



# **A Consumer Guide to Drug Formularies: Understanding the Fundamentals of Behavioral Health Medications**

KENNEDY FORUM ISSUE BRIEF (AUGUST 2017)

## Contents

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Executive Summary .....	<b>1</b>
Introduction.....	<b>3</b>
Part I: Prescription Drug Formulary Overview .....	<b>3</b>
Part II: State and Federal Laws Impacting Drug Formularies.....	<b>6</b>
Part III: Common Challenges with Drug Formularies.....	<b>7</b>
Part IV: Identifying Potential Solutions .....	<b>10</b>
Part V: Summary .....	<b>13</b>
Appendix: Consumer Resources.....	<b>14</b>

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## Executive Summary

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Formularies are the lists that act as the gateways to prescription drug coverage in health plans in the United States, and impact every prescriber, pharmacist, purchaser and patient. The purpose of a drug formulary is to provide high quality care using the most cost-effective medications.

By establishing coverage limitations for prescription drugs, formulary guides are intended to make sure patients receive the most appropriate medications and reduce the utilization of unnecessary medical resources. The drugs in the lowest tier have the smallest patient cost-sharing while the drugs in the highest tier have the highest patient cost-sharing. Generic drugs—which generally have the same active ingredients as brand name drugs—are often assigned to the lowest tiers, with brand name and specialty drugs populating the higher tiers.

Most health plans contract with a separate company to administer their prescription drug formulary, known as a pharmacy benefit manager (PBM). PBMs are responsible for negotiating drug prices with pharmaceutical manufacturers and pharmacies. PBM advocates note that these organizations aggregate purchasing power to lower drug costs for health plans and patients, and many PBMs provide strategic services to avoid medication errors and drug misuse.

However, drug formulary design and reimbursement policies also receive substantial criticism. Problems accessing prescription drugs—especially behavioral health medications—are commonly reported. Many health policy experts believe that formularies inherently limit prescriber autonomy. Consumer advocates argue that formulary design is overly focused on cost control, resulting in formulary structures that impose substantial barriers to necessary medications. Critics assert that PBMs unfairly prosper from formularies in part by benefiting from contractual arrangements that reduce or lock out competition in return for discounts and rebates for health plan clients. Cost-sharing requirements, burdensome authorization protocols, and “fail first” policies encouraging the use of generics and less expensive,<sup>1</sup> sometimes older drugs, are often cited as reasons for poor medication adherence, which can negatively impact patient health.

As a general matter, the complexity of drug formulary design not only confuses patients but also their doctors, leading to prescribing practices that do not always consider the best interests of patients, who often suffer from complex conditions. For example, individuals with mental health and substance use disorders (behavioral health conditions) are particularly subject to these challenges. Historically, treatments for behavioral health conditions, including prescription drugs, were subject to more restrictive limits than other health services and medications.

“The complexity of drug formulary design not only confuses patients but also their doctors, leading to prescribing practices that do not always consider the best interests of patients, who often suffer from complex conditions.”

Despite the Mental Health Parity and Addiction Equity Act of 2008 (the Federal Parity Law), many health plans still apply overly stringent cost-sharing and medical management practices to behavioral health medications. Some health plans continue to exclude some of these treatments from their drug formularies completely. However, the Federal Parity Law, the Affordable Care Act (ACA) and new state laws provide opportunities for patients to overcome the historic barriers to accessing behavioral health medications.

This publication provides an overview of how prescription drug formularies work and how they are regulated. The issue brief is designed to help consumers and advocates identify, understand, and advocate for their rights regarding medically necessary and evidence-based medications to improve clinical outcomes. It also highlights five common barriers restricting access to behavioral health medications. The analysis concludes with 10 action steps that consumers and others can take to address problems with prescription drug formularies and improve general access to behavioral health medications:

1. Increase awareness of drug formularies
2. Study your drug formulary
3. Understand your medications' placements
4. Consider drug coupon and assistance programs
5. Increase enforcement of the Federal Parity Law
6. Advocate to maintain prescription drug coverage as an essential health benefit
7. Learn the relevant laws in your state
8. File a complaint
9. Know how to file an appeal
10. Advocate for legislative solutions

Although this report is tailored to remedy the systemic drug formulary barriers facing patients with behavioral health issues, many of the lessons are also applicable to patients with other health conditions.

*The issue brief also includes an Appendix, which references useful consumer resources discussing medications and drug formularies.*

## Introduction

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**D**rug formularies attempt to encourage appropriate and high-value prescribing through the use of a tiered structure, in which lower-cost medications are placed in tiers with minimal cost sharing for patients. The purpose of a tiered structure is to incentivize prescribers and health plan members to avoid higher cost medications. Higher-tiered (more costly) medications are a particular concern for health plans, as behavioral health medications tend to be taken on an ongoing basis, rather than on a short-term basis.

The impact of drug formularies on access to behavioral health medications cannot be understated. For example, the number of Americans dying from suicide<sup>2</sup> and overdoses<sup>3</sup> is alarming. Yet, many individuals experiencing behavioral health disorders do not have timely access to the life-saving medications critical to their recovery. For example, medication assisted treatment (MAT) for opioid use disorder (e.g., buprenorphine, methadone, naltrexone) are often subject to stringent prior authorization and cost-sharing requirements, and sometimes these medications are not even included within formularies.<sup>4,5</sup>

Drug formularies should aim to encourage the proper use of resources while not restricting or adversely delaying medically necessary care. This issue brief provides information and tools to help consumers, prescribers, and policymakers advocate for solutions critical to accomplishing this balance.

“Drug formularies should aim to encourage the proper use of resources while not restricting or adversely delaying medically necessary care.”

## Part I: Prescription Drug Formulary Overview

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**A** prescription drug formulary is a list of approved drugs that a health plan, often through the help of a PBM, has agreed to cover, and defines the prescription drug benefit. The purpose of using a drug formulary is to provide high-quality care using the most cost-effective medications. Typically, a drug formulary is developed by experts using clinical evidence. A drug formulary usually consists of two to five groups of drugs—called tiers—with different levels of copayments or coinsurance by tier. The drugs in the lowest tier will have the smallest patient cost-sharing, while the drugs in the highest tier will have the highest patient cost-sharing. Generic drugs—medications that are essentially copies of brand name drugs with similar dosage, intended use, and side effects—are often assigned to the lowest tiers, with brand name and specialty drugs populating the higher tiers.

PBMs are responsible for negotiating drug prices with pharmaceutical manufacturers and pharmacies. PBMs may also design and manage the prescription drug benefit for health plans via a Pharmacy and Therapeutics (P&T) committee, which typically consists of a group of doctors, nurses, and pharmacists tasked with selecting the medications included within a formulary. The P&T committee develops, reviews, and updates the formulary so it reflects the

most current clinical guidelines, FDA-approved prescribing protocols, published literature, and clinical trial results.<sup>6</sup> Although the tiering is typically left up to the health plan sponsor or insurer, the information submitted by the P&T committee is valuable in determining the final formulary structure.

The P&T committee recommendations extend beyond the drugs to be included in the formulary. They are also responsible for designing and implementing formulary policies that address utilization and access to medications. These policies aim to promote appropriate use, enabling patients to receive necessary services while limiting over-utilization of medical resources.

Examples of utilization management protocols common within drug formularies include:

- **Coverage Restrictions**—Determines the medications that are included within a formulary.
- **Quantity Limits**—Establishes limits on the amount of medication a patient may receive during a designated period or in a single refill, such as a 30, 60, or 90-day supply.
- **Fail First Protocols**—Requires a demonstration that a generic drug, lower level of treatment or lower-cost drug fails to work for the patient before a health plan will approve a more expensive medication or treatment.
- **Prior Authorization Criteria**—Requires the submission and approval through the telephone, an online portal/website, or written coverage request for the health plan to cover the drug.
- **Mail-Order Criteria**—Requires a higher copay if the patient obtains the drug from a retail pharmacy versus the PBM's mail-order pharmacy.



Some health plans may offer a preferred drug list (PDL), which is a list of medications that are covered without the need to obtain prior authorization. However, the term is used inconsistently, and some health plans describe their complete tiered formulary as a PDL, noting the drugs that require prior authorization. Patients are strongly encouraged to read the fine print associated with any applicable PDL and drug formulary to make sure they understand what their cost-sharing responsibilities are.

Here is an example of one health plan’s three-tiered formulary structure, along with the general types of medications placed into each tier:<sup>7</sup>

**Three-Tiered Formulary Framework Example**

	<b>Tier 1</b>	<b>Tier 2</b>	<b>Tier 3</b>
<b>Copay</b>	\$6	\$12	\$24
<b>Type of Medications</b>	Generic medications	Preferred brand name medications	Non-preferred brand name medications

Here is a more detailed example of how specific medications were placed into the three-tiered formulary:<sup>8</sup>

**Three-Tiered Formulary Medication List Example**

<b>Drug Class</b>	<b>Tier 1</b>	<b>Tier 2</b>	<b>Tier 3</b>
<b>ACE Inhibitors</b>	<ul style="list-style-type: none"> <li>■ Captopril</li> <li>■ Enalapril maleate</li> </ul>	<ul style="list-style-type: none"> <li>■ Accupril (<i>quinapril</i>)</li> <li>■ Capoten (<i>captopril</i>)</li> <li>■ Lotensin (<i>benazepril</i>)</li> <li>■ Prinivil (<i>lisinopril</i>)</li> </ul>	<ul style="list-style-type: none"> <li>■ Aceon (<i>perindopril erbumine</i>)</li> <li>■ Altace (<i>ramipril</i>)</li> <li>■ Mavik (<i>trandolapril</i>)</li> <li>■ Monopril (<i>fosinopril</i>)</li> <li>■ Univasc (<i>moexipril</i>)</li> <li>■ Vasotec (<i>enalapril maleate</i>)</li> <li>■ Zestril (<i>lisinopril</i>)</li> </ul>
<b>Statins</b>	<ul style="list-style-type: none"> <li>■ Lovastatin</li> </ul>	<ul style="list-style-type: none"> <li>■ Baycol (<i>cerivastatin</i>)</li> <li>■ Lipitor (<i>atorvastatin</i>)</li> <li>■ Pravachol (<i>pravastatin</i>)</li> <li>■ Zocor (<i>simvastatin</i>)</li> </ul>	<ul style="list-style-type: none"> <li>■ Lescol (<i>fluvastatin</i>)</li> <li>■ Mevacor (<i>lovastatin</i>)</li> </ul>

Some plans require patients to pay the full cost of their prescribed medications until they reach their deductible, and only afterwards charge patients copays according to the formulary. Plans may also use a coinsurance system where the patient pays a percentage of the drug cost, rather than a fixed dollar copay amount.

Drug formularies can be an open or closed model. Under an open formulary model, non-formulary drugs are included but require a higher copayment. Under a closed formulary model, non-formulary drugs are not included, unless a plan grants an exception due to extraordinary circumstances. Some formularies include components of both open and closed formulary models.<sup>9</sup>

## Part II: State and Federal Laws Impacting Drug Formularies

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State laws regulating prescription drug coverage vary across the country and address a range of issues spanning from coverage mandates to utilization management protocols. Several states have passed laws mandating coverage of certain behavioral health medications. For example, Illinois passed a law in 2015 that requires the state Medicaid plan, and all Medicaid managed care plans operating in Illinois, to cover all FDA-approved medications for the treatment of substance use disorders.<sup>10</sup> Indiana also enacted a similar law in 2015 that requires Medicaid managed care organizations to cover medications used to treat substance use disorders as part of medication-assisted treatment.<sup>11</sup>

Some states have passed laws limiting the application of medical management protocols to prescription drugs, especially in the context of Medicaid. For example, New Hampshire<sup>12</sup> prohibits Medicaid managed care plans from using prior authorization requirements for medications used in the treatment of schizophrenia, bipolar disorder, and major depression, and New York<sup>13</sup> recently enacted a law barring all Medicaid plans from imposing prior authorization for preferred versions of MAT drugs for opioid use disorder. Although these laws play an important role in protecting those with Medicaid plans, it is important to recognize that state laws do not apply to “self-funded” employer health plans, which cover almost two-thirds of American workers.<sup>14</sup> This is due to the fact that the Employee Retirement Income Security Act of 1974 (ERISA) preempts state law to the extent that such laws relate to employer-sponsored health plans.<sup>15</sup> To learn more about state laws governing prescription drug coverage, visit [www.paritytrack.org](http://www.paritytrack.org).

Two laws, the Federal Parity Law and the Affordable Care Act (ACA), greatly impact behavioral health prescription drug coverage by expanding the coverage requirements for mental health and substance use disorders. Enacted in 2008, the Federal Parity Law requires health plans treat behavioral health benefits (including prescription drugs) in a manner comparable to physical health benefits. This means any utilization management strategy a health insurer may employ for behavioral health medications, such as prior authorization, must be comparable to the protocols in place for physical health medications (e.g. diabetes, hypertension, arthritis, etc.). Many state parity laws include similar requirements.

“State laws regulating prescription drug coverage vary across the country and address a range of issues spanning from coverage mandates to utilization management protocols.”



The ACA increased the number of health plans that are required to comply with the Federal Parity Law, and enhanced coverage protections. Prior to the ACA, the Federal Parity Law only applied to large group health plans with 50 or more employees, Medicaid managed care, and the Children’s Health Insurance Program (CHIP). The ACA expanded parity protections to the individual and small group markets, and to additional Medicaid plans. The ACA also mandated qualified health plans cover prescription drugs, mental health services, and addiction services as essential health benefits. This mandate prohibits individual and small group insurers from excluding behavioral health medications from their benefit packages. The federal mandate, however, does not delineate which mental and substance use disorder medications must be covered, but some state laws do contain specific measures.

## Part III: Common Challenges with Drug Formularies

Most drug formularies have restrictions that limit access to certain medications. These restrictions are put into place to help health plans maintain a competitive premium, to steer patients towards treatments with lower out-of-pocket costs, to limit the potential for medications to be diverted for resale, to ensure that prescribing is consistent with clinical best practices, and to increase the value delivered by prescriptions.<sup>16</sup> While restrictions can be potentially beneficial to patients and are not inherently illegal, some health plans impose restrictions that are more stringent for behavioral health medications than for physical health medications—actions which may violate the Federal Parity Law.

Below are five key issues impacting access to behavioral health medications:

“While restrictions can be potentially beneficial to patients and are not inherently illegal, some health plans impose restrictions that are more stringent for behavioral health medications than for physical health medications—actions which may violate the Federal Parity Law.”

### **1. Lack of formulary inclusion of evidence-based treatments.**

Formularies sometimes do not include certain prescription drugs used in the treatment of behavioral health disorders. This is particularly common for antipsychotics and MAT for substance use disorders. Some FDA-approved drugs used for MAT are absent from formularies despite numerous studies demonstrating that MAT reduces drug use, disease rates, and criminal activity. As of 2013, only 28 states covered all three FDA-approved medications for opioid use disorder (i.e. methadone, buprenorphine, and naltrexone) within their Medicaid programs,<sup>17</sup> while some private health plans have excluded coverage of methadone maintenance treatment entirely. Since patients respond differently to individual medications, it is important that health insurers cover applicable FDA-approved treatments that are clinically effective. This should include newer medications that are implanted or injected by a physician<sup>18</sup>—particularly in the midst of the national opioid crisis.

The complete exclusion of certain behavioral health medications from a prescription drug benefit is likely a violation of the Federal Parity Law or the ACA. The Federal Parity Law requires health plans to offer prescription drug coverage for mental and substance use disorders if plans offer behavioral health services and cover prescription drugs for other medical conditions. As above, the ACA extended this requirement to individual and small group plans that cover prescription drug treatment for behavioral health disorders. Unfortunately, neither the Federal Parity Law or the ACA mandates which prescription drugs are to be covered.

The Kennedy Forum encourages regulators to mandate, and health plans to offer, coverage for all clinically effective, FDA-approved MAT therapies for opioid-use disorders and to facilitate access to other behavioral health medications for mental health and addiction conditions that can improve clinical outcomes.

## 2. Cost-sharing requirements

Consumer cost-sharing requirements for behavioral health treatments can limit patient access to evidence-based medicine needed for effective treatment. These requirements can be particularly severe for antipsychotics and MAT for opioid-use disorders. For example, behavioral health drugs are sometimes placed on higher tiers, requiring the patient to pay a higher out-of-pocket amount for their medication.

The Federal Parity Law treats tiering (and its impact on cost-sharing) as both a quantitative and a non-quantitative treatment limitation. For a more detailed discussion on parity compliance requirements and how to file an appeal, see *Parity Resource Guide for Addiction and Mental Health Consumers, Providers, and Advocates*, which can be downloaded or viewed at [www.thekennedyforum.org/resources/issue-briefs/](http://www.thekennedyforum.org/resources/issue-briefs/).<sup>19</sup>

“Behavioral health drugs are sometimes placed on higher tiers, requiring the patient to pay a higher out-of-pocket amount for their medication.”

Generally, the cost-sharing for a behavioral health service (which may be dictated by formulary tiering) cannot be higher than the cost-sharing for a comparable physical health service, as determined by a quantitative analysis of plan claims data.<sup>20</sup> Additionally, if a plan creates prescription drug tiers based on reasonable factors (such as quality, performance, and market standards), it must do so without regard to whether a provider renders services with respect to medical/surgical benefits or mental health or substance use disorder benefits.<sup>21</sup>

## 3. Quantity limits

Formularies frequently restrict the amount of medications an individual can receive within a given time period. FDA-approved treatments for substance use disorders are sometimes subject to limits. For example, buprenorphine can be subject to quantity limits that restrict the number of doses an individual can receive in a given period. Sometimes, these requirements can only be lifted if the patient meets specific criteria, such as failing at a lower level of care or demonstrating the need for increased treatment.

Although some restrictions are medically appropriate (such as limiting quantities of immediate-release opioids that can be prescribed for non-cancer pain),<sup>22</sup> others may inhibit access to evidence-based care. Limiting these types of prescription drugs to a 14- or 30-day supply, for example, can be an attempt to control cost and limit use. Although such supply limits reduce medication waste by patients who discontinue usage and reduce the potential for diversion, they impose a burden on patients taking medications on an ongoing basis. Requiring an individual to constantly refill their prescription may create medication adherence issues impacting the effectiveness of treatment. This can be particularly counterproductive with a disease that fundamentally diminishes motivation, such as addiction.

“Requiring an individual to constantly refill their prescription may create medication adherence issues impacting the effectiveness of treatment.”

#### **4. Prior authorization requirements**

Health plans often impose prior authorization requirements for certain medications offered within both open and closed drug formulary models. When such requirements are in place, a request must be submitted and approved in advance before the health plan will cover the medication. While these requirements may benefit patients by adding an extra layer of verification to prove that their medications are clinically necessary, they may also serve as barriers to care.

Under the Federal Parity Law, health plans may impose prior authorization on behavioral health treatments only when prior authorization requirements applied to behavioral health services and medications are comparable to those applied to similar physical health treatments. For example, a health insurer may claim it follows nationally-recognized guidelines in determining its prior authorization protocols. However, a health insurer that requires prior authorization every thirty days for buprenorphine/naloxone refills for substance use disorder treatment may deviate from the American Society of Addiction Medicine (ASAM) national practice guidelines, a recognized clinical standard.<sup>23</sup> If the health plan does not deviate from established treatment protocols for prescription drugs used to treat physical health conditions, the lack of comparability between the processes used in determining the prior authorization requirements for behavioral health and physical health conditions is a likely violation of the Federal Parity Law.<sup>24</sup>

Prior authorization requirements for behavioral health treatments are particularly important because of their impact on medication adherence. One study found prior authorization policies for psychiatric medications are associated with increased medication discontinuation.<sup>25</sup> The hurdles associated with prior authorization requirements for MAT are of particular concern given the ongoing opioid crisis. However, in agreements with the New York State Attorney General, two major insurance companies—Anthem and Cigna—recently changed their policies and have removed all prior authorization requirements for buprenorphine for addiction treatment.<sup>26</sup> Several other health plans, including Aetna, have dropped similar prior authorization requirements.<sup>27</sup>

### **5. Fail-first/step therapy protocols**

Fail-first or step therapy protocols require an individual try a medication or treatment before an insurer will approve another drug. These fail-first requirements are commonly applied to behavioral health medications. Although step therapy requirements for certain medications may be appropriate, protocols must consider the likelihood of severe side effects and challenges with medication adherence. Delaying access to the most effective treatment for an individual can impact health status, quality of life, education, and employment. Such delay may also result in higher costs to the patient and the system if emergency care or hospitalization is needed, at odds with the cost savings intent. When fail-first protocols are applied more stringently to behavioral health medications than to other medications, it might be a violation of the Federal Parity Law.

Health insurers may attempt to require individuals try generic drugs prior to approving a branded behavioral health drug. For example, in order to receive authorization for Abilify, a drug used to treat schizophrenia and bipolar disorder, an individual might be required to first try aripiprazole, the generic version of Abilify. Although generic versions of drugs are often as safe and as effective as brand-name versions, a subset of the population may not respond as well based upon differences between the two versions of the drug, especially for medications that fall under the “Narrow Therapeutic Index.”<sup>28</sup> This issue exists because generic drugs and branded drugs may contain crucial differences in their inactive ingredients which impact absorption by the body.

## **Part IV: Identifying Potential Solutions**

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**T**he common problems with formularies outlined in Section III call for action by individuals, advocates, health plan sponsors and policymakers. The following ten action steps will advance access to medications and improve equity in prescription drug coverage related to both behavioral and physical health drugs. Resources listed at the end of this brief will help individuals take steps to improve their understanding of formularies and prescription drug barriers and how to overcome them.

### **1. Increase public awareness of drug formularies**

The design and application of drug formularies is a complex process, and many individuals do not know the basic elements of accessing prescription drugs through their health plan. Health plans, consumer advocates, PBMs, prescribers, and regulators should work together to develop public education campaigns that increase consumer and provider knowledge of formulary design and prescription drug access coverage, and how it affects access to effective treatment.

**2. Learn about your drug formulary before you need it**

Information on drug formularies is publicly available online for most health plans, and varies from plan to plan.<sup>29</sup> We encourage patients, doctors, purchasers and others to review this information before purchasing health plan coverage so they can compare the different formularies and find the design that is best suited to their needs. Patients or their caregivers should check whether the medications they need are covered and the cost-sharing requirements associated with each of them. Consumer groups, state agencies, online tools, and health plan representatives can review the formulary with them as needed.

**3. Understand the placement of your medications on your formulary**

If a patient is being treated with prescription drugs, it is important to learn about any medical management practices, such as prior authorization or cost-sharing requirements, applied to the patient’s medications. By knowing this information, patients can limit gaps in access by being aware of financial obligations and by submitting the proper paperwork on time.

**4. Consider drug coupon and assistance programs**

Pharmaceutical companies sponsor drug coupon and patient assistance programs<sup>30</sup> to help individuals pay for medications when formulary placement imposes a cost-sharing requirement that places the drug out of financial reach. These programs may be a useful tool if your doctor or physician assistant prescribes a medication not included within your prescription drug benefit or with high cost-sharing. These are sometimes accessible via an online search. It is important to talk with your health plan or the PBM about why medications are placed in lower tiers.

**5. Improve and expand enforcement of the Federal Parity Law**

The Federal Parity Law requires medical management practices applied to behavioral health care, including



formulary design, prior authorization requirements, and fail first protocols, be comparable to those applied to physical health care. If this law were properly enforced, many of the restrictions outlined above would be investigated by federal and state agencies for potential violations. If violations were identified, health plans would be required to change their practices to apply the same restrictions for behavioral health and physical health care. You can help advocate for full enforcement of the Federal Parity Law and state parity laws by contacting your employer's benefits office, legislators and regulators, or by joining or starting a local parity implementation coalition. We also encourage you to log any complaints at [www.parityregistry.org](http://www.parityregistry.org), a Kennedy Forum website that collects examples of potential parity violations to advocate for improved enforcement and better coverage.

### ***6. Advocate to maintain prescription drug coverage as an essential health benefit***

The Affordable Care Act (ACA) requires individual and small group health plans provide prescription drug coverage. Prior to the ACA, nearly one in ten health insurance plans purchased by individuals did not provide this coverage.<sup>31</sup> As Federal law evolves, it may be necessary to advocate for the maintenance of this consumer protection.

### ***7. Learn the state laws that impact drug formularies***

Drug formularies are often regulated at the state level, with diverse requirements across the country. It is useful to know about the basic provisions regarding formulary design and prescription drug coverage in your state so you can become a well-informed advocate for stronger consumer protections. Visit [www.paritytrack.org](http://www.paritytrack.org) for a state-by-state map of legislation related to parity, including drug formularies. At the same time, state law has limitations and often does not apply to self-funded employer plans, Medicare plans and several other insurance arrangements.

### ***8. File a complaint with state and federal agencies***

State departments of insurance, state attorneys general, federal agencies such as the Centers for Medicare and Medicaid Services (CMS), the U.S. Department of Labor (DOL), and other regulatory agencies maintain consumer complaint systems that allow individuals to submit information about problems regarding their insurance, including challenges to accessing prescription drugs.<sup>32</sup> Agencies use this information to trigger investigations of health plans. If you are struggling to obtain coverage for a prescribed medication, we encourage you to contact your employer's benefits office, broker or other applicable contact, and to submit a consumer complaint to the agency that regulates your insurance. To learn more about who regulates your health plan, visit [www.parityregistry.org](http://www.parityregistry.org) and go to the "Resources" page for a comprehensive list of regulatory agencies within your state and other helpful resources including groups that can help you file a complaint.

### **9. Know how to file an insurance appeal when your prescription drug is not covered**

In addition to filing insurance complaints, if not resolved, insured individuals can take advantage of the health plan appeals process. Filing an appeal provides an opportunity for individuals, their advocates and doctors to investigate if a health plan unfairly denied or restricted access to treatment, including prescription medication. To learn more about the appeals process—including what you need to do and timeframes—read *The Kennedy Forum's Parity Resource Guide for Addiction & Mental Health Consumers, Providers and Advocates* and the Issue Brief, *Filing an Appeal Based on a Parity Violation*.<sup>33</sup> To download a free electronic version of this document, visit [www.thekennedyforum.org/resources/issue-briefs/](http://www.thekennedyforum.org/resources/issue-briefs/)

### **10. Advocate for legislative solutions that protect consumers' rights**

Few state legislatures have successfully passed bills concerning prescription drug coverage to ensure parity compliance. However, legislators throughout the country continue to introduce bills that increase access to mental health and addiction medications.<sup>34</sup> Many of these bills address cost-sharing requirements, prior authorization or step therapy protocols, and medical necessity criteria used in designing formularies. For example, a 2015 Maryland bill (HB 534), entitled “Health Insurance—Coverage of Brand Name Prescription Drugs for Mental Health Treatment,” attempted to remove differences in cost-sharing requirements between branded and generic behavioral health medications. In 2016, New York enacted a law that created an expedited appeals process allowing consumers and their providers to challenge health plans’ step therapy decisions.<sup>35</sup> Consumers, providers, and advocates are encouraged to support similar legislation that helps promote medication equality.

## **Part V: Summary**

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Formulary design, especially for behavioral health medications, remains a complex area. Health insurers continue to struggle with balancing the proper use of resources while not restricting medically necessary care. By developing and promoting awareness of applicable federal and state laws, consumers, healthcare providers, and patient advocates can ensure those in need of behavioral health medications receive them in an equitable manner.

Additional consumer resources listed in the Appendix contain useful information about prescription coverage and drug formularies. For more information on this topic or issue brief reprints, contact Garry Carneal, JD, Senior Policy Advisor, The Kennedy Forum, at [info@thekennedyforum.org](mailto:info@thekennedyforum.org) or call (732) 908-1111. See also [www.thekennedyforum.org](http://www.thekennedyforum.org) and [www.paritytrack.org](http://www.paritytrack.org).

## Appendix: Consumer Resources

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Listed below are resources that consumers can use to learn more about how to get prescriptions filled and covered by their health plan, and how drug formularies work:

Appleby J. Filling A Prescription? You Might Be Better Off Paying Cash. *Kaiser Health News*. June 24, 2016. Available at: <http://khn.org/news/filling-a-prescription-you-might-be-better-off-paying-cash/>.

Prescription Assistance Programs: Health Information for Older People. *Federal Trade Commission*. Available at: <https://www.consumer.ftc.gov/articles/0319-prescription-assistance-programs-health-information-older-people>

Save Money on Meds: 9 Tips for Finding the Best Prescription Drug Prices. *Consumer Reports*. Available at: <http://www.consumerreports.org/drugs/6-tips-for-finding-the-best-prescription-drug-prices/>.

Your Health Plan's Formulary: The List of Preferred Prescription Drugs. *Consumer Reports: Health.org*. Available at: <http://consumerhealthchoices.org/wp-content/uploads/2012/01/Formulary.pdf>.

Getting Prescription Medications: Using Your Health Insurance Coverage. *Healthcare.gov*. Available at: <https://www.healthcare.gov/using-marketplace-coverage/prescription-medications/>.

M. Meadows. (September 2005). Saving Money on Prescription Drugs. *US Food & Drug Administration*. Available at: <https://www.fda.gov/Drugs/EmergencyPreparedness/BioterrorismAndDrugPreparedness/ucm134215.htm#companies>.

Frequently Asked Questions About Patient Assistance Programs. *RxAssist*. Available at: <http://www.rxassist.org/faqs>.

My insurance won't pay for the drug my doctor prescribed. What are my options? *The Myositis Association*. Available at: <http://www.myositis.org/learn-about-myositis/faqs/545-my-insurance-wont-pay-for-the-drug-my-doctor-prescribed-what-are-my-options>.

Parity Registry Resources. *The Kennedy Forum*. Available at: <https://parityquest.org/#resources>.

Participating Patient Assistance Programs. *Partnership for Prescription Assistance*. 2017. Available at: [https://www.pparx.org/prescription\\_assistance\\_programs/list\\_of\\_participating\\_programs](https://www.pparx.org/prescription_assistance_programs/list_of_participating_programs).

Get Prescription Health. *Partnership for Prescription Assistance*. Available at: <https://www.pparx.org/>.

Save Money on Meds: 9 Tips for finding the Best Prescription Drug Prices. *Consumer Reports*. March 8, 2017. <http://www.consumerreports.org/drugs/6-tips-for-finding-the-best-prescription-drug-prices/>.

Schiff GD, Galanter WL, Duhig J, Koronkowski MJ, Lodolce AE, Pontikes P, Busker J, Touchette D, Lambert BL. A prescription for improving drug formulary decision making. *PLoS Medicine*. 2012 May 22;9(5):e1001220. Available at: <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001220>.

Skinner G. 4 Ways to Get Insurance to Cover Your Prescription Drugs. *Consumer Reports*. February 12, 2016. Available at: <https://www.consumerreports.org/health/4-ways-to-get-insurance-to-cover-your-prescription-drugs/>

What to Do When Your Insurance Company Says "No." *Texas Medical Association*. Available at: <https://www.texmed.org/Template.aspx?id=4537>.



## About The Kennedy Forum

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### A Message from Patrick J. Kennedy

I founded The Kennedy Forum in 2013 as a way to convene cutting-edge thinkers who are united by the potential for reform in behavioral health service delivery made possible by new laws, revolutionary technologies and an enhanced understanding of effective services and treatments. Our inaugural event in October of that year called for The Forum to develop a platform to advance thinking across a host of issues in our field. To meet this demand, The Kennedy Forum is organized as a think tank poised to drive real, lasting and meaningful policy change to bring the nation closer to fulfilling President Kennedy's vision as outlined in the 1963 Community Mental Health Act.

Today, The Kennedy Forum's work is not singular in its focus. We are promoting mental health coverage through a series of initiatives, which include:

- Ensuring health plan accountability and compliance with the letter and spirit of the parity law by educating consumers, providers, and regulators, so that each group holds themselves and others accountable for proper enforcement.
- Establishing ways to promote provider accountability through evidence-based outcomes measures that are validated and quantifiable.
- Implementing proven collaborative practice models that promote the integration of mental health and substance use disorder services into mainstream health care.
- Using technology to optimize electronic/digital communications and enhance assessment/treatment tools.
- Promoting brain fitness and wellness, which includes identifying opportunities to translate neuroscience research findings into preventive and treatment interventions.

Please visit our website, [www.thekennedyforum.org](http://www.thekennedyforum.org), to track our ongoing activities in support of these five initiatives and other activities central to The Kennedy Forum's mission.

### **Patrick J. Kennedy**

*Founder*

## Endnotes

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- <sup>1</sup> Fail-first policies, also known as step therapy requirements, are health insurance requirements that encourage or mandate that it be demonstrated that the patient has not responded to less expensive drugs before more expensive drugs may be covered.
- <sup>2</sup> Suicide Statistics—AFSP. American Foundation for Suicide Prevention. 2017. Available at: <https://afsp.org/about-suicide/suicide-statistics/>. Accessed July 25, 2017.
- <sup>3</sup> Katz J. Drug Deaths in America Are Rising Faster Than Ever. The New York Times. <https://www.nytimes.com/interactive/2017/06/05/upshot/opioid-epidemic-drug-overdose-deaths-are-rising-faster-than-ever.html>. Published June 5, 2017. Accessed July 25, 2017.
- <sup>4</sup> Brown A. 'Comes close to malpractice:' Barriers keep effective treatment away from South Carolina opioid addicts. The Post and Courier. [http://www.postandcourier.com/news/comes-close-to-malpractice-barriers-keep-effective-treatment-away-from/article\\_e649d40c-689d-11e7-b32e-07f5d93265f6.html](http://www.postandcourier.com/news/comes-close-to-malpractice-barriers-keep-effective-treatment-away-from/article_e649d40c-689d-11e7-b32e-07f5d93265f6.html). Published 2017. Accessed July 25, 2017.
- <sup>5</sup> Horgan CM, Reif S, Hodgkin D, Garnick DW, Merrick EL. Availability of addiction medications in private health plans. *J. Subst. Abuse Treat.* 2008;34(2):147-56.
- <sup>6</sup> Vogenberg FR, Gomes J. The changing roles of P&T committees: A look back at the last decade and a look forward to 2020. *Pharmacy and Therapeutics.* 2014 Nov; 39(11):760-72.
- <sup>7</sup> Huskamp HA, Deverka PA, Epstein AM, Epstein RS, McGuigan KA, Frank RG. The effect of incentive-based formularies on prescription-drug utilization and spending. *New England Journal of Medicine.* 2003 Dec 4;349(23):2224-32.
- <sup>8</sup> Ibid.
- <sup>9</sup> Edlin M. Closed formularies hold the line on costs. Managed Healthcare Executive. March 12, 2015. Available at: <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/closed-formularies-hold-line-costs>. Accessed July 25, 2017.
- <sup>10</sup> Legislative Overview in Illinois. ParityTrack. Available at: <https://paritytrack.org/report/illinois/illinois-legislation/>. Accessed July 26, 2017.
- <sup>11</sup> Legislative Overview in Indiana. ParityTrack. Available at: <https://paritytrack.org/report/indiana/indiana-legislation/>. Accessed July 26, 2017.
- <sup>12</sup> Legislative Overview in New Hampshire. ParityTrack. Available at: <https://paritytrack.org/report/new%20hampshire/new%20hampshire-legislation/>. Accessed July 26, 2017.
- <sup>13</sup> Townley C. New York Joins State-Led Fight to Combat Opioid Crisis, Passes New Legislation—NASHP. National Academy for State Health Policy. July 11, 2016. Available at: <http://nashp.org/new-york-joins-state-led-fight-to-combat-opioid-crisis-passes-new-legislation/>. Accessed July 25, 2017.
- <sup>14</sup> 2015 Employer Health Benefits Survey—Section Ten: Plan Funding. The Henry J Kaiser Family Foundation. September 22, 2015. Available at: <http://www.kff.org/report-section/ehbs-2015-section-ten-plan-funding>. Accessed July 25, 2017.
- <sup>15</sup> ERISA Preemption Primer, National Academy for State Health Policy. Available at: [http://www.nashp.org/sites/default/files/ERISA\\_Primer.pdf](http://www.nashp.org/sites/default/files/ERISA_Primer.pdf). Accessed July 31, 2017. ERISA stands for Employee Retirement Income Security Act (ERISA) of 1974.
- <sup>16</sup> Soumerai SB. Benefits and risks of increasing restrictions on access to costly drugs in Medicaid. *Health Affairs.* 2004 Jan-Feb;23(1):135-46.
- <sup>17</sup> Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment. The American Society of Addiction Medicine. 2013. Available at: [https://www.asam.org/docs/default-source/advocacy/aaam\\_implications-for-opioid-addiction-treatment\\_final](https://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final). Accessed July 25, 2017.
- <sup>18</sup> Confronting an Epidemic: The Case for Eliminating Barriers to Medication Assisted Treatment of Heroin and Opioid Addiction—Legal Action Center. Legal Action Center. March 2015. Available at: <https://lac.org/wp-content/uploads/2014/07/LAC-The-Case-for-Eliminating-Barriers-to-Medication-Assisted-Treatment.pdf>. Accessed July 25, 2017.

- <sup>19</sup> Available at [https://www.thekennedyforum.org/wp-content/uploads/2017/06/KennedyForum-ResourceGuide\\_FINAL\\_2.pdf](https://www.thekennedyforum.org/wp-content/uploads/2017/06/KennedyForum-ResourceGuide_FINAL_2.pdf). Accessed August 1, 2017.
- <sup>20</sup> 45 C.F.R. 146.136(c).
- <sup>21</sup> 45 C.F.R. 146.136(c)(3)(iii)(A).
- <sup>22</sup> Guideline for Prescribing Opioids for Chronic Pain. Centers for Disease Control and Prevention Available at: [https://www.cdc.gov/drugoverdose/pdf/guidelines\\_factsheet-a.pdf](https://www.cdc.gov/drugoverdose/pdf/guidelines_factsheet-a.pdf). Accessed July 25, 2017.
- <sup>23</sup> Advancing Access to Addiction Medications: Implications for Opioid Addiction Treatment. The American Society of Addiction Medicine; 2013. Available at: [https://www.asam.org/docs/default-source/advocacy/aaam\\_implications-for-opioid-addiction-treatment\\_final](https://www.asam.org/docs/default-source/advocacy/aaam_implications-for-opioid-addiction-treatment_final). Accessed July 25, 2017.
- <sup>24</sup> FAQs About Affordable Care Act Implementation Part 34 And Mental Health and Substance Use Disorder Parity Implementation, Q.8. United States Department of Labor. October 27, 2016. Available at <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-34.pdf>. Accessed July 31, 2017.
- <sup>25</sup> Lu CY, Adams AS, Ross-Degnan D, Zhang F, Zhang Y, Salzman C, Soumerai SB. Association between prior authorization for psychiatric medications and use of health services among Medicaid patients with bipolar disorder. *Psychiatric Services* (Washington, DC). 2011 Feb;62(2):186-193.
- <sup>26</sup> A.G. Schneiderman Announces National Settlement with Cigna To Discontinue Pre-Authorization for Opioid Addiction Treatment Drugs. New York State Attorney General. October 21, 2016. Available at: <https://ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-cigna-discontinue-pre-authorization>. Accessed July 25, 2017.
- <sup>27</sup> Changes that are streamlining the process to treat opioid addiction. Aetna. March 2017. Available at: <https://news.aetna.com/2017/03/streamlining-to-help-treat-opioid-addiction/>. Accessed July 25, 2017.
- <sup>28</sup> The Truth About Generic Vs. Brand-Name Medications. The Huffington Post. February 22, 2015. Available at: [http://www.huffingtonpost.com/2015/02/22/generic-prescriptions\\_n\\_6730194.html](http://www.huffingtonpost.com/2015/02/22/generic-prescriptions_n_6730194.html). Accessed July 25, 2017.
- <sup>29</sup> For example, see: National Drug List. Anthem BlueCross BlueShield; June 15, 2017. Available at: [https://fm.formularynavigator.com/FBO/143/National\\_5\\_Tier\\_ABCBS.pdf](https://fm.formularynavigator.com/FBO/143/National_5_Tier_ABCBS.pdf). Accessed July 25, 2017.
- <sup>30</sup> For example, see: Participating Patient Assistance Programs. Partnership for Prescription Assistance. 2017. Available at: [https://www.pparx.org/prescription\\_assistance\\_programs/list\\_of\\_participating\\_programs](https://www.pparx.org/prescription_assistance_programs/list_of_participating_programs). Accessed July 25, 2017.
- <sup>31</sup> Jost T. Essential Health Benefits: What Could Their Elimination Mean? *Health Affairs*. 2017. Available at: <http://healthaffairs.org/blog/2017/03/23/essential-health-benefits-what-could-their-elimination-mean/>. Accessed July 25, 2017.
- <sup>32</sup> To file a complaint, access the CMS website at <https://www.medicare.gov/claims-and-appeals/file-a-complaint/quality-of-care/complaints-about-quality-of-care-.html> and the US DoL website at <https://www.dol.gov/whd/howtofilecomplaint.htm>. For state-based information, go to [www.parityregistry.com](http://www.parityregistry.com) and click on the resource navigation button. Click on your state for additional information on how to file a complaint.
- <sup>33</sup> Parity Resource Guide for Addiction & Mental Health Consumers, Providers and Advocates. The Kennedy Forum; Winter 2015. Available at: [http://thekennedyforum.org/wp-content/uploads/2017/06/KennedyForum-ResourceGuide\\_FINAL\\_2.pdf](http://thekennedyforum.org/wp-content/uploads/2017/06/KennedyForum-ResourceGuide_FINAL_2.pdf). Accessed July 25, 2017.
- <sup>34</sup> Filing an Appeal Based on a Parity Violation. The Kennedy Forum; 2017. Available at: <https://paritytrack.org/wp-content/uploads/2017/06/20170615-The-Kennedy-Forum-Filing-an-Appeal-Issue-Brief-Final-1.pdf>. Accessed July 25, 2017.
- <sup>35</sup> HB 534 Fiscal and Policy Note: Health Insurance—Coverage of Brand Name Prescription Drugs for Mental Health Treatment. Department of Legislative Services, Maryland General Assembly; 2015. Available at: [http://mgaleg.maryland.gov/2015RS/fnotes/bil\\_0004/hb0534.pdf](http://mgaleg.maryland.gov/2015RS/fnotes/bil_0004/hb0534.pdf). Accessed July 31, 2017.
- <sup>36</sup> Goldberg D. Cuomo Signs Step Therapy Bill, Vetoes Enhanced Safety-net Legislation. Mental Health Association in New York State, Inc. December 31, 2016. Available at: <https://mhanys.org/mha-update-1517-governor-cuomo-signs-step-therapy-bill-law-thank-great-advocacy-support/>. Accessed July 31, 2017.

