CMS Pharmacy Guidelines: Medicare Part D

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Agenda

- Pharmacy Access
- National Provider Identifier
- Drug Coverage Issues
- Specialty Pharmacy Issues
- Specific Issues for Pharmacy Providers
- Medication Therapy Management

Pharmacy Access Issues

- Requirements
- Preferred vs. Non-Preferred Pharmacy
- Out of Network Drugs
- Mail Order vs. Retail

Pharmacy Access Requirements

- TRICARE standards for convenient access to pharmacies
  - Urban – 90% within 2 miles
  - Suburban – 90% within 5 miles
  - Rural – 70% within 15 miles
- Only retail pharmacies count toward TRICARE standards except:
  - I/T/U Pharmacies
  - Federally Qualified Health Center Pharmacies
  - Rural Health Center Pharmacies

Any Willing Provider Requirement

- Plans must contract with any pharmacy that meets standard terms & conditions
- Standard terms & conditions may vary (e.g., by geography, type of pharmacy)
- Any willing provider requirement applies to all pharmacies, whether retail, mail, long term care, or home infusion.

Preferred vs. Non-Preferred Pharmacy

- PDPs may offer preferred pharmacies within the pharmacy network
  - “Preferred Pharmacy” = location where beneficiary can obtain lower cost sharing
- Limitations
  - Geographical Discrimination – Can’t have unequal access to preferred pharmacies
  - Price Discrimination – Can’t have “overt” price discrimination between pharmacy types
  - Actuarial Equivalence – Must maintain actuarial equivalency over entire network

Out of Network Access

- When Enrollee cannot reasonably be expected to obtain that drug at a network pharmacy
  - Traveling outside service area and runs out or loses drugs
  - Cannot obtain drugs in timely manner within service area
  - Must fill prescription for orphan drug not normally stocked
  - Is provided drug dispensed at institutional pharmacy while at facility (ER, outpatient surgery)
  - Vaccine administered in physician's office
- Enrollee cannot access covered drugs at an OON pharmacy on a routine basis

Mail Order vs. Retail

- Plans must allow retail pharmacies to offer extended supply of covered drugs
  - Pharmacy can either match mail order pricing
  - Beneficiary can pay any higher cost-sharing associated with purchasing the 90 day supply
    - Cannot charge CMS more than would for mail-order
    - Cannot charge beneficiary more than would have paid for three – 30 day supply

Home Infusion Pharmacy Access

- Part B covers:
  - Home infusion therapy in case of DME supply drugs
  - Parenteral nutrition under the prosthetic benefit
  - Intravenous immune globin provided under certain conditions
- Infusion drugs not covered by Part B will be covered under Part D

  HOWEVER…
  - Supplies, equipment, and services involved in delivering home infusion are not covered

Drug Coverage Issues

- What is a Part D Drug?
- Part B vs. Part D
- Part D Drug vs. Covered Part D Drug
- Drug Formularies
- Medicare vs. Medicaid

What is a Part D Drug?

- Prescription drugs, biologicals, insulin
- Medical supplies associated with injection of insulin
- When a drug is not FDA approved for an indication but it has clinical literature to support its use
- Vaccines not covered by Part B
- A PDP or MA-PD is not required to cover all drugs
- Brand name and generic drugs will be listed in each formulary

Part A vs Part B vs Part D

- There WILL still be Part A and Part B drugs
- Part A drugs
  - Drugs bundled together with hospital payment
- Part B drugs
  1. Drugs delivered in MD office
  2. Drugs delivered by medical equipment
  3. Few outpatient chemo and immunosuppressants
  4. Hospital outpatient drugs billed separately
  5. ESRD drugs (i.e. EPO)

Part D Drug vs. Covered Part D Drug

- Covered Part D drug are those drugs on the PDP's formulary
- Formularies must include at least 2 drugs in each therapeutic category and class
- In certain categories, the formulary must contain all or substantially all medications:

  - Antidepressants
  - Antipsychotics
  - Anticonvulsants
  - Antiretrovirals
  - Antineoplastics
  - Immunosuppressants

Denial of Part A or Part B

- A Part D Plan cannot required that coverage be denied under Part A or Part B before making payment under Part D
  - Exception:
    - If a PDP had evidence that a particular claim for parenteral nutrition should be covered under Part B
    - Could use prior authorization programs to determine whether claim should be submitted under Part A, Part B, or Part D

Excluded Drugs

- Drugs for
  - Anorexia, weight loss, or weight gain
  - Fertility
  - Cosmetic purposes or hair growth
  - Symptomatic relief of cough and colds
- Prescription vitamins and mineral products
  - Except prenatal vitamins and fluoride preparations
- Non-prescription drugs
- Barbiturates
- Benzodiazepines

Exception Process

- Ensures access to medically necessary Medicare covered prescription drugs
- Different from an appeal or grievance
- Two types
  - Tiering exception: drug obtained at more favorable cost sharing level
  - Formulary exception: drug not covered under PDP formulary

Exception Process Timeline

- Determination and re-determination must occur within 7 days
  - Expedited = 24 hours
  - Standard = 72 hours
  - Re-determination = 7 days

Pharmacy Specific Issues

- Drug Coverage and Formulary Notification
- Pharmacy Billing
- What to Collect from Beneficiaries
- TrOOP
- Plan and Eligibility Verification
- Beneficiary Disputes

Drug Coverage and Formulary Notification

- Medicare drug plans current information will be the basis for coverage and payment to the pharmacies
- Pharmacies must post a general notice to enrollees or provide a handout to enrollees
- Enrollees must contact plans to request coverage determination

Formulary Changes

- Prior to removing/changing drug from formulary, the PDP must provide 60 day written notice to:
  - CMS
  - Prescribers
  - Network Pharmacy
  - Pharmacists
- Plan must cover 60 day supply if notice not provided 60 days prior to change
- Exception if FDA or manufacturer removes drug from the market

Notice Requirement

- The written notice must contain the following information (written notice content):
  - name of the affected covered Part D drug;
  - whether the plan is removing the covered Part D drug from the formulary or changing its preferred or tiered cost-sharing status;
  - the reason why the plan is removing such covered Part D drug from the formulary, or changing its cost-sharing status;
  - alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and
  - the means by which enrollees may obtain a coverage determination or undertake an appeal of the coverage determination.

Pharmacy Billing

- Drug Cost – as determined by the recipient’s plan pharmacy reimbursement negotiated rate
- Dispensing Fee – will not include fees for administration, professional services, or supplies and equipment
- Member Cost Share – amount the pharmacy is to collect from the recipient will be passed back by the TrOOP facilitator
- Amount to be paid by Medicare Plan(s) or other
    - Primary Payor
    - Secondary Payor

TrOOP

- TrOOP= True Out Of Pocket Costs
  - Made by beneficiary or another individual, charity, State Pharmacy Assistance Program (SPAP); or Personal Health Savings Vehicle (HSA, FSA, or MSA)
    - 21 states have state funded assistance programs
    - 10 states have discount programs
    - 4 states have clearing houses
  - Coverage by workers' compensation; Medicare supplemental plans, Automobile/No-fault/Liability etc., employer supplemental, or other insurance plans **do not** count.

TrOOP (cont.)

- Only Part D medication purchased counts towards TrOOP.
- Part D plans are responsible for correctly determining TrOOP.
  - If there is a disagreement about TrOOP at the Pharmacy – then beneficiary must pay or decline purchase until after the dispute with the drug plan and patient are resolved.

TrOOP Facilitator and the Pharmacist

The TrOOP Facilitator will provide the pharmacist with:

- Billing insurance information
- Correct order of billing (e.g. multiple payers)
- Explanation of benefit design

Pharmacy Verification of Plan, Eligibility, and Benefit

- Pharmacies, Medicare Drug Plans, Insurers, Employers and CMS will work together electronically to coordinate benefits
- Beneficiary look-up will be available to the pharmacist
- Pharmacy will be informed in real time by the TrOOP facilitator of primary and secondary payers
- The TrOOP facilitator routes the claim to the appropriate primary or secondary payer

Pharmacy Collections from Beneficiaries

Beneficiaries pay the pharmacy:

- The first $250 in drug costs annually (annual deductible)
- 25% of the drug costs between $250.01 and $2,250
- 100% of the drug costs between $2,250.01 and $5,100
- 5% of drug costs above $5,100 (catastrophic coverage)
  - Catastrophic coverage begins when the beneficiary satisfies the $3,600 TrOOP requirement
  - Medicare is liable for 80% and the PDP liable for 15% of drug costs over $5,100

Pharmacy Collections from Recipients with Limited Incomes

Those recipients with limited incomes eligible for Medicare drug coverage will be required to pay the following amounts based on their income level:

- Group 1 (<=100% FPL): No deductible, $1 generic and $3 brand copay up to $3,600 out of pocket (OOP) and nothing after $3,600
- Group 2 (>100 & <135 FPL): No deductible, $2 generic and $5 brand copay up to $3,600 out of pocket (OOP) and nothing after $3,600
- Group 3 (>=135 & < 150% FPL): $50 annual deductible, 15% coinsurance up to $3,600 OOP, then $2 generic and $5 brand copay after $3,600 OOP

Waiving of Co-Payment

- Pharmacies can waive or reduce cost-sharing amounts if done in an unadvertised, non-routine manner
  - Determine whether beneficiary is financially needy or
  - After failing to collect the cost-sharing portion, co-pay may be waived

Medication Therapy Management

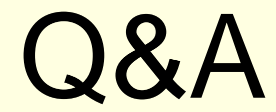
- Individual PDPs will determine the fees associated with MTM programs
- Providers of MTMPs may include pharmacists and other providers
- Fees established by PDPs must take into account the time and resources of the provider
- CMS will require PDP sponsors to explain how their fees account for the time and resources associated with their MTM programs
- MA-PD plans are exempt from the previous provision

Requirements for MTMPs

- Designed to optimize therapeutic outcomes through appropriate or improved use of prescribed medications for targeted beneficiaries
- Designed to reduce risk of adverse drug interactions including adverse drug interactions for targeted beneficiaries
- Provided by a pharmacist or other qualified provider
- May distinguish between services in ambulatory and institutional settings
- May be provided by both retail and mail order pharmacies

Targeted Beneficiaries of MTMPs

- Have multiple chronic diseases;
- Are taking multiple Part D drugs; and
- Are likely to incur annual costs for covered Part D drugs that exceed $4000


Q&A

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