Comments
Maryland Prescription Drug Affordability Board draft regulation comments
Title 14, Subtitle .01, Chapter .01, Section .01 Definitions and
Title 14, Subtitle .01, Chapter .03, Sections .02, .03, .04, and .05

May 1, 2023

Chairman Mitchell:
Thank you for the opportunity to offer comments on the draft regulations referenced above. I believe there are levels of market dysfunction that create drug affordability problems that I encourage the board to consider in its work. In these comments, I suggest looking at the market during drug cost review to determine if upper payment limits or other policies can mitigate the dysfunction and reduce costs. I am happy to answer any questions about these comments.

Thank you for your important work.

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College Park, MD

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Comments Part One
Title 14.01.03.02 2023-04-11 v1.1
Identifying Drugs Eligible for Cost Review

.02 A – Suggest adding a fourth data source, voluntary submissions from health plans including employer sponsored plans. A rule is not needed for this, but it would create awareness among plans that this is possible and helpful.

.02 B – Use of the NDC. The board should specify when/if it will use the 9-digit NDC and when/if it will use the 11/12-digit NDC.

.02 D – It is not clear whether the spending data runs are applied only to drugs that meet the statutory thresholds for review eligibility or whether the data runs will be applied to all drugs regardless of statutory criteria.

.02 D (1) – Aggregated spending data. The rule should specify the NDC level at which the data will be run. For each data run, the data source that will be used should be specified – such as 'claims' data or other data source type.

(1)(a) – 'Total spending' is not described and would be best described in this section rather than in the definitions

(1)(b) – It seems that 'total' is missing from the formula and would add some clarity, particularly if "total spending – patient and plan, plan, or patient" are each described in this section.

(1)(e) and (f) – "Price" is not defined. The data source (or type of data) should be specified. For instance, if claims data is used, then price is a measure of either pharmacy charges or plan payments and would be distilled as an average or a range, rather than one price. If a pricing file or a state price transparency database is used, price would be defined by whatever data field in the dataset the board will use.

.02 D(2) – The regulation should explain how patient out of pocket costs will be calculated and the data source for this. Are volume-based adjustments needed depending on if the prescription is filled by mail order or retail? Will the formula adjust for 30, 60, 90-day prescriptions?

.02 D(4) – What analysis will be performed on all insulins? Will analysis and board consideration of insulins remain distinct from other drugs? How will the board accommodate the recent state and federal insulin market disruptions in its analysis (manufacturers lowering the list price, Medicare, and statewide patient insulin copay caps)? The importance of a data lag for this class of drugs could be discussed.

.02 D(5) What analysis will be performed on any drug product added by the board?

Suggest a culling process before the board is presented with a vast list of drugs that may include numerous duplications across lists and within lists depending on the NDC level applied. It will be difficult to fine tune the board's interest in particular drugs if the next set of screens/metrics are applied to a thousand drugs.

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Winnowing the results down to some more manageable number would allow a more nuanced review at the next step. To winnow, suggest

- If not done already, the results could be truncated to the NDC 9 which would hopefully reduce the number of data points while preserving the findings.
- The board should also consider removing drugs that have a Medicare Fair Price (MFP) or are in the MFP negotiation process since the board may not be able to establish a statewide UPL that is different from the Medicare Fair Price.
    - Adopting an MFP as a UPL should not require all the analytics required to assess other drugs--which is another reason to remove them from the process developed in this regulation.
- Also remove drugs that are *in active shortage status* and appear on national drug shortage lists *in active shortage status.* Any action by the board will not alleviate (and may exacerbate) the drug shortage. The board could come back to that product at another time.
- Finally, the board could be presented with a list of drugs, each of which appeared in the results of multiple data runs.

Comments Part Two
Title 14.01.03.03 2023-04-11 v1.1
Selecting Drugs for Cost Review

.03 B(1) Suggest adding (d) orphan drug status to the FDA approval information provided to the board. This information should be somewhat detailed – how many orphan indications does the drug have? How many years of orphan market exclusivity remain? Are there additional orphan drugs that treat the same disease? Orphan drugs are no longer the small market, high risk, low return products that they were in the 1980's and understanding if there is a relationship between orphan designation, cost and affordability would be useful to the board's analyses.

.03 B(1)(b) – Suggest in addition to patent expiry information, provide the board with information on the number of patents a drug has and how long the in-market (post approval) patent protection has existed. (Without additional patents, a drug's patent protection would be expected to last no more than ten years once launched. Humira had 23 years of in-market patent protection.) Because the focus of Medicare price negotiation is sole source drugs, it is probable that manufacturers of sole source drugs will ensure that their products have market competition within the two-year window that exempts the product (and its generic or biosimilar competition) from Medicare price negotiations. If these products – which are close to patent or data exclusivity expiration – are found in the results of the data runs, the board may want to focus on these products to consider affordability issues and upper payment limits. Upper payment limits would reset the cost to the consumer for the product and have a sentinel effect on its generic or biosimilar that comes to market.

.03 B(3) – The suggestions for this section on aggregated data are the same as the suggestions for aggregated data in .02 – specify the type of data, describe the formula, define "price". If this is the same

data as developed in .02, directly reference the .02 provision to minimize any unintended variation in the description.

At this stage of the process, the board could be looking for signals of an affordability problem and size of the population using the drug.

In selecting a drug for cost review the board should know the demographics of the disease – prevalence, social determinants associated with the illness, access to care for the illness. If the illness associated with the drug is prescribed by specialists, a survey of specialists or consumers may be helpful for their sense of patient affordability of the drug.

If a retail drug, the board could try to discern if independent pharmacists are generally under-reimbursed for the product which indicates there may be a patient access problem and an affordability problem and if a UPL would be a way to alleviate the problem. These topics can be explored in more detail in the cost review process itself.

The board should also want to know about the competitive landscape for the product – are there lower cost biosimilars or generics on the market and do consumers have access to them through their health plans? If a branded product is under review that has a generic or biosimilar competitor that is not gaining traction in the market, consider if an upper payment limit would improve competition and undermine the use of large manufacturer rebates for the branded, innovator product to the detriment of lower cost versions of the drug.

The regulations and board considerations should incorporate the impact of all the market disruption that is occurring and will continue to occur – how should the board's processes address (or not) changes in the market?

One of the most significant changes is employer efforts to get out from under pharmacy benefit managers that make our system more complex, more opaque, more costly, and create the need for employer auditing PBM activities. CIVICARx, CIVICA Script, CostPlus Drugs are the most notable examples of this trend. They have incentivized the creation of new PBMs and supply chains with more cost control accountability to manufacturers and payors. Importantly, these initiatives are foregoing opaque rebates that do not help consumers in favor of lower cost, on-invoice discounted products.

The board could leverage this growing movement: for those drugs that surface through the data runs and for which it is known that there are very significant rebates and patient assistance programs, the board could consider the merits of turning rebates into upper payment limits so that money already paid by manufacturers gets to where it needs to go – points of service providers and consumers. This strategy improves affordability for everyone, including insurers and recognizes the money the product manufacturers already provide to improve affordability. Such a strategy should remove the PBM role controlling rebates for the product.

Manufacturers are dropping their list prices. Long-acting insulins are an example. Janssen dropped the price of its anti-diabetic product to be listed on CostPlus drugs thereby accessing its drug distribution

channel that commits to sale of the product at the CostPlus price and accessing the employer groups with arrangements with CostPlus to use the pharmacy for health plan enrollees.

There is also a growing trend where manufacturers bring drugs to market with two list prices – one for PBMs that demand rebates rather than lower cost products and one for uninsured and health plans/PBMs that prefer the lower priced product. The board could make the lower cost manufacturer option the state UPL. It seems particularly important that the board incorporate this type of thinking into its regulations and its reports to the legislature. The board should support nascent market-based efforts to provide relief to consumers, and support employer and manufacturer efforts to improve transparency that lowers costs.

Comments Part Three
Title 14.01.03.04 2023-04-11 v1.1
Request for Information

The board could include a public hearing at this point in the process to hear from patients, families, drug/disease relevant physicians, pharmacists, and facilities.

It would be useful to look more specifically at indicators of access and affordability that are more patient-centric than cost sharing data.

04. B(1)(i) – Manufacturer Information: Suggest more specificity in the request for international prices of the drug under review. Specify the countries for which manufacturers report. Those countries should have government-established national pricing or price limits for the drug. Obtaining other information may not be useful because it could be one of many different prices outside a government healthcare system.

04.B(1)(j) – The manufacturer request should be clear that the board wants prices charged to *direct* purchasers such as wholesalers, and *large* purchasers such as hospital systems (which may purchase from wholesalers but negotiate price concessions from manufacturers). The manufacturer could report by class of trade.

Suggest that a manufacturer give the board information on the type of patient assistance provided for the drug selected for review. If that assistance is *copay* assistance, provide the board with the annual per patient dollar amount of assistance. (This information can sometimes be found on product websites.) Manufacturers could also be asked to inform the board how many Marylanders receive the manufacturer's assistance. The purpose is not to determine affordability in the context of financial assistance, since Medicare and Medicaid do not permit such assistance, rather the purpose is to see whether a manufacturer acknowledges an affordability problem and if so, the board should know the amount of money the manufacturer is spending to address the affordability problem.

.04 B(2)(a) – Health Carriers: Suggest rewording to clarify that all plans are to report individually…"Each health carrier….shall report…."

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04. B(2)(b) – It is not clear what 'the average price concession' means. Clarifying the time period used to create the average would be helpful.

04. B(2)(c) – Suggest the board ask for tier placement, cost share for the tier, and any utilization management tools applied to the drug. This is more specific information than aggregate and average cost sharing information. Specifically, tiering informs how a health plan views the product cost and affordability. Patient specific utilization management is also an indicator of affordability in most instances where it is used.

Suggest – if relevant – the plans report formulary placement of generics or biosimilars of the product under review. Affordability can be enhanced by timely coverage of a product's lower cost versions.

04. B(3)(a) – PBMs: A large PBM has a national formulary that health plan clients may elect to use, or the health plan/employer may request a different/modified formulary. The board should either specify the national formulary or the PBM's formulary that affects the greatest number of covered lives in the State. The board has to ensure that reported information is consistent among reporting PBMs so the information can be compared. Alternatively, this information request could be made of each carrier and ERISA plan in the state.

04. B(3)(b) – Suggest rewording for clarity: "The total amount of manufacturer price concessions received by the PBM for the product under review expressed ..." This language is clearer unless the board wants manufacturer total price concessions for all its drugs on a PBM formulary.

.04 B(3)(d) — It is not clear what data the board wants here that is different from what carriers will provide for the exact same question. A PBM may operate different formularies for different health plans and the data request should accommodate this somehow.

.04 B(3)(e) – The regulation should specify if the revenue to be reported is national or state-level.

.04 B(4)(a) – The request as worded suggests the board may want either a precise number or an estimate. Delete "typical" before 'purchasers' if a precise number is requested. Does the board want this information as a dollar amount of total price concessions?

Suggest that information could be requested from independent pharmacies concerning the adequacy of reimbursement for each drug selected for cost review. If independent pharmacies are under-reimbursed, there will be an access problem if those pharmacies will not stock the drug or under reimbursement compromises their financial stability. Express Scripts recently announced that independent rural pharmacies will get higher reimbursement than other pharmacies which is in part an acknowledgement that high drug costs in low volume facilities is an affordability problem. This is part of a broader ES rural pharmacy initiative. There is a requirement that the pharmacy not be associated with a wholesaler – which could serve certain Express Scripts market objectives as well.

Suggest that a sample of all independent and chain pharmacies be asked how often it is that patients do not pick up the medicine selected for cost review. Depending on the drug product, the sample could be

of the specialists that administer the drug, and the question could be the extent to which patients terminate treatment because of cost.

Comments Part Four
Title 14.01.03.05 2023-04-11 v1.1
Cost Review

This section of the regulation reprises the data that has been collected thus far in the process and adds some new data and analysis including cost and comparative effectiveness analysis.

.05 C(2)(e) – Cost effectiveness analysis: Suggest that if the board commissions a cost effectiveness analysis the board should consider stipulating in regulation that it will set the results of that analysis in the context of affordability for patients and the healthcare system -- in both the near term and in the long term. It is also important to acknowledge if the comparators are high cost and possibly creating affordability challenges of their own.

.05 F – Final affordability report: Suggest that the board's summary report frame all the analyses and its decisions in the context of the current US industry business model which gave rise to the board in the first place and how the board's activities can support recent efforts to improve the system and affordability for consumers.

Comment Part Five
Section 14.01.01.01 v1.1
All New Definitions:

Def #3 Active Moiety: Can this term be linked in any way to the term "therapeutic agent" in definition #57 – 'therapeutic alternative"?

Def # 5 Average Cost Share: The language is not altogether clear in part because of terminology.

Def #6 – Average Patient Copay: "Copay" has an accepted meaning as set cost share amount regardless of the cost of the drug or service. This is distinct from 'coinsurance' which is a set percentage of the variable cost of a drug or service. This could be clearer by adding that it is a subset of #5. The data run provisions could specify if there will be an adjustment for 30, 60, 90-day prescriptions for 'average patient copay' The definition should specify the time period for the calculation. This definition can be synchronized with #5, #9, #18, #19, #45

Def #7 – Average Payor Cost per Patient: Does the formula include an unduplicated count of patients or are pharmacy claims a proxy for individual patients?

Def #9 – Average total out of pocket costs: The formula described would seem to produce a per patient number and if so, the term should include 'per patient'. Out of pocket cost is not defined, and it would

include deductible, copay and/coinsurance. It may be worthwhile to examine definitions 5, 6, and 9 together

Def #18 – Coinsurance: Suggest the definition: the patient share of the cost (cost share) of a service after the deductible is paid, calculated as a percentage of the cost of the drug or service.

Def #19 – Copay: Suggest the definition: the patient share of cost (cost share) of a service after the deductible is paid, expressed as a flat dollar typically based on where the drug is placed on a formulary.

Defs #18 & 19 – The cost sharing terms should use very similar language and definition structure.

Suggestion – Create a definition of "Cost Sharing" described as patient out of pocket costs and under that definition, define deductible, copayment, and coinsurance and indicate they are distinct types of out-of-pocket costs/cost sharing.

Def #22 – Coupon: This term does not seem to be used in the current draft regulations and the question is whether it will be used in other sections of the PDAB regulations.

Def #23 – Deductible: Suggest a revision: The amount an insured person pays for health care services before health plan begins to share in the cost of services.

Def #24 – Discount: It may be good to source this definition. Discounts are often offered at the purchase – an "on-invoice" discount. Discounts may be proportional to the volume purchased or the time period purchased. Industry rebates are paid after the purchase and are typically based on moving/increasing the market share of a product relative to competitors. "Price concessions" is the term that may be best for describing the range financial incentives in the pharmaceutical market, rather than a specific type of financial incentive. Instead of saying rebates, discounts and price concessions or other price concessions, use 'price concessions' alone after defining the term and be more specific when necessary.

Def #26 – Drug Specific Patient Access Program: Suggest one sentence saying a variety of programs designed to help a patient afford their medicine from free goods to substantial subsidy of patient cost sharing. Delete the phrase 'assistance obtaining.' Suggest noting that most of these programs are not permitted in Medicare or Medicaid under anti-kickback rules.

Def #27 – Exclusivity: Suggest distinguishing exclusivity from patent protection. Biologics and orphan drugs have particular, and somewhat different exclusivity rules.

Def #29 – Federal Supply Schedule: Replace "a" with "the".

Def #35 – Insurance Benefit Design: If cost sharing is defined elsewhere, this can be shortened. Suggest 'utilization' management tools rather than just 'management tools.' Drug quantity limits, prior approval and step therapy are specific utilization management tools.

Defs #40 & 41 – Medicaid, Medicare: these are insurance programs more than public health programs mentioned in the definitions. CMS specifically describes Medicare as insurance. There is a good, short

description of Maryland Medicaid, a short description Medicare, and a description of Medicaid from CMS.

Def #42 – NADAC: Suggest saying that this is a public database. Here is short description of the file content.

Def #45 – OOP: Suggest defining 'cost sharing' and using the term OOP in that definition. Then 'cost sharing' can be used when describing calculations. Cost sharing should be defined to include deductible, copay, and coinsurance.

Def #47 – Per Patient Total OOP: This exact term is not used in the draft regulation but there may be plans to use it in other parts for future parts of the regulation. Also, total cost sharing includes specific costs, so 'such as' indicates there are more types of spending not otherwise discussed.

Def #52 – Rebate: Rebates can be 100% of the product costs, not just partial refunds. There are 100% product cost rebates in Medicaid. Rebates are paid sometime after the product purchase. Note that discounts associated with on-invoice is described as a rebate in this definition and but 'on invoice' is specifically excluded from the definition of 'discount' in #24 and #24 is correct.

Def #57 – Therapeutic Alternative: The term 'therapeutic agent' is used in the definition but not defined. Is there any link between 'active moiety,' therapeutic alternative or therapeutic agent?

Def #58 – Therapeutic Class: Can a therapeutic class contain therapeutic alternates? If so, this would be helpful to include. Def #25, "drug class" – does not seem to be used in the regulation but if it is the same as therapeutic class, please clarify. If #25 has a different meaning, the meaning should be made clear in definition #25.

Def #60 –Total OOP: Suggested addition: include discussion of formulas in the part of the regulations that lists the spending metrics that the board may use.