NCPA summary of Part D Final Rule for contract year 2019

The Centers for Medicare and Medicaid Services ("CMS") recently issued its final rule (the "Final Rule") to revise the Medicare Advantage and Part D prescription drug benefit programs. In the Final Rule, CMS finalizes certain proposals that are important to community pharmacy, while leaving other issues, including a proposal on pharmacy DIR fees, for future rulemaking. The Final Rule also provides some insightful CMS commentary of their continued thinking on issues including any willing pharmacy and mail-order pharmacy. This document will analyze the relevant issues important to independent pharmacists.

NCPA advocacy at work

CMS asserts its authority to set pharmacy DIR at point of sale in future rulemaking. Although CMS did not make any final decisions related to pharmacy DIR fees, the agency states that rulemaking on this issue is likely to occur in the future. CMS' recognition of the need to address the issue at all is largely the result of NCPA's forceful lobbying efforts and input.

CMS clarifies that standard terms and conditions must be offered to "any willing pharmacy" for participation in Part D standard networks. CMS cites NCPA's efforts to bolster its clarification, stating that maintaining access to small businesses in rural areas may help maintain beneficiary access to specialty drugs from community pharmacies.

CMS emphasizes that Part D plan sponsors cannot use additional accreditation standards to limit pharmacies in a network under certain circumstances. NCPA highlighted in its comments to CMS that PBMs utilize additional accreditation standards to keep independent pharmacies out of their networks.

CMS finalizes the CARA drug management program that includes a prescriber/pharmacy "lock-in." NCPA agrees with CMS' decision to ensure plan sponsors consider beneficiary preference. NCPA urges CMS to remain vigilant in ensuring appropriate patient access in drug management programs.

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Provisions resolved in the Final Rule

The Final Rule clarifies that standard terms and conditions must be offered to "any willing pharmacy" in standard networks

NCPA recommended in its comments to CMS that CMS further clarify the "any willing pharmacy" provision in the Part D program. In response, CMS clarifies in its Final Rule that a Part D plan sponsor is required to contract with any pharmacy that meet's the sponsor's standard terms and conditions for network participation. CMS emphasizes that "the any willing pharmacy requirement is statutory, and CMS does not have the discretion to abandon it."[1] CMS further states that it will specify "reasonable and relevant" standard terms and conditions if it finds that these current requirements fall short of implementing the any willing pharmacy requirement.

CMS acknowledges that many pharmacies perform multiple pharmacy practice functions, such as compounding and specialty pharmacies. Therefore, although Part D plan sponsors may continue to tailor their standard terms and conditions for various types of pharmacies, the Final Rule indicates that Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network simply based on not fitting in a Part D plan sponsor's pharmacy type classification. Part D plan sponsors may not exclude these pharmacies from Part D retail networks.

Further, the Final Rule indicates that it is not intending to restrict Part D plan sponsors' ability to maintain preferred pharmacy networks. Part D plan sponsors can continue to create preferred networks while complying with the any willing pharmacy requirement, which applies to standard terms and conditions. Therefore, plans can still form preferred networks and not offer the preferred terms and conditions to community pharmacies. CMS cites NCPA to further bolster its clarification of the law by stating, "we believe this proposal may support small businesses in rural areas and may help maintain beneficiary access to specialty drugs from community pharmacies."[2] This emphasis protects pharmacies' participation in contracted pharmacy networks with Part D pan sponsors.

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[1] *Medicare Program; 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*, released Apr. 2, 2018, *available at* https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/CY2019-Medicare-Advantage-Part-D-Final-Rule.pdf.

[2] Id. at 976.

The Final Rule finalizes the requirement that requesting pharmacies may receive timely access to standard terms and conditions

CMS finalizes the requirement that Part D plan sponsors develop standard terms and conditions and have them ready for distribution for requesting pharmacies by September 15th for the succeeding benefit year. It is important to note this timely access standard only applies to requesting pharmacies. Part D plans must provide the applicable standard terms and conditions to a requesting pharmacy within seven business days of the receipt of the request. In this requirement, CMS states that, "it is incumbent upon the pharmacy to request terms and conditions that are applicable to the business model(s) and types of services the pharmacy provides so that the terms and conditions offered are reasonable and relevant."[3]

The Final Rule confirms its changes to the days' supply required by the Part D transition process

CMS finalizes its proposal to change the 91 to 98-day supply of nonformulary drugs for patients transitioning from another health plan to a 30-day supply. NCPA had requested CMS reconsider this change and retain the current requirement or at a minimum allow for a two-month supply for LTC transitions. CMS did not accept this request because CMS believes that a month's supply is adequate. In response to industry comments regarding beneficiaries in LTC facilities, CMS states that it does not believe that beneficiaries would require transition supplies for all the drugs they are taking. The Final Rule further states that LTC facilities could be relying on the 90-day supplies rather than transitioning Part D beneficiaries to new plans sooner, which could lead to increased program expenditures.

The Final Rule adopts new e-prescribing standards

CMS adopts NCPDP SCRIPT Standard Version 2017071 and retires the current NCPDP SCRIPT Version 10.6 as the official electronic prescribing standard for transmitting prescriptions and prescription-related information for covered part D drugs and Part D eligible individuals. The effective date for this transition is January 1, 2020, although NCPA asked for an effective date of twenty-four months after the Final Rule. CMS stated a phased-in transition is not possible because the new version is not backwards compatible to the current version.

[3] Id. at 527.

Additionally, NCPA asked that CMS include NCPDP SCRIPT Standard Version 2017071 for prior authorization transactions to replace the current HIPAA named standard. CMS indicates that the HIPAA standard transaction for prior authorization does not accept the NCPDP SCRIPT ePA, and that the HIPAA standard would need to be altered to allow this use. CMS emphasizes that such HIPAA changes are not under CMS' regulatory authority and would have to be effectuated in a regulation via the Department of Health and Human Services.

The Final Rule confirms the preclusion list for prescribers

The Final Rule states that for a prescription drug to be eligible for coverage, the prescriber must have: 1) an approved enrollment record in the Medicare fee for service program; or 2) a valid opt out affidavit on file with a Part A/Part B Administrative Contractor. CMS states that its intention is to ensure that only qualified prescribers can prescribe Part D drugs. The prescriber and provider enrollment requirement for Part C and D is replaced with a "preclusion list." This includes prescribers, individuals, and entities that fall within any of the following categories:

a) Are currently revoked from Medicare, are under an active reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or
b) Have engaged in behavior for which CMS could have revoked the prescriber, individual, or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

CMS will make the preclusion list available to Part D and Medicare Advantage plans. Under this provision, plans are required to deny payment for claims submitted by or associated with prescriptions written by individuals on this list. This means Part D plan sponsors must reject a pharmacy claim for a Part D drug prescribed by an individual on the preclusion list.

Further, CMS affirms that the timeline for changes to the Medicare prescriber enrollment process is January 1, 2019.

The Final Rule finalizes the definition of frequently abused drug to include opioids and benzodiazepines for drug management programs under CARA

Congress passed the Comprehensive Addiction and Recovery Act (CARA) in 2016, which, among other requirements, directs CMS to implement through regulation several policies to combat overutilization of opioids and other frequently abused drugs in the Medicare space.

Specifically, CARA requires plan sponsors to create drug management programs for Part D beneficiaries that are considered at-risk for frequently abused drugs. These drug management programs may include allowing plans to lock patients into one or more prescriber(s) and one or more pharmacy(ies) to receive their frequently abused drugs. CARA also allows CMS to define what constitutes a frequently abused drug and who is an at-risk patient for drug overutilization as well as set certain limitations on the amount of frequently abused drugs that are dispensed at the pharmacy counter.

CMS decided to include opioids and benzodiazepines in the definition of frequently abused drugs. CMS made this decision largely on CDC Guidelines recommendation and some CMS studies that found the inclusion of benzodiazepines persuasive.[4] Further, the Final Rule excludes buprenorphine for medication-assisted ("MAT") treatment from the definition of frequently abused drugs so that access to MAT, such as buprenorphine, is not impacted.

The Final Rule exempts hospice, cancer, and LTC patients from drug management programs, including lock-ins

In NCPA's comments to CMS, NCPA supported CMS' proposal to exempt hospice, cancer, and long-term care ("LTC") patients from drug management programs. NCPA also supported exempting residents of any facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy.

In the Final Rule, CMS adopts these exemptions with a few changes. CMS tailors its cancer exemption to require plan sponsors to identify such exempted beneficiaries through the case management process.[5] Hospice and LTC patients are also exempt, but CMS notes that this does not exempt LTC patients from retrospective DUR processes.[6]

Further, CMS acknowledges and clarifies that beneficiaries serviced by LTC pharmacies may meet another exemption, such as the one for beneficiaries residing in facilities which frequently abused drugs are dispensed for residents through a contract with a single pharmacy.[7]

[4] Id. at 23.
[5] Id. at 47.
[6] Id. at 48.
[7] Id. at 49.

However, CMS did point out that beneficiaries in assisted living facilities are not exempt from part D drug management programs because CMS does not think that these facilities routinely dispense drugs to their residents through a contract with a single pharmacy.[8] Thus, patients in assisted living facilities are not exempt from drug management programs.

The Final Rule finalizes that the Secretary must approve beneficiary notices for lock-ins

CMS states that plan sponsors may use a beneficiary specific point-of-sale edit, or prescriber or pharmacy lock-in, or any combination of these three tools to limit an at-risk beneficiary's access to coverage of frequently abused drugs under its drug maintenance program.[9] Plans are not required to do a lock-in in their plan. If a plan chooses to implement a lock-in, beneficiaries, however, must be given two notices before a beneficiary can be locked in to a prescriber or pharmacy. Notices for beneficiaries are subject to approval by the Office of Management and Budget. Further, the notices will be posted on the Federal Register to give stakeholders an opportunity to review and comment before final versions of the notices are posted.[10] NCPA supports Secretary approval of notices and will closely monitor the Federal Register to comment on published notices at a future date. Specifically, NCPA will advocate that the notices make clear that any lock-in program applies only to frequently abused drugs.

Finally, the Final Rule notes that beneficiaries who change plans should have an opportunity to change their preferences for pharmacies and beneficiaries also have the right to submit new preferences when they switch plans. NCPA is supportive of this requirement in the Final Rule.

The Final Rule states that prescriber agreements are no longer necessary for pharmacy lock-ins

CMS originally proposed a requirement for prescriber agreement to any lock-in. However, in the final rule, CMS stated that prescriber agreements for a pharmacy lock-in are not essential because "pharmacy lock-in is primarily about where the drugs are dispensed and not who wrote the prescription or its dosage."[11] CMS highlights, however, that prescribers should still proactively alert plan sponsors if lock-ins are not appropriate.

[8] Id. at 50.
[9] Id. at 67.
[10] Id. at 79.
[11] Id. at 70.

The Final Rule deletes the six-month waiting period for a plan to place at at-risk patient in a prescriber lock-in

CMS deletes the six-month waiting period they had proposed before a plan may limit an at-risk beneficiary to a prescriber for frequently abused drugs.[12] There will now be no wait period following a lock-in in which a patient can be locked into one pharmacy, subject to certain notification requirements. A plan may choose to implement a pharmacy lock-in and not a prescriber lock-in. CMS makes clear, however, that the elimination of the need for a prescriber agreement to a pharmacy lock-in does not eliminate the requirement for plans to comply with other lock-in requirements found under the law.

The Final Rule requires beneficiary preference to prevail for in-network pharmacies only, subject to certain requirements. The Final Rule also clarifies that chain pharmacies would be considered one pharmacy for lock-in purposes

CMS clarifies that beneficiary preference prevails over sponsor/PBM choice.[13] NCPA advocated for this clarification in its comments to the proposed rule. The Final Rule also states that there is no limit to the amount of times beneficiaries can submit their preferences to a sponsor/PBM. However, CMS states it was unpersuaded that sponsors should have to accept a beneficiary's selection of an out of network pharmacy, unless needed to maintain reasonable access or if the plan does not have a relevant network.[14]

CMS also comments that if the beneficiary's selection would contribute to prescription drug abuse or drug diversion by the beneficiary, CMS would question why such pharmacy or prescriber is in the sponsor's network. Further, CMS reiterates that the sponsor may have to permit a beneficiary to obtain frequently abused drugs from more than one pharmacy and/or more than one prescriber to provide reasonable access. Finally, CMS is not persuaded by commenters' arguments that there is a conflict of interest for a lock-in of a beneficiary in a PBM's network at a PBM-owned pharmacy.[15]

[12] Id. at 108.
[13] Id. at 113.
[14] Id. at 111.
[15] Id. at 144.

Provisions not finalized at this time

The Final Rule indicates future rulemaking regarding the application of manufacturer rebates and pharmacy price concessions to drug prices at the point of sale

CMS asserted that it has the statutory authority to require some portion of rebates and all retroactive pharmacy fees to be applied at point of sale. CMS did not move forward with these requirements, but instead stated "any new requirements regarding the application of rebates at the point of sale would be proposed through notice and comment rule-making in the future."[16] CMS' recognition of the need to address the issue is a positive response to NCPA's forceful lobbying and input.

The Final Rule does not provide a definition of "mail-order pharmacy"

In CMS' proposed rule, NCPA expressed its support for CMS to provide a definition of a "mail-order pharmacy." CMS originally clarified that pharmacies mailing to their patients in "snowbird" like situations were not pharmacies acting as mail-order pharmacies. The proposed definition would require mail order to be delivered via common carrier at mail-order cost sharing. CMS states in the Final Rule that the proposed definition of mail-order pharmacy was to clarify Part D enrollee cost-sharing expectations and differentiate national mail-order pharmacies that contract with Part D plan sponsors to provide the Part D sponsor's mail-order benefits from pharmacies that otherwise deliver some or all of their business through mail service without providing the Part D plan sponsor's' mail-order benefits. CMS states, "we recognize that our proposed definitions of retail and mail-order pharmacy could be narrower."[17]

However, CMS did not finalize its proposed definition of mail-order pharmacy in the Final Rule because its "proposed definition of mail-order pharmacy was fundamentally unlike [CMS'] other pharmacy type definitions which are necessary to establish access standards." Thus, there is no CMS definition of mail-order pharmacy. CMS clarifies that it "will rely on Part D plan sponsors to make sure their Part D enrollees understand which pharmacies are contracted to provide their mail-order benefit and to ensure they have reasonable and relevant terms and conditions for all pharmacies that deliver by mail that take into consideration the difference between traditional mail-order pharmacy that services the entire country from those that operate in more targeted geographic areas."[18]

[16] Id. at 619.
[17] Id. at 535.
[18] Id. at 543.

Although NCPA would have preferred the proposed mail-order definition be finalized, NCPA is pleased with CMS' recognition of different scenarios that do not constitute being a mail-order pharmacy.

CMS also proposed to refine its definition of retail pharmacy to include key concepts of being open to the public and subject to retail cost-sharing. CMS states that the clarification was for the purposes of establishing which pharmacies in a Part D plan sponsor's contracted pharmacy network can count toward Part D convenient access standards. The current definition of "retail pharmacy" is "any licensed pharmacy that is not a mail-order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy."[19] The proposed definition was "any licensed pharmacy that is open to dispense 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."[20] In the Final Rule, CMS removes the concept of retail cost sharing from its definition of retail pharmacy. The new definition of retail pharmacy now reads:

> *Retail pharmacy means any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.*

[19] Id. at 531.
[20] Id. at 532.