NCPA Member Summary of CMS COVID-19 Guidance to Medicare Advantage and Part D Plans

A guidance document dated April 21, 2020 from CMS to Medicare Advantage Organizations (MAOs), Part D Sponsors, and Medicare-Medicaid Plans updates previously released information dated March 10, 2020 and includes several relevant provisions for community and long-term care (LTC) pharmacies.

NCPA advocacy at work for you

<table>
<thead>
<tr>
<th>NCPA successfully advocated that CMS temporarily waive Part D medication delivery documentation and signature log requirements during the public health emergency.</th>
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<td>NCPA successfully advocated that CMS adopt a temporary policy suspending plan-coordinated pharmacy audits.</td>
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<td>NCPA successfully advocated for community and LTC pharmacies regarding relaxing prior authorization, point-of-sale edits, and short-cycle dispensing requirements.</td>
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On March 10th, CMS issued guidance outlining the flexibilities Medicare Advantage and Part D plans have to waive the following requirements to help combat the disease:

- Waiving cost-sharing for COVID-19 tests;
- Waiving cost-sharing for COVID-19 treatments in doctor’s offices or emergency rooms and services delivered via telehealth;
- Removing prior authorization (PA) requirements;
- Waiving prescription refill limits;
- Expanding access to certain telehealth services.

Reimburse Enrollees for Prescriptions Obtained from Out-of-Network Pharmacies
CMS directs Part D sponsors to ensure enrollees have adequate access to Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. Enrollees remain responsible for any cost sharing or additional charges.

Home or Mail Delivery of Part D Drugs
In situations when a disaster or emergency makes it difficult for enrollees to get to a retail pharmacy, or enrollees are actually prohibited from going to a retail pharmacy (e.g., in a quarantine situation), Part D sponsors are permitted to voluntarily relax any plan-imposed policies that may discourage certain methods of delivery, such as mail or home delivery, for retail pharmacies.

Prior Authorization for Part D Drugs
As is the case for MAOs, consistent with flexibilities available to Part D Sponsors absent a disaster or emergency, Part D Sponsors may choose to waive prior authorization requirements at any time that they otherwise would apply to Part D drugs used to treat or prevent COVID-19.
On April 21st, CMS updated the guidance to include additional flexibilities outlined below that supersede and replace the March 10th memo. These program instructions apply to fills and refills on or after March 27, 2020 and will remain in place for the remainder of the emergency period.

Coverage of Testing and Testing-Related Services for COVID-19
Under Section 6003 of the Families First Coronavirus Response Act (FFCRA) and Section 3713 of the CARES Act, MAOs must waive cost sharing for:

- Clinical laboratory tests for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and the administration of such tests;
- Specified COVID-19 testing-related services;¹ and
- COVID-19 vaccines and the administration of such vaccines.²

Vaccines Section 3713 of the CARES Act specifies that a COVID-19 vaccine and its administration will be covered under Medicare Part B, and therefore would be excluded from Part D coverage.

Signature Log Requirements, Prior Authorization, and Audits
CMS is adopting a temporary policy of relaxed enforcement related to the following:

- Waiving Part D medication delivery documentation and signature log requirements;
- Relaxing to the greatest extent possible PA requirements; and/or
- Suspending plan-coordinated pharmacy audits.

MAOs and Part D Sponsors may and should waive PA requirements for Part D drugs used to treat or prevent COVID-19. Sponsors can also choose to waive or relax PA requirements at any time for other formulary drugs in order to facilitate access with less burden on beneficiaries, plans, and providers.

90-Day Fills
Consistent with section 3714 of the CARES Act, Part D sponsors must permit enrollees to obtain a covered Part D drug for up to a 90-day supply in one fill, refill, or transition fill if:

- Requested by the enrollee,
- PA or step therapy (ST) requirements have been satisfied; and
- No safety edits otherwise limit the quantity or days’ supply.

Safety edits that may limit the quantity or days’ supply, include, but are not limited to:

- Quantity Limits (QLs) based on clearly stated maximum dosing limits specified in the FDA-approved label;
- QLs that are intended to prevent clinical abuse/misuse or hoarding by limiting quantities/days supply of specific Part D drugs that the sponsor determines are at risk while continuing to allow for dispensing of sufficient quantities/days supplies to treat medically accepted indications;

¹ As described in section 1833(cc)(1) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2). CMS has identified the specified services and outpatient payment provisions in section 1833(cc) of the Act in recent guidance: https://www.cms.gov/outreach-and-education/outreachffsprovpartprogpvdmpartnership-email-archive/2020-04-07-mlnc-se#_Toc37139913.
² As described in section 1861(s)(10)(A).
• **Refill-too-soon edits**: Part D sponsors must relax these edits;³
• **Point-of-sale claim edits** for frequently abused drugs that are specific to an at-risk beneficiary in a drug management program; and/or
• **Opioid safety edits**, including: care coordination edit at 90 morphine milligram equivalents (MME) per day, optional hard edit at 200 MME per day or more, hard edit for seven-day supply limit for initial opioid fills (opioid naïve), soft edit for concurrent opioid and benzodiazepine use, and soft edit for duplicative long-acting (LA) opioid therapy. **However, CMS encourages plans to waive requirements for pharmacist consultation with the prescriber to confirm intent.**

**Long-term Care Dispensing: Short-Cycle Fills**
For enrollees residing in LTC facilities, **Part D sponsors may permit pharmacies to expand the use of submission clarification code 21 to allow for greater than 14 day supplies for all applicable Part D drugs to provide more flexibility for LTC facilities and pharmacies to coordinate with each other.**⁴

On April 21st, CMS also issued [FAQs on Issuer Flexibilities for Utilization Management and Prior Authorization](https://www.cms.gov/newsroom/press-releases/cms-also-issued-faqs-on-issuer-flexibilities-utilization-management-and-prior-authorization), which applies to health insurance issuers that are offering coverage in the individual and large and small group markets, stating that issuers (as permitted by federal and state law):

- **Must provide benefits for certain items and services related to diagnostic testing for COVID-19 without imposing any cost-sharing, prior authorization, or other medical management requirements;⁵**
- **May relax utilization management processes, such as, prior authorization requirements;**
- **Should work with out-of-network providers that provide (or may provide) services to their enrollees to agree upon a rate to ensure that enrollees are not balance billed;**
- **May apply utilization management practices to treatments to prevent drug shortages; and**
- **Must remain compliant with applicable prescription drug essential health benefits (EHB) regulations, thus ensuring that any changes to prior authorization requirements and utilization management practices are clinically based and are applied in a non-discriminatory manner.**

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³ Part D sponsors have discretion as to how these edits are relaxed as long as access to Part D drugs is provided at the point-of-sale.
⁴ 42 CFR § 423.154(a)(1)(i).
⁵ As required by Section 6001 of FFCRA, as amended by section 3201 of the CARES Act.