



## CUR<sub>x</sub>ED

### Cornell University Resource Education for Medicare Part D

## THE SILENT DROP

### THE CASE

Judy is a volunteer case worker who helps out at the local SHIP center, assisting seniors with their healthcare insurance. As a former Pharmacy technician, now retired, she has a special interest in prescription drug insurance, especially Medicare Part D. She counsels beneficiaries three hours a week, every Wednesday morning.

CT will turn 65 next month. He is new to Medicare and is exploring his options. He has come to Judy to try to better understand Medicare Part D. He has an extensive list of drugs, including hyoscyamine, which he takes for urinary spasms. Judy inputs his medications into the plan finder tool on medicare.gov but is unable to find hyoscyamine in the drug list.

Last week, Judy received a call from BF, a beneficiary who had been having some cardiac problems. His doctor diagnosed BF with angina and prescribed for him nitroglycerin tablets to put under his tongue at the onset of chest pain. BF was curious about the pricing of nitroglycerin and when searching the plan finder tool, found nitroglycerin patches listed but could not find the sublingual tablets.

Judy starts thinking back to a phone call she remembers receiving a couple of months ago. It was from a beneficiary who did not change plans with the new year and uses pilocarpine eye drops. The eye drops were covered by the plan last year but this year coverage was denied. A search on the plan finder shows pilocarpine tablets listed but not the eye drops.

Having a pharmacy background, Judy is aware that these medications, hyoscyamine, nitroglycerin sublingual tablets, and pilocarpine eye drops, have been on the market for years. She also realizes that they are safe and wonders if there is some type of new regulation that she has missed. Judy would like to find out why these medications are not being listed, in the plan finder, nor covered by Part D plans.

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**WHAT WOULD YOU DO?**  
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### Part D Trivia Question

What percent of Medicare beneficiaries do not have prescription drug coverage?

- A. 10%
- B. 17%
- C. 25%
- D. 38%
- E. 47%

## **THE STUDY**

CMS has a Formulary Reference File (FRF) that Part D prescription Drug plans utilize when they submit their formularies to CMS. The FRF is not a coverage list and may not include representation of all Part D drugs. Rather, it is a tool used by CMS to determine if a plan formulary meets the requirements of Part D legislation.

The Food and Drug Administration (FDA) is the regulatory agency which determines approval for all prescription medications. The Orange Book is a publication of the FDA which lists all drugs that have FDA approval. At the start of plan year 2008, CMS removed from its formulary files all of those medications which do not appear in the Orange Book.

More than 1,500 drugs were deleted by CMS from its FRF, going from 7,100 drugs to 5,500 drugs. In response, Part D plans have dropped many drugs from their formularies from 2007 to 2008. CMS has not made any coverage determinations on these medications however, and has not determined that these medications are not Part D drugs. Plans retain the ability to decide on coverage for the deleted drugs.

Many medications which continue in use today pre-date the 1962 FDA requirement for proof of safety and efficacy. Prior to this, prescription drugs were approved based solely on safety, according to the Federal Food, Drug, and Cosmetic Act of 1938. These earlier medications are not included in the Orange Book and were therefore deleted from the FRF.

Volunteer case worker Judy has encountered three different situations involving older medications which do not have FDA approval, are not in the Orange Book, and therefore have been deleted from the FRF. In addition to dropping unapproved medications from the FRF, CMS also deleted discontinued drugs, Part A or Part B items, products with redundant coding, and products not reimbursable due to statute such as nonprescription medication or agents used to treat weight gain, weight loss, or anorexia, or used for cosmetic purposes.

Changes to the 2008 CMS Part D FRF may have significant impact on patients, Pharmacists, and Physicians. Outcomes might include the need to pay out-of-pocket for uncovered but needed drugs, switching to alternative medications, filing more requests for exceptions, and changing to a different plan

### **Part D Trivia Answer**

Prior to the enactment of the Medicare Modernization Act of 2003, it is estimated that approximately 25% to 38% of the Medicare population did not have prescription coverage. Currently, about **10%** remain without coverage.

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