

Comments on June 2023 revisions to PDAB definition rule and cost review rule

Chairman Mitchell:

Thank you for the opportunity to provide additional comments on the draft definitions and cost review regulations which follow this cover sheet. I appreciate the hard work of the Board and its staff.

*Jane Horvath
College Park, MD*

The definitions still may need some refinement. As is, they might create confusion and lead to problems in the analysis, or disagreement on how some data was analyzed. If edits to the definitions are accepted, changes in the reg text may be needed.

Proposed changes to existing definition language in red. Deletions of existing language in strikeout. Places in the Review reg text that may need to be edited follow the definition suggestions.

COST SHARING DEFINITIONS

NEW Cost Sharing means any insured patient's spending on covered services which includes deductible, copayment, or coinsurance.

(18) "Coinsurance" means the percentage of costs paid by the insured patient after meeting the deductible.

(19) "Copayment" means the set dollar amount **that a paid by the insured patient after meeting the deductible.** ~~atient pays for prescriptions or services covered by the patient's health insurance.~~

(22) "Deductible" means the set amount **an insured** patient pays for health and medical services and products **each calendar year** before a health insurance plan begins to provide coverage, usually expressed in dollars ~~in the form of an annual fee.~~

~~(46) "Other cost-sharing" means a program, benefit design, or other mechanism that determines a patient's financial responsibility for a prescription drug product, other than a deductible, copayment, or coinsurance, such as a copayment, coinsurance, deductible, formulary or other management tool.~~

OUT OF POCKET COSTS DEFINITIONS

(8) "Average **patient** total out-of-pocket **cost**" means the total **of** patients' out-of-pocket costs ~~over~~ **during** the most recent calendar year divided by the number of patients. *This definition is worded in two ways in the Review reg*

(47) "Out-of-pocket costs" means **a patient's cost-sharing for insured, covered services and spending for any non-covered services.** ~~the expenses for medical care, including prescription drug therapy, that are not reimbursed by insurance and are paid by a patient, including copayments, coinsurance, and deductibles for covered services, and the costs for all non-covered services.~~

(49) “Per patient total out-of-pocket costs” means the sum of a patient’s total out-of-pocket costs, ~~including items such as copayments, coinsurance, and deductibles~~ at a certain percentile.

(64) “Total patient out-of-pocket cost” means the sum of all of a patient’s total out-of-pocket costs, ~~including items such as copayments, coinsurance, and deductibles~~.

The Review reg text

COST SHARE DEFINITIONS

(20) “Cost share” means **for a specified time period, a** patient’s total out-of-pocket costs divided by the patient’s total spending for a prescription drug **product**.

5) “Average cost share” means the sum of the cost share of a prescription drug product for each patient divided by the total number of **patients**.

(50) “Person” includes an individual, limited liability company, partnership, corporation, association, county, and public or private organization of any character other than **a-government** agency. [state agency, state & local, any govt agency?]

Reg Text That May Need Edits if Definitions are Edited.

.03(3)(B)(1) The average cost share for the prescription drug product;

.03(D)(3) The average cost share of the prescription drug product, the average patient total out-of-pocket cost, and the average total payor cost. ; and

03.(H)3)(b) The average cost share of the prescription drug product, the average patient total out-of-pocket cost and, the average total payor cost

.05(C)(1)(f) Cost Sharing:

(i) The average patient copay and other cost-sharing data for the prescription drug in the State; and

(ii) The average cost share;

(g) Additional Board Factors: