National Patient Advocate Foundation

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WHITE PAPER: Specialty Tiers

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Background

Patients struggling with chronic, debilitating and life-threatening diseases must have access to cutting-edge drug therapies to stay alive. Unfortunately for patients, many insurance plans now place these drugs, which often do not have generic equivalents, on specialty tiers. These specialty tiers require patients to pay a percentage of the cost of the drug, (i.e., co-insurance) rather than the lower, fixed co-payment amount required for the drugs placed on lower tiers. This co-insurance can cost patients thousands of dollars per treatment. In 2012, 64.7 percent of patients who reached out to Patient Advocate Foundation (PAF) for assistance reported annual household income of less than $23,000; 32.5 percent reported less than $11,000.[1] Patients who must rely on drugs placed in specialty tiers often cannot afford the out-of-pocket costs and, as a result, may be forced into insurmountable medical debt crises. There are about nine co-pay relief organizations in the United States, but they are unable to meet the demands of all consumers who need copayment support; thus, relief is often unavailable.

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Since the Centers for Medicare and Medicaid Services (CMS) implemented the Medicare Part D benefit, the agency has allowed Part D plans to create and use formulary tiers dedicated exclusively to specialty drugs. By placing medicines that, under CMS regulations, exceed an established dollar amount per prescription on a specialty tier, Part D plans shift a substantial portion of the cost of these less-frequently used treatments to enrollees, permitting the plans to reduce overall premiums and to offer lower flat-dollar cost sharing for preferred generic and brand drug therapies used by the majority of patients enrolled in their plans. The option quickly gained popularity and, by 2009, the Kaiser Family

[1] Patient Advocate Foundation 2012 Patient Data Analysis Report.

Foundation reported that 87 percent of stand-alone Medicare Part D Prescription Drug Plans and 98 percent of Medicare Advantage-Prescription Drug Plans employed specialty tiers[2].

Since 2009, CMS approval of Part D specialty drug tiers has continued to increase,[3] with dramatic cost implications for Medicare Part D beneficiaries. Per CMS guidance issued in 2013, only drugs that cost more than $600 per month may be placed on the specialty tier of a Medicare Part D plan's formulary. Furthermore, although CMS limits the specialty tier coinsurance requirement to 25 percent of a prescription's total cost for plans that use the standard benefit design, actuarially equivalent designs are permitted that, for example, waive the standard deductible but raise the coinsurance rate for specialty tiers to 33 percent.[4] For beneficiaries enrolled in Medicare Part D plans with 33 percent co-insurance, the minimum cost-sharing obligation is $198 per month for each specialty medication. Since the price of specialty medications generally exceeds the $600 per month threshold, most Part D beneficiaries using a single specialty-tier product will have a cost-sharing obligation in excess of $198 per month.

Moreover, preferred specialty drug tiers no longer automatically shield patients from high costs. A February 2009 report from the University of Chicago's National Opinion Research Center (NORC) created for the Medicare Payment Advisory Commission (MedPAC) noted that 14 percent of Medicare Part D plans place specialty drugs on a non-preferred formulary tier.[5] Because CMS permits co-insurance on medications in a non-preferred formulary tier of up to 50 percent in the initial coverage phase of the Part D benefit,[6] a Medicare Part D beneficiary's cost-sharing obligation for a specialty drug in a non-preferred formulary tier can be substantial.

Patients who need such specialty drugs typically have no generic alternative, and many will go into medical debt in order to continue their life-saving treatment. Medical expenses are contributing factors in more than 62% of individual (as opposed to business) bankruptcy filings, and the number of bankruptcy filings that attribute medical debt as a significant factor is increasing.[7] PAF data support this trend: requests for copayment assistance at PAF continually increase as more plans use specialty and non-preferred formulary tiers.[8] Although the Medicare Part D benefit contains an out-of-pocket maximum, which will be $4,550 for the 2014 plan year, after which enrollees incur only a de minimis co-payment for covered drugs, the use of substantial co-insurance amounts for such specialty products causes this vulnerable population to incur a significant financial liability in a short period of time. Medicare Part D beneficiaries often have limited incomes with little or no access to substantial cash

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[2] The Henry J. Kaiser Family Foundation, "Medicare Part D 2009 Data Spotlight: Specialty Tiers, *available at* http://www.kff.org/medicare/upload/7919.pdf.

[3] *Ibid*.

[4] Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter, February 15, 2013.

[5] NORC at the University of Chicago, "Drugs on Specialty Tiers in Part D," *available at* http://www.medpac.gov/documents/feb09_drugsonspecialtytiers_contractor_rs.pdf.

[6] *See* Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, *available at* http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf.

[7] David U. Himmelstein, MD, Deborah Thorne, PhD, Elizabeth Warren, JD, Steffie Woolhandler, MD, MPH. "Medical Bankruptcy in the United States, 2007: Results of a National Study." American Journal of Medicine, 2009. http://www.pnhp.org/new_bankruptcy_study/Bankruptcy-2009.pdf.

[8] Patient Data Analysis Report, *op. cit*.

savings or credit cards with which to defray such significant cost-sharing liabilities. Consequently, Medicare Part D beneficiaries often either experience a medical debt crisis or simply fail to adhere to their regimens to avoid incurring substantial medical debt.

A study published in the Journal of Managed Care Pharmacy[9] showed that, for multiple sclerosis drugs, the abandonment rate for patients with out-of-pocket (OOP) costs of less than $100 is 6 percent, compared to more than 25 percent for OOP expenses exceeding $200. In a 2011 study published in the Journal of Oncology Practice[10], researchers found that patients taking oncology medications with an OOP cost greater than $200 are at least three times more likely to choose not to fill their prescriptions than those with OOP costs of $100 or less. Researchers estimate that non-adherence to medication regimes contributes $100 billion in annual direct costs to the United States health care system and costs the United States over $2 billion per year in lost patient earnings and lost productivity.[11]

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Congress certainly intended to avoid these consequences and limit the cost-sharing burden on patients. In the MMA, Congress prescribed standard cost-sharing and insurance coverage splits and other required plan design features for Medicare Part D plans offering standard prescription drug coverage while also permitting plans to offer alternative prescription drug coverage for which the "actuarial value of the total coverage is at least equal to the actuarial value of the standard prescription drug coverage."[12] In other words, plans may offer an alternative prescription drug plan (e.g., flat dollar co-payments in lieu of co-insurance, etc.) as long as the percentage of medical expenses paid by the insurer is comparable to the standard plan.

With this in mind, CMS has indicated that it has the authority to implement regulations or guidance to limit specialty drug tiers in Medicare Part D plans and their related cost-sharing obligations. Nothing in the MMA prohibits CMS from mandating or prohibiting specific plan design features. CMS therefore has placed restrictions on cost sharing associated with a Medicare Part D plan's proposed specialty drug and/or non-preferred drug tiers within these parameters. In fact, the MMA requires CMS to implement regulations for actuarially validating all Part D Plan offerings, regardless of benefit design. Under that authority, CMS has declared in regulation its ability to deny multiple Medicare Part D plan bids from sponsors that are not significantly different in design, including beneficiary out-of-pocket costs. The agency also has adopted related benefit parameters for each plan year upon which to measure plan bids

[9] Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications. October 15, 2009. (http://www.ncbi.nlm.nih.gov/pubmed/19803554)

[10] Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions. May 7, 2011. (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3092458/)

[11] Andrew M. Peterson, Liza Takiya, Rebecca Finley, "Meta-Analysis of Trials of Interventions to Improve Medication Adherence," American Journal of Health-System Pharmacy 2203: 60(7).

[12] Social Security Act § 1860D-2(c).

for significant differences, and it has imposed limitations on Medicare Part D plan sponsors' plans and formulary designs by mandating coverage of substantially all drugs in certain protected classes.

Unfortunately, these protections are still insufficient to alleviate patient medical debt crises and ensure adherence. Although CMS limits coinsurance for preferred specialty tier drugs under the standard benefit design to 25 percent of the total prescription cost, patients who have contacted PAF for assistance have reported cost-sharing requirements of 60 percent or more for specialty tier drugs per annum. These cost-sharing requirements may include deductible requirements and cost-sharing amounts associated with prescriptions filled in the "donut hole" coverage gap, for which the coinsurance requirement in plan year 2013 is 47.5% for brand name drugs and 79% for generic drugs. Patients generally cannot determine what portion of their bills reflects deductible, coinsurance, or donut hole requirements; however, there is no doubt that 40 to 60 percent cost sharing over the course of a plan year for prescriptions that cost $600 or more per month limits their access to needed therapies.

National Patient Advocate Foundation (NPAF) and other patient organizations have long recognized the devastating financial impact that specialty drug tiers have on patient access to critical and often life-saving specialty medications. We stress the importance of limiting drugs included in the definition of "specialty drug", permitting tiering exceptions for drugs on specialty drug tiers, capping monthly out-of-pocket spending by beneficiaries on specialty drugs and non-specialty drugs alike, and increasing the minimum dollar threshold for drugs to be included on a Medicare Part D plan's specialty drug tier.

Legislative and Regulatory Options

Legislators have introduced bills at both the state and federal levels to limit patient out-of-pocket costs for specialty tier drugs. Representatives David McKinley (R-WV) and Lois Capps (D-CA), along with 15 bipartisan cosponsors, introduced The Patients' Access to Treatments Act (H.R. 460) on February 4, 2013. This important legislation would limit cost-sharing requirements incurred by patients who are enrolled in commercial health plans and need access to drugs placed on specialty tiers by private-sector drug plans. Specifically, it also would restrict co-insurance for these specialty drugs to no more than 10 percent above the cost-sharing amounts patients incur for medications in a non-preferred drug tier, such as those in Tier III of a three-tier formulary. Tier III drugs typically have flat-dollar co-payments, making them far more affordable than specialty tier coinsurance for drugs costing $600 or more per month. Therefore, the lower cost-sharing requirement would greatly enhance patient access to essential medications.

NPAF supports the McKinley-Capps legislation, which would enhance patient access to desperately needed medications. The bill's press release quoted NPAF Founder and CEO Nancy Davenport-Ennis, who thanked Representatives McKinley and Capps for introducing this legislation and declared it will help "level the playing field for patients by providing equal access to innovative and standard therapies alike." However, the legislation falls short of reaching all payers by limiting the impact to commercial payers, so NPAF supports additional legislation to extend these changes to Medicare Part D plans. The organization currently is in discussions with Members of the House of Representatives to find a sponsor to offer legislation that would limit cost-sharing for specialty tier drugs in Medicare Part D plans. NPAF

additionally is actively seeking a Senate sponsor of companion legislation to the McKinley-Capps bill. NPAF has also sought administrative solutions to the hardship and confusion caused by specialty tiers. NPAF strongly opposes the designation of specialty drug tiers and specifically the use of co-insurance for specialty drug tiers when flat dollar co-payments are utilized for other drug tiers. Such tiers impede beneficiary access to necessary and innovative biologics and other unique drug therapies and create confusion among Medicare beneficiaries as to their potential cost-sharing obligations.

Based on PAF's experience with Medicare Part D enrollees and NPAF's discussions within the patient advocate community, it is clear that Medicare Part D enrollees do not understand that out-of-pocket expenses for specialty medications included on a Part D plan's formulary may exceed 25 percent during the initial coverage phase of the Part D benefit. CMS does not define a specialty drug as any medication that costs $600 or more per month in its proposed Summary of Benefits Report (SBR) for Medicare Part D Prescription Drug Plans (PDP), despite its previous guidance. Therefore, at the very least, NPAF recommends that CMS provide educational outreach that would specifically define specialty drugs and explain the potential cost-sharing obligation that beneficiaries might incur if they need access to medications placed on a specialty tier. CMS should provide, in this outreach, websites, literature, press releases and non-profit patient advocacy organization resources to explain beneficiary's minimum cost-sharing requirements for a specialty drug. CMS has noted that, for many plans, the cost-sharing obligation for drugs on the specialty drug tier is 33 percent. Therefore, a beneficiary's cost-sharing obligation on such a plan for a drug on the specialty tier would be $198 (33 percent of $600). However, most PAF patients paid a much larger percentage than even this high estimate: in 2012, over half of these patients, or 52.57 percent, paid over the CMS-allowed 33 percent for their specialty drug. Their average OOP expense was $547.07 per prescription[13].

In 2012, 52.57% of PAF patients paid over the CMS-allowed 33% for their specialty-tier drug. Their average OOP expense was $547.07 per prescription.

NPAF has urged CMS to use its authority, via regulation or guidance, to place limitations and restrictions on Medicare Part D plans' design of specialty drug tiers on their formularies and the establishment of associated cost-sharing obligations.

In an October 25, 2012 letter to CMS Acting Director Marilyn Tavenner, NPAF proposed several recommendations through which CMS can alleviate the burden on Medicare Part D beneficiaries. They included the following:

1. NPAF recommended that CMS cap the co-insurance that may be imposed on any drug on a Medicare Part D plan's formulary at 25 percent.

A Medicare Part D plan offering coverage alternatives to the standard benefit should not be permitted to charge beneficiaries a co-insurance of 33 percent on medications placed on a designated specialty drug tier or up to 50 percent when included on a non-preferred drug tier, in light of the fact that the

[13] Patient Advocate Foundation Patient Information for 2012.

plan would not be permitted to charge more than 25 percent if it offered standard prescription drug coverage. Even a Part D plan that offers alternative prescription drug coverage may not charge a 33 percent co-insurance for drugs in the generic and preferred brand formulary tiers. Furthermore, specialty drugs included on a non-preferred brand formulary tier are still deemed covered Part D drugs under the Medicare Part D plan, the same as drugs on preferred formulary tiers with materially different cost-sharing obligations.

Exorbitant co-insurance obligations on specialty medications can have a disproportionate impact on patient access to needed and potentially life-saving medications because many specialty drugs, whether included on a designated specialty drug tier or in a non-preferred brand formulary tier, do not have generic alternatives or even therapeutically interchangeable brand drugs available on other formulary tiers that could be obtained for a significantly lower co-insurance or flat dollar co-payment. Either through regulation or guidance, CMS should cap the cost-sharing percentage that may be imposed by a Medicare Part D plan on drugs included on formulary at 25 percent or its flat-dollar equivalent, regardless of the drug's tier. Twenty-five percent co-insurance is already mandated by Congress under the MMA for standard Medicare Part D prescription drug coverage.

While it is true that Congress stated in the MMA that alternative coverage in the initial coverage phase after the deductible must be actuarially equivalent to an average expected payment of 25 percent of enrollee costs, the purpose of this exception was to allow the provision of actuarially equivalent flat dollar co-payments in the initial coverage phase of the Part D benefit, not to permit Medicare Part D plans to discriminate by charging co-insurance greater than 25 percent on certain drugs, classes of medications or formulary tiers of drugs. Furthermore, in the MMA, Congress expressly gave CMS the authority to prescribe a methodology for actuarially validating plans. Pursuant to this authority, CMS can interpret what is meant by actuarial equivalent, employing standards upon which it can measure proposed Medicare Part D plan designs for actuarial equivalence. One such standard might be a cap of 25 percent co-insurance, or its actuarially equivalent co-payment, on all formulary drugs, which would be consistent with the standard Part D benefit.

2. NPAF urged CMS to prohibit the use of co-insurance for some formulary tiers when co-payments are used for drugs in other formulary tiers.

While the MMA expressly permits Medicare Part D plans to use tiered co-payments in lieu of co-insurance, nothing in the MMA even remotely suggests that a Medicare Part D plan should be able to utilize a flat-dollar co-payment for one or some drugs tiers of a tiered formulary while utilizing co-insurance for other tiers.[14] CMS should, through regulation or guidance, prohibit Medicare Part D plan sponsors from using co-insurance for some tiers of a multiple tier formulary and co-payments for other tiers. As such, Medicare Part D plans offering alternative prescription drug coverage would have to elect to either utilize co-payments or co-insurance for all formulary tiers. CMS has imposed similar plan design limitations on Medicare Part D plans via regulation and/or guidance in the past. As noted above, CMS requires Medicare Part D plans to cover substantially all drugs in certain protected classes.

[14] Social Security Act § 1860D-2(b)(2)(B).

Furthermore, CMS has mandated that only drugs with a monthly cost $600 or greater can be placed on a designated specialty drug tier.

3. NPAF recommended that CMS revise its regulation and require Medicare Part D plans to entertain tiering exceptions for specialty drugs.

CMS adopted a regulation that permits Medicare Part D plan sponsors to exempt drugs on the designated specialty drug tier of a formulary from beneficiary tiering exception requests. We urge CMS to consider revising this regulation and permit beneficiaries to request tiering exceptions for medications included on the specialty drug tier of a formulary. We believe the current CMS regulatory exception violates the MMA, specifically Section 1860D-4(g)(2) of the Social Security Act, which requires Medicare Part D plan sponsors to entertain tiering exception requests from beneficiaries. This statutory mandate contains no exception to the right of a beneficiary to request a tiering exception nor does it permit or require CMS to promulgate regulations to permit exceptions to the statutorily mandated right of beneficiaries to request tiering exceptions.

NPAF's Position

In summary, to control disease and manage life-altering and life-threatening illnesses, patients must have access to the full range of medications available, including newer, targeted therapies intended to treat these diseases. Specialty tiers present a serious access barrier to patients unfortunate enough to be diagnosed with debilitating diseases, whether they have private or public insurance.

NPAF supports the H.R. 460, "The Patients' Access to Treatments Act", to limit patient cost-sharing in commercial plans for specialty tier medications to within 10 percent of the amount plans require for medications placed on non-preferred brand tiers, such as Tier III. NPAF continues to work with Congress to gain co-sponsors for H.R. 460 in the House and to engage Senate leadership to develop companion legislation. Building on discussions with CMS officials in 2012 and early 2013, NPAF will continue to work with CMS to explore possible regulatory solutions to specialty tiers in Medicare.

NPAF urges the elimination of the co-insurance option and the adoption of one consistent standard of cost-sharing participation across all tiers for Medicare beneficiaries with limited household income and resources. Finally, NPAF also proposes a revision of CMS regulations to require Medicare Part D plans to entertain exceptions for specialty drugs.

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