2019 Checklist for Community Pharmacists

NCPA has provided the following checklist to assist community pharmacists understand the various federal legislative and regulatory changes that have occurred over the past year. Further, this checklist outlines important dates that community pharmacists should be aware of for 2019. Should community pharmacists have questions regarding this checklist, please reach out to the Policy and Regulatory team in NCPA's Advocacy Center: https://www.ncpanet.org/advocacy.

Prohibition of Gag Clauses

This past fall, the President signed into law two pieces of legislation that prohibited the use of so-called gag clauses in contracts for private and Medicare plans. Under the new law this prohibition means that pharmacists serving patients with Medicare coverage may tell a patient about the difference between the price for a drug obtained on insurance (the pharmacy's negotiated price or the patient's copayment/coinsurance) and a lower price if obtained off insurance. The new law will apply to Medicare plans beginning on or after Jan. 1, 2020.

For patients using private insurance plans, a pharmacist may tell a patient about the difference between the patient's out-of-pocket costs (i.e., a deductible, copayment, or coinsurance) for a drug obtained on insurance and the patient's out-of-pocket costs to obtain the drug off insurance. The provisions of the new law pertaining to private plans are now in effect.

NCPA has prepared the following fact sheet for community pharmacists on the provisions of the new law: http://www.ncpa.co/pdf/qAM/pharmacist-fact-sheet-prohibition-gag-clauses.pdf.

New Opioid-Related Policies for Medicare Part D

Implementation of hard, soft, and care coordination edits

Starting Jan. 1, 2019, Part D sponsors were required to follow opioid-related safety edits when opioid prescriptions are dispensed at the pharmacy. Of note, a community pharmacist may see hard and soft edits implemented from plan sponsors for the following:

- Soft edits for concurrent opioid and benzodiazepine use;
- Soft edits for duplicative long-acting opioid therapy;
- Care coordination edits at 90 morphine milligram equivalents;
- Hard edits at 200 MME or more (optional); and
- Hard edits 7 day supply limit for initial opioid fills for opioid naïve patients.

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The implementation of soft and hard edits is a common tool used in the pharmacy space. Pharmacists know that a pharmacist can generally override a soft edit at the point of sale. In contrast, pharmacists also know that hard edits generally require action from a Part D plan before the claim can be adjudicated. CMS' care coordination edit however, is a new tool that may wade into unfamiliar territory for some pharmacists.

In the 2019 Call Letter, CMS states that a care coordination edit would be triggered when a beneficiary's cumulative morphine milligram equivalent (MME) per day across all the beneficiary's opioid prescriptions reaches or exceeds 90 MME. In implementing a care coordination edit, CMS states that "sponsors should instruct the pharmacist (e.g., through messaging to the pharmacist through the claim billing transaction communications) to consult with the prescriber, document the discussion, and if the prescriber confirms intent, use an override code that indicates the prescriber has been consulted." The prescriber contact and attestation requirement distinguish the care coordination edit from a soft edit.

For more information on these edits, CMS has prepared three sets of outreach materials designed for physician, pharmacist, and beneficiary audiences. Materials can be found here: https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html.

Likewise, NCPA has prepared a summary of these edits in a summary of the 2019 Final Call Letter: http://www.ncpa.co/pdf/summary-2019-final-call-letter.pdf

Lock-in requirements for at-risk beneficiaries

The recently passed *Comprehensive Recovery and Addiction Act* ("CARA") encouraged Medicare plan sponsors to utilize lock-in programs, a type of drug management program for patients determined to be at-risk for misuse or abuse of opioids or other frequently abused drugs (including benzodiazepines). This past spring, CMS outlined how these voluntary lock-in programs should be structured in Medicare plans starting on Jan. 1, 2019. Of particular note, patients can be locked-in to a pharmacy without a prescriber agreement or a waiting period. Lock-in programs, however, cannot be utilized for hospice, cancer, and LTC patients as these patient groups are exempt under CMS regulations.

NCPA has provided this summary of regulations related to lock-in programs: http://www.ncpa.co/pdf/member-analysis-2019-part-d-final-rule.pdf

Opioid-related policy changes on the horizon

This fall, the Congress passed the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act* (the "Opioids Package"). The Package details a number of changes and important implementation dates for such changes, including:

- Required e-prescribing for controlled substances in Medicare Part D (starting Jan. 1, 2021);
- Required drug management programs (prescriber and/or pharmacy lock-ins) in Medicare Part D (starting Jan. 1, 2022);
- Suspension of payments for fraud (starting Jan. 1, 2020);
- Required electronic prior authorization for Part D drugs (starting Jan. 1, 2021); and
- Expanded eligibility for medication therapy management programs in Part D (starting Jan. 1, 2021).

For more information on these upcoming changes including a summary of NCPA's successful advocacy efforts to prevent harmful amendments to the practice of community pharmacy, check out NCPA's summary: http://www.ncpa.co/pdf/ncpa-member-summary-hr6.pdf.

General Medicare Part D Changes

For more information on the following Medicare Part D changes, please see NCPA's summary of the 2019 Part D Final Rule: http://www.ncpa.co/pdf/member-analysis-2019-part-d-final-rule.pdf

Timely access to terms and conditions

A new CMS regulation makes clear that requesting pharmacies may receive timely access to standard terms and conditions from Part D plan sponsors so long as the request such terms and conditions. Further, Part D plan sponsors are required to develop standard terms and conditions and have them ready for distribution for requesting pharmacies by Sept. 15th for the succeeding benefit year.

Clarification to "any willing pharmacy"

CMS acknowledges that many pharmacies perform multiple pharmacy practice functions, such as compounding and specialty pharmacies. CMS has clarified in its Part D Final Rule 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.

Changes to days' supply requirements

As of Jan. 1, 2019, a pharmacy can only dispense a 30-day supply of nonformulary drugs to patients transitioning from another health plan. This is a change from the previous 91 to 98-day supply of nonformulary drugs for patients transitioning from another health plan.

Update to the SCRIPT standard

CMS has adopted the NCPDP SCRIPT Standard Version 2017071 and retired the 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 Jan. 1, 2020.

Implementation of the provider preclusion list

Starting on Jan. 1, 2019, the prescriber and provider enrollment requirement for Parts C and D was replaced with a provider "preclusion list" and on April 1, 2019, plans must begin denying payment/rejecting claims based on the January 1, 2019 preclusion list with dates-of-service of April 1, 2019 and later. Plans are required to deny payment for claims submitted by or associated with prescriptions written by individuals on this list. Likewise, Part D plan sponsors must reject a pharmacy claim for a Part D drug prescribed by an individual on the preclusion list. CMS will only make the list available to Part D and Medicare Advantage plans, not providers. It is important to note that providers must still query the LEIE list. In the Medicare space, only plans must query the preclusion list as well as the LEIE list.

For more information on the Medicare preclusion list, CMS has prepared the following information: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html

Changes to Medicare Eligibility Verification

Under current practice, pharmacies can submit either their NPI or their NCPDP number as the Service Provider ID. Effective Jan. 1, 2019, all Medicare Part A/B and D E1 transactions can only be submitted with the pharmacy's NPI. If an E1 is received that does not contain the code that corresponds to an NPI number, the transaction facilitator will reject the E1 with a "7B - Service Provider ID Qualifier Value Not Supported For Processor/Payer."

If you have any concerns about this requirement, contact your pharmacy system vendor to update your pharmacy system to comply with this change.

Continued Compliance with "Track and Trace" Law

Industry has now entered "Phase 2" of the *Drug Supply Chain Security Act* ("DSCSA" or "Track and Trace"), which focuses on drug product serialization and enhanced verification of serialized product. Community pharmacists should continue to comply with the requirements under the law including only trading with authorized trading partners and holding transaction data elements. Community pharmacists should also be aware that starting on Nov. 27, 2020, dispensers must only accept a product that is affixed or imprinted with a product identifier pursuant to the DSCSA. For more information, see FDA guidance on requirements under the DSCSA statute: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm424963.htm

Eligibility for Pass-Through Tax Deduction

In early 2019, the IRS finalized its rules on the applicability of the pass-through deduction (a deduction of up to 20 percent of qualified business income) to certain small businesses as a result of the 2017 Tax Cuts and Jobs Act. In sum, a pharmacy owner can qualify for the pass-through deduction if the pharmacy only sells pharmaceutical product or medical devices, or gross receipts are less than $25 million and 10 percent or less of those gross receipts are attributable to the performance of medical services.

NCPA has developed the following one-page summary on the pass-through deduction: http://www.ncpa.co/pdf/pharmacy-fact-sheet-pass-through-deduction.pdf

NCPA recommends that pharmacy owners talk to their accountant or tax counsel on the applicability of this pass-through deduction to their business based on the types of services and product dispensing conducted at their pharmacy.

Changes to Management Standards for Handling Hazardous Waste Pharmaceuticals

Earlier this year, the Environmental Protection Agency ("EPA") finalized a rule that requires healthcare facilities (including pharmacies) to determine what is hazardous and non-hazardous waste as well as whether this waste is potentially creditable or non-creditable at their facility prior to sending the product to a reverse distributor. If the product is hazardous, it must be sent to a reverse distributor via a manner outlined in the final rule. If the product is non-creditable, it may not be sent to a reverse distributor. The final rule goes into effect August 21, 2019.

NCPA has prepared a summary of the final rule that will be made available on NCPA's website. Check back for updates to the summary as NCPA continues to evaluate the final rule. At this time, NCPA recommends that community pharmacists speak to their reverse distributors about anticipated changes to their business relationship in light of this final rule.

Upcoming Dates to Know in the Compounding Space

The USP Revised General Chapters <795>, <797>, and <800> will go into effect December 1, 2019. The revisions to USP <795> Nonsterile Compounding include expanded guidance for assigning beyond-use dates (BUD) for compounded nonsterile preparations (CNSP) in the absence of stability information and defines personnel and facility requirements. The Revised General Chapter USP <797> Sterile Compounding modifies simplified compounded sterile preparation (CSP) microbial risk levels from three (low, medium, and high) to two—Category 1 CSPs and Category 2 CSPs. Category 1 and 2 CSPs are distinguished primarily by the facility in which they are made and the BUD.

Lastly, General Chapter USP <800> Safe Handling of Hazardous Drugs requirements include responsibilities of personnel handling hazardous drugs; facility and engineering controls;

procedures for deactivating, decontaminating and cleaning; spill control; and documentation. USP has developed USP <800> education courses to help pharmacists develop risk assessments and comply with these standards: http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare. For more information on USP <800>, NCPA recommends that compounding pharmacists review a webinar from NCPA and the American Society of Consultant Pharmacists (ASCP): http://www.ncpa.co/media/video/ce/usp800.mp4.

NCPA recommends that compounding pharmacists become familiar with their state's USP <800> regulatory activity and start evaluating their compounding facilities to be in compliance with USP <800>, as well as USP <795> and USP <797>.