the plan sponsor accept FDR-developed training programs as meeting any such requirements. In the alternative, we ask that CMS maintain the CMS-developed training as an acceptable form of training, for cases where plans choose to require FDR compliance training. Without such assurances, the proposed changes could inadvertently lead to FDRs being subject to multiple training programs, as has been a concern in the past.

CMS acknowledged this concern in the 2014 Part D Final Rule,¹ which established the CMS training module as the only acceptable training program. In the final rule, CMS stated "we were concerned that these FDRs would potentially have to participate in (largely duplicative) training for each organization with whom they contract." CMS also stated, "if we continue to allow sponsors to modify or utilize their own training in lieu of using the CMS Compliance Training, it will no longer ensure the elimination of the prior duplication of effort that so many FDRs stated was creating a huge burden on their operation." Clarification on this point by CMS will help prevent those concerns from becoming an issue once again.

Prescriber NPI Validation on Part D Claims

CMS is proposing that a Part D plan sponsor must reject, or must require its pharmacy benefit manager (PBM) to reject, a pharmacy claim for a Part D drug unless the claim contains the active and valid National Provider Identifier (NPI) of the prescriber who prescribed the drug. NACDS requests CMS to confirm that with the revisions to section 423.120 (c)(5) and based on section 507 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the 24-hour follow-up for the plan sponsor to work with the pharmacy to identify the prescriber NPI and resubmit the claim is no longer applicable.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

NACDS supports the CMS proposal to permit Part D sponsors to immediately remove or change the preferred or tiered cost sharing of brand name drugs and substitute or add therapeutically equivalent generic drugs. Under current policy, delaying substitution of a generic medication not only reduces access to lower cost medications for beneficiaries

¹ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/CMS-4159.pdf>

but also increases costs to retail pharmacies through increased inventory carrying costs for brand name drugs.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom O'Donnell". The signature is fluid and cursive, with a prominent loop at the end.

Tom O'Donnell
Senior Vice President
Government Affairs and Public Policy