



Promoting Access to Affordable Prescription Drugs:

Policy Analysis and Consumer Recommendations for State Policymakers, Consumer Advocates, and Health Care Stakeholders

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Introduction



The high price of prescription drugs combined with increasingly higher cost-sharing has shifted significant costs to consumers. This is particularly true for new therapies that, in some cases, cost hundreds of thousands of dollars for a single course of treatment. Pharmaceutical innovation remains vital for consumers: New products offer fewer side effects, improved quality of life, and the possibility of living a longer, more productive life. But the cost of prescription drugs is straining family budgets and putting treatment out of reach for many consumers. Given the impact of high drug prices on consumers, payers, and government budgets, prescription drug costs are a matter of serious public concern.

State and federal insurance regulators, marketplace officials, and lawmakers play a critical role in ensuring that consumers in the commercial health insurance market have access to the affordable prescription drugs they need. This report includes a series of recommendations to assist regulators, lawmakers, and the National Association of Insurance Commissioners (NAIC) on ways to promote access, affordability, nondiscrimination, transparency, and meaningful oversight of prescription drug coverage.

Prescription Drug Prices Continue to Increase.

Spending on prescription drugs in the United States was about \$457 billion in 2015, accounting for 16.7 percent of total health care spending.¹ The rate of drug spending has grown significantly in recent years, rising by a remarkable 12.6 percent in 2014 alone.² This trend is expected to continue: From 2013 to 2018, prescription drug spending is projected to rise by an average of 7.3 percent annually, far faster than the growth rate of all health care spending.³ Given these trends, the price of prescription drugs will continue to be a contributor to long-term growth in health care costs.

Prescription drug spending is increasing for a number of reasons. First, more people are living with chronic conditions that require prescription drug treatment. The total number of prescriptions increased by 11 percent between 2010 and 2014,⁴ up to 3.92 billion prescriptions in 2014. Prescription drug affordability is especially important for the 191 million Americans with at least one chronic condition and the 75 million Americans with multiple chronic conditions who may rely on more than one costly medication.⁵

Second, there have been significant advances in the treatment of certain high-cost conditions like hepatitis C and heart disease but often at hefty price tags. Spending on drugs used to treat these conditions—often known as specialty drugs, whose prices range from several thousand dollars to hundreds of thousands of dollars annually—could quadruple between 2012 and 2020, reaching about \$400 billion, or 9.1 percent of national health spending.⁶ Specialty drugs alone can account for more than half of total annual health costs for many chronic conditions.⁷

Finally, some drug manufacturers have been aggressive about raising prices for older brand-name drugs, many of which have been on the market for years, at rates that outpace inflation. A recent survey found that about half of 3,000 older brand-name drugs increased in price between December 2014 and January 2016.⁸ For nearly a third of these drugs, the increase was above 10 percent while some drugs, such as Daraprim, have seen increases of more than 5,000 percent.⁹ Generic drug prices are also rising: In 2015, federal regulators found that 22 percent of the top 200 generic drugs from 2005 to 2014 had prices that exceeded the cost of inflation.¹⁰

Consumers Need Access to Affordable Prescription Drugs.

Consumers are bearing the burden of these high drug prices through higher premiums and cost-sharing. In 2015, 24 percent of people taking prescription drugs reported having a difficult time affording their medication, and 76 percent of Americans favored limiting the amount that drug manufacturers can charge for high-cost drugs to treat illnesses like hepatitis or cancer.¹¹

Plan features used to manage drug costs, such as cost-sharing, can reduce drug adherence, potentially resulting in worse outcomes and higher health care costs. Recent studies show that high cost-sharing for specialty drugs to treat rheumatoid arthritis, multiple sclerosis, and cancer can make enrollees more likely to fail to start, to abandon, or to delay treatment.¹² Consumers are also reducing the dosage and regularity of their prescription drug intake, asking providers to prescribe less-expensive medications, or using alternative therapies to offset high out-of-pocket costs.¹³

Although high drug prices affect all employers and consumers, marketplace enrollees may be uniquely affected by high out-of-pocket costs for prescription drugs. Recent studies show that out-of-pocket prescription drug costs in average silver marketplace plans are twice as high as in average employer-sponsored plans, resulting in fewer prescriptions filled and refilled and in higher spending on other medical services.¹⁴ And 26 percent of marketplace enrollees report that their plan either would not cover or required a very expensive copay for a prescribed drug.¹⁵ Other studies have shown that about 10 percent of lowest-income marketplace enrollees—those with incomes below 200 percent of the federal poverty level in 2016—will spend nearly 20 percent of their annual income on premiums and out-of-pocket medical costs, including prescription drugs.¹⁶

How to Use This Report.

As consumer representatives to the NAIC, access to affordable prescription drugs is of critical importance to the millions of individuals and families we represent nationwide. The purpose of this report is to convey our perspective on appropriate standards and guidelines for promoting access to affordable prescription drugs.

The primary audiences for our recommendations are state insurance regulators and lawmakers, consumer advocates, and other stakeholders who play a critical role in establishing new standards for prescription drug access and enforcing consumer protections. We hope this analysis and report will inform your efforts to promote access to affordable prescription drugs.

To assist you in these efforts, each section includes an overview of a specific issue, examples of state approaches to addressing that issue, and recommendations for consumer-protective policies to be considered by state and federal policymakers. The recommendations address a variety of topics, including the following:

- Pharmacy & Therapeutics Committees
- Exceptions and Appeals Processes
- Continuity of Drug Coverage
- Addressing Health Disparities
- Drug Cost-Sharing
- Adverse Tiering
- Formulary Transparency
- Mid-Year Formulary Changes
- Consumer Support Tools
- Data Collection and Analysis
- Pharmacy Benefit Managers
- Value-Based Pricing

We recognize that rising prescription drug prices are a complex public policy issue and that the recommendations in this report—which are limited to reforms in the commercial health insurance market—will not fully address all concerns related to prescription drug prices. In addressing these issues, we encourage federal, state, and industry decision-makers to adopt policies that protect consumers and incentivize the development of new therapies that provide real value to patients and the health care system.

DISCLAIMER

The enclosed chapters were reviewed by teams of professionals who are currently serving as consumer representatives to the NAIC. We were selected to serve by the NAIC Commissioners and represent millions of American health care consumers across the country. The specific recommendations contained in the materials were not presented to the NAIC or the organizations with which the drafters are affiliated for formal endorsement. Organizational affiliations are listed for identification purposes only.

These recommendations are limited to the role of regulators and private health insurers in promoting access to affordable prescription drugs in the commercial health insurance market. As such, we do not address other critical reforms of equal importance to millions of consumers, such as drug development and approval processes, federal and state efforts to address prescription drug prices set by manufacturers, and direct-to-consumer advertising, among other topics. Although outside of the scope of these recommendations, we will continue to be engaged on these issues and work collaboratively with the NAIC, state regulators and lawmakers, and the federal government to help ensure that consumer needs are met.

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Improving Access to Comprehensive Prescription Drug Coverage



Although more Americans have health insurance than ever before, consumers still face barriers in accessing the drugs they need.

Limited access may be due to gaps in formulary composition, gaps in a plan's pharmacy network, or gaps when a plan changes its formulary from one year to the next. Drug access is also limited by drug tiering, high cost-sharing, or restrictive utilization management (UM) criteria, which can result in reduced drug adherence and potentially worse health outcomes and higher health care costs. For instance, seven insurers in New York recently entered into an agreement to cover medications for hepatitis C for nearly all commercially insured patients after an investigation by the state attorney general found wide discrepancies in how these drugs were being covered.¹⁷

Insurers and their designees continue to retain significant flexibility in drug benefit design. However, minimum standards can be set to ensure that consumers have access to medically necessary medications when they transition from one plan to another—or can take advantage of standardized drug exceptions and appeals processes if they need a drug that is not covered on a formulary. Stakeholders—including insurers, their designees, pharmacists, and others—can also do more to actively reduce drug-specific health disparities that disproportionately impact underserved communities, such as communities of color, individuals with disabilities, and individuals with limited English proficiency.

This section discusses the ways that state and federal regulators, lawmakers, marketplace officials, industry representatives, and other stakeholders can improve access to comprehensive prescription drug coverage in the areas of **pharmacy and therapeutics committees, exceptions and appeals processes, pharmacy network access, continuity of drug coverage, and addressing health disparities**. Each section includes background information, examples of state and federal approaches, and recommendations for consumer-protective policies.



Key Recommendations for Improving Access to Comprehensive Prescription Drug Coverage

- Require P&T committees to meet minimum standards for membership, conflicts of interest, and coverage decisions
- Adopt transparent, easy-to-understand exceptions processes that allow enrollees to request nonformulary drugs, tiering exceptions, and utilization management exceptions
- Adopt minimum quantitative access standards for retail pharmacies and ensure that pharmacy networks are not designed in a way that is potentially discriminatory or discourages enrollment of consumers in a given service area
- Provide a one-time, temporary supply of medically necessary formulary or nonformulary drugs within the first 90 days of coverage for all enrollees
- Address health disparities by promoting equal access to prescription drug utilization, adopting comprehensive nondiscrimination policies, and ensuring that all drug-related information is accessible to individuals with disabilities and individuals with limited English proficiency

PHARMACY AND THERAPEUTICS COMMITTEES

Drug coverage can be highly complex and requires insurers and their designees to grapple with whether and how to cover costly treatments and therapies. These decisions extend far beyond determining whether a drug is listed on a given plan's formulary; rather, insurers and other designees must determine what tier a covered drug will be placed on and whether to apply UM, such as step therapy or prior authorization. Each of these decisions has significant consequences for consumers and the health insurance market as a whole as it appears some plans continue to use formulary design to limit the risk of adverse selection.

To make these complex decisions, many insurers rely on **pharmacy and therapeutics (P&T) committees**. A P&T committee is a group of practicing medical professionals—including physicians, pharmacists, and other prescribers—that is responsible for managing a plan's formulary. In this role, a P&T committee will make coverage determinations; establish tiering and utilization management criteria; review medical and scientific evidence on the safety and effectiveness of drugs and biologics; and evaluate drugs or indications that are newly approved by the Food and Drug Administration (FDA). Most pharmacy benefit managers (PBMs) also use a P&T committee or similar clinical review body to determine how and whether a given drug will be covered under a formulary.

Given their importance, state and federal regulators and the NAIC have established minimum standards for P&T committees. The NAIC addresses P&T committees in its Health Carrier Prescription Drug Benefit Management Model Act, and the U.S. Department of Health and Human Services (HHS) has established P&T committee standards for new plans in the individual and small group markets and Medicare prescription drug plans (Figure 1). Despite these standards, P&T committees have significant flexibility in formulary design, and enforcement gaps persist in areas such as conflicts of interest among P&T committee members.¹⁸

P&T committees must first ensure that plan formularies meet **minimum coverage standards**. New individual and small group plans, for instance, must cover at least the greater of one drug in every United States Pharmacopeia category or class or the same number of drugs in each category and class as the state’s essential health benefits benchmark plan.¹⁹ In designing formularies for these plans, P&T committees must make coverage and UM decisions based on accepted best medical practices or standards of care and ensure that formularies cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states.²⁰ Medicare Part D prescription drug plans must also meet specific adequacy standards.²¹ However, the current version of the NAIC Health Carrier Prescription Drug Benefit Management Model Act—which is currently in the process of being revised—does not include a specific minimum coverage standard for P&T committees at this time.²²

Second, P&T committees should **meet at least quarterly** and evaluate and update formulary treatment protocols and procedures at least annually. Regular meetings help ensure that P&T committees review newly approved drugs and indications in a timely manner and allows for ongoing evaluation of other changes related to UM, exceptions processes, and therapeutic interchange as needed. In particular, P&T committees should be required to review a newly approved therapy or indication within 90 days of approval by the FDA and make a coverage determination within 180 days of the therapy’s release onto the market. All coverage decisions should be based on clinical appropriateness, therapeutic advantage, safety, and effectiveness. For more information on newly approved therapies, please see the section of this report on “Addressing Emerging Therapies.”

Third, insurers and their designees should document all procedures, and P&T committees should maintain written documentation of the rationale for all coverage decisions. P&T committees should also have to meet **transparency requirements**, including holding public meetings, giving public notice of meeting times, publicly posting agendas and minutes on the plan’s website, and allowing for public input on proposed changes to a formulary that could negatively affect enrollees. Such changes include the removal of a drug from a formulary (except for safety reasons which should be allowed as needed), moving a drug to a higher formulary tier, or imposing new or more restrictive UM. This additional transparency will help increase the availability and accessibility of information for consumers, consumer advocates, and other stakeholders.

Fourth, P&T committees should have **at least 15 members**, a majority of which are practicing physicians, pharmacists, and other health care professionals who are licensed to prescribe drugs. Members should represent a sufficient number of clinical specialties and sub-specialties to adequately meet the needs of enrollees, including experts in providing care for older Americans, individuals with disabilities, children, and individuals with rare diseases. Where members do not have sufficient clinical expertise, P&T committees should use expert panels, subcommittees, specialists and subspecialists, and other consultation processes as needed to obtain relevant expertise. Regulators and plans should also consider ensuring that P&T committees include at least two consumer representatives who represent patient or consumer advocacy organizations.

Finally, P&T committee standards should have **strong conflict of interest protections**. All P&T committee members should sign a conflict of interest statement revealing economic or other relationships with entities that could influence a member’s decisions, and at least 20 percent of P&T committee membership must not have a conflict of interest with respect to the insurer, any designee, or any pharmaceutical manufacturer.²³ Members should be prohibited from voting on any matters for which the conflict exists.

State Action.

State-specific standards for P&T committees do exist but do not appear to be widespread. Only a handful of states have adopted standards that are similar to the NAIC's Health Carrier Prescription Drug Benefit Management Model Act, which is currently being revised. In North Carolina, for instance, closed formularies must be developed in consultation with and with the approval of a P&T committee that must include physicians who are licensed to practice medicine in North Carolina.²⁴ Virginia requires formularies to be developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a P&T committee, a majority of whose members must be practicing licensed pharmacists, physicians, and other licensed health care providers.²⁵ Maryland has adopted more extensive requirements for P&T committees established by PBMs, and California modeled its new P&T committee standards after Affordable Care Act standards and extended these protections to all state-regulated plans in the individual, small group, and large group markets.²⁶

Even where states have not adopted explicit standards in the context of private health insurance, many have P&T committee requirements for state Medicaid programs or state employee health plans. And many insurers are familiar with P&T committee standards under the Medicare program. These standards can inform efforts by state regulators and policymakers to develop P&T committee standards for private health insurance coverage.

Consumer Recommendations on Pharmacy and Therapeutics Committees



CONSUMER
RECOMMENDATIONS

State and federal insurance regulators, marketplace officials, and state lawmakers should require insurers and designees to establish one or more P&T committees that:

- Make all drug coverage decisions based on accepted best medical practices or standards of care adopted by medical specialty societies and ensure that formularies cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states.
- Comply with minimum transparency requirements, including holding public meetings, providing public notice of meeting times, posting the meeting agenda and minutes on the plan's website so that they are readily and easily accessible for consumers and other stakeholders, and allowing for public input or comment on proposed changes to a formulary that could negatively affect enrollees.
- Meet at least quarterly; evaluate and analyze formulary treatment protocols and procedures at least annually; and review a newly approved therapy or indication within 90 days of approval by the FDA and make a coverage determination within 180 days of the therapy's release onto the market.
- Have at least 15 members, a majority of which are practicing physicians, pharmacists, and other health care professionals who are licensed to prescribe drugs, which represent a sufficient number of clinical specialties and sub-specialties to adequately meet the needs of all enrollees.
- Have at least 20 percent of P&T committee members without a conflict of interest with respect to the insurer, any designee, or any pharmaceutical manufacturer and require all members to sign a conflict of interest statement revealing economic or other relationships that could influence a member's decisions and refrain from voting on any matters for which a conflict exists.

FIGURE 1:
Summary of Select Standards for Regulating P&T Committees

STANDARDS	MEMBERSHIP STANDARDS	COVERAGE STANDARDS
<p>ACA-Compliant Plans</p> <p>SOURCE 45 C.F.R. § 156.122</p> <p><i>These requirements apply to non-grandfathered plans in the individual and small group markets for plan years beginning on or after January 1, 2017.</i></p>	<p>Must consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health care professionals who are licensed to prescribe drugs and have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees</p> <p>Must have at least 20 percent of its membership with no conflict of interest with respect to an insurer or any pharmaceutical manufacturer</p> <p>Prohibits any member with a conflict of interest from voting on any matters for which the conflict exists</p>	<p>Must cover at least the greater of one drug in every United States Pharmacopeia category and class or the same number of drugs in each category and class as the essential health benefits-benchmark plan; must ensure that the formulary drug list covers a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states, does not discourage enrollment by any group of enrollees, and provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time</p>
<p>Medicare Part D Prescription Drug Plans</p> <p>SOURCE 42 C.F.R. § 423.120</p> <p><i>Additional information on prescription drug coverage under Medicare Part D is available in the Medicare Prescription Drug Benefit Manual.</i></p>	<p>Must include a majority of members who are practicing physicians and/or practicing pharmacists and include at least one practicing physician and one practicing pharmacist who are experts regarding care of older individuals or individuals with disabilities</p> <p>Must include at least one practicing physician and a pharmacist who are independent and free of conflict relative to the Part D sponsor, Part D plan, and pharmaceutical manufacturers</p> <p>Must articulate and document processes to determine that membership requirements have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts</p>	<p>Must cover all or substantially all drugs in six protected classes of drugs without step therapy or prior authorization requirements; must include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs (except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug); and include adequate coverage of the types of drugs most commonly needed by Part D enrollees, as recognized in national treatment guidelines</p>
<p>NAIC Health Carrier Prescription Drug Benefit Management Model Act</p> <p>SOURCE Model Law 22, available at: http://www.naic.org/store/free/MDL-22.pdf</p> <p><i>The Model Act is in the process of being revised by the NAIC, but the requirements below reflect existing, unrevised standards to allow for a comparison to federal standards. As such, the content below does not include revisions recommended by the NAIC consumer representatives.</i></p>	<p>Must be comprised of individuals who are either employed by or under contract with the insurer or its designee, a majority of whose membership includes health care professionals, such as physicians and pharmacists, who, collectively, have current knowledge and expertise in clinically appropriate prescribing, dispensing, and monitoring of outpatient prescription drugs and drug use review, evaluation, and intervention</p> <p>Must have policies and disclosure requirements in place that address potential conflicts of interest that members of a P&T committee may have with pharmaceutical developers or manufacturers</p>	<p>None</p>

REVIEW STANDARDS	UTILIZATION MANAGEMENT AND EXCEPTIONS	WRITTEN DOCUMENTATION
<p>Must meet at least quarterly; must evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually; must review new FDA-approved drugs and new uses for existing drugs within 90 days and make a coverage determination within 180 days</p> <p>Must base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate; must consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs</p>	<p>Must review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug; must review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange</p>	<p>Must develop and document procedures to ensure appropriate drug review and inclusion; must maintain written documentation of the rationale for all coverage decisions</p>
<p>Must evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually consistent with written policy guidelines and other CMS instructions</p> <p>Must base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate; must consider whether the inclusion of a particular Part D drug in a formulary or formulary tier has any therapeutic advantages in terms of safety and efficacy</p>	<p>Must review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered Part D drug; must review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange</p>	<p>Must document in writing decisions regarding formulary development and revision and utilization management activities</p>
<p>Must use a process to enable a P&T committee to, in a timely manner but at least annually, to consider the need for and implement appropriate updates and changes to the formulary or other pharmaceutical benefit management procedures based on: 1) newly available scientific and medical evidence or other information concerning current formulary drugs; 2) scientific and medical evidence or other information on newly approved prescription drugs and other nonformulary drugs; 3) information received from the carrier with respect to medical exception requests; and 4) information relating to the safety and effectiveness or current formulary drugs and nonformulary clinically similar drugs from the insurer's quality assurance activities or claims data</p> <p>Must use a process to evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs, including available comparative information on clinically similar prescription drugs, when deciding what prescription drugs to include on a formulary</p>	<p>Must evaluate applicable medical and scientific evidence concerning the safety and effectiveness of prescription drugs when developing any other pharmaceutical benefit management procedure</p>	<p>Must maintain documentation of the process for evaluating medical and scientific evidence and make any records and documents relating to the process available, upon request, to the insurer</p>

EXCEPTIONS AND APPEALS PROCESSES

Consumers may need to request an exception to a plan’s formulary for a number of reasons. In some cases, a consumer may have unique health needs that require access to a drug that is not covered under the plan. Cancer patients, for instance, often need products and services that are not listed on the formulary.²⁷ In addition to nonformulary drugs, consumers may need to access drugs at a different cost-sharing level or request an exception to UM restrictions that could adversely affect a consumer’s health. People living with HIV/AIDS, for instance, may need to waive step therapy or other UM restrictions for treatments that are known to be ineffective for them and to avoid the potential of nonadherence and drug resistance.²⁸

In these circumstances, enrollees should be able to seek and gain access to medically necessary, clinically appropriate medications. Access to nonformulary medications benefits consumers as well as plans. Consumers can receive the life-saving or life-sustaining medications they need while plans can promote patient adherence and help keep enrollees healthy, thereby avoiding potentially costly complications.

FIGURE 2:
Options to Request Access to Nonformulary Drugs for Individual and Small Group Enrollees

PROCESS	DESCRIPTION	TIMEFRAME	DURATION OF COVERAGE
STANDARD EXCEPTIONS ¹	Enrollee, designee, or provider can request access to nonformulary drugs even in the absence of exigent circumstances	Insurer must issue coverage decision within 72 hours of request	Duration of the prescription, including refills
EXPEDITED EXCEPTIONS ¹	Enrollee, designee, or provider can request access to nonformulary drugs during exigent circumstances (i.e., serious health condition, current course of treatment)	Insurer must issue coverage decision within 24 hours of request	Duration of the exigency
EXTERNAL EXCEPTION REQUEST REVIEW ¹	Enrollee, designee, or provider can request that an independent review organization review a plan’s refusal to cover a nonformulary drug under the expedited or standard exceptions process	STANDARD EXCEPTIONS REQUEST	Duration of the prescription, including refills
		EXPEDITED EXCEPTIONS REQUEST	Duration of the exigency
CONTRACEPTION EXCEPTIONS ²	Enrollee can request access to clinically appropriate contraceptive methods without cost-sharing	Nonstandardized — Based on nature of the claim	Nonstandardized — Based on nature of the claim

¹ This requirement applies to non-grandfathered plans in the individual and small group markets that must provide essential health benefits.

² This requirement applies to all policies or plans that must comply with Section 2713 of the Affordable Care Act, including non-grandfathered policies or plans in the individual, small group, and large group markets.

Source(s): 45 C.F.R. § 156.122(c); U.S. Departments of Labor, Health and Human Services, and the Treasury, FAQs About Affordable Care Act Implementation (Part XXVI), 4-5 (May 2015).

Recognizing the importance of access to nonformulary drugs, HHS has created a number of drug-specific exceptions and appeals processes for new plans in the individual and small group markets (Figure 2). These processes are distinct from other coverage appeals processes—such as internal review—and include an expedited exceptions process, a standardized drug exceptions process, and an external review process. (In states where coverage appeals standards are at least as stringent as those required under the federal exceptions process, plans may only need to comply with the state’s coverage appeals process without having to adopt a separate exceptions process for nonformulary drugs.²⁹) Plans must also have an exceptions process that is specific to the coverage of contraceptive methods and that extends to many plans in the large group market (Figure 3).

FIGURE 3:
Contraceptive Exceptions Process

Many health plans are required to cover FDA-approved prescription contraceptives and services without cost-sharing. However, plans have considerable flexibility in how they do so using reasonable medical management. Studies show that this flexibility has resulted in uneven contraceptive coverage.

In response to gaps in contraceptive coverage, HHS required plans that use medical management to establish “an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome on the individual or a provider.”³⁰ HHS did not, however, create a standardized exceptions process. Rather, plans and insurers are directed to “make a determination of the claim according to a timeframe and in a manner that takes into account the nature of the claim (e.g., pre-service or post-service) and the medical exigencies involved for a claim involving urgent care.”

Despite this requirement, gaps remain. A 2015 study from the Kaiser Family Foundation found significant variation in waiver request processes and that none of the policies it reviewed among 20 different insurers in five states had established an expedited appeals process for timely access to nonformulary emergency contraceptives. State and federal regulators should actively monitor and enforce these standards to ensure that consumers have access to contraceptive exceptions processes.

Source(s): Laurie Sobel et al., *Coverage of Contraceptive Services: A Review of Health Insurance Plans in Five States*, Kaiser Family Foundation (Apr. 2015); U.S. Departments of Labor, Health and Human Services, and the Treasury, *FAQs About Affordable Care Act Implementation (Part XXVI)*, 4-5 (May 2015).

The expedited exceptions process is particularly critical for consumers who need access to medically necessary nonformulary drugs based on exigent circumstances. Exigent circumstances occur when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee’s life, health, or ability to regain maximum function—or when an enrollee is undergoing a current course of treatment using a nonformulary drug.³¹ In these cases, an enrollee or an enrollee’s provider can request access to the nonformulary drug, and the insurer must issue a coverage determination within 24 hours of receiving the request.³²

Any nonformulary drug covered under a plan’s exceptions or appeals process is considered an essential health benefit and thus all drug-associated cost-sharing must count towards an enrollee’s annual limitation on cost-sharing and the plan’s actuarial value. This is an important protection because it caps a consumer’s overall out-of-pocket costs on approved drugs.

However, there are otherwise no limits on the level of cost-sharing that plans can impose for approved drugs. As a result, a consumer could receive approval for a nonformulary drug through the exceptions process only to find cost-sharing of hundreds, or even thousands, of dollars to be prohibitively expensive. To address this issue, policymakers should prohibit plans from imposing cost-sharing for drugs approved through an exceptions process that exceeds cost-sharing for formulary drugs.

The exceptions processes outlined above apply to access to drugs that are not listed on the formulary at all. While critical, these exceptions processes should be expanded to also include tiering exceptions and UM exceptions. These processes are already required for Medicare prescription drug plans.³³ A **tiering exception** is a request for an exception to a plan's tiered cost-sharing structure. A tiering exception allows an enrollee to request a nonpreferred drug at the cost-sharing level that applies to preferred tier drugs. A **UM exception** is a request to access a formulary drug without UM restrictions that the enrollee or prescriber believes should not apply. The same requirements that apply to the exceptions processes noted above—such as timeframes for a response and the opportunity for external review—should also apply to tiering and UM exception requests.

Finally, plans should prominently display information about the availability of plan exceptions processes, which many consumers are not familiar with and struggle to find information about.³⁴ Formularies should include a clear explanation of all of a plan's drug-related exceptions processes in the formulary introduction and plan documents. This explanation should include how and where consumers can request an exception, links to any required forms, and a timeline for each process. Plan-specific exceptions information should also be publicly accessible on an insurer's website. To further streamline this process, regulators should, with public input, develop standardized exceptions and appeals request forms for use by all insurers and plans and collect and report data on the use of these processes.

Insurers and their designees should also provide clear information to enrollees throughout the exceptions and appeals processes, including specific reasons for an adverse determination, the evidence or documentation used in making the adverse determination, notice of the right to appeal, and a referral to the appropriate independent review organization. In particular, regulators should extend the notice requirements for coverage appeals in 45 C.F.R. § 147.136 to include the exceptions process.³⁵

State Action.

Many states, such as California, Delaware, Indiana, Louisiana, North Carolina, Texas, and Virginia, have adopted standards for formulary exceptions and appeals. These laws vary by state and address a range of consumer concerns, including access to internal and external review processes, cost-sharing limitations, and UM restrictions. Louisiana, for instance, requires plans that use a specialty tier to adopt an exceptions process specifically for nonformulary specialty drugs.³⁶ In Texas, a plan's refusal to cover a medically necessary nonformulary drug is recognized as an adverse event, meaning an enrollee can pursue formal internal and external review processes.³⁷ And North Carolina and Virginia prohibit plans from imposing cost-sharing for a drug approved through the exceptions process that exceeds cost-sharing for formulary drugs.³⁸

Other states already allow UM exceptions. In California, enrollees can request an exception to step therapy requirements.³⁹ And, in Indiana, insurers must establish a “protocol exception” process to allow an enrollee or provider to challenge a fail first protocol.⁴⁰ Insurers in Indiana are also required to publicly post the procedure for requesting a protocol exception on their website and comply with certain notification requirements, such as providing a coverage determination no later than three business days after receiving a nonurgent request.

As noted above, states may have coverage appeals standards that mirror or exceed federal exceptions requirements. To meet this standard, the appeals processes must include an internal review, an external review, the ability to expedite the reviews, and timeframes that are the same as or shorter than the timeframes established under the exceptions process for standard and expedited exceptions.⁴¹ If these standards are met, the state itself may determine that compliance with the coverage appeals process satisfies the need for compliance with an exceptions process for nonformulary drugs.⁴² In these circumstances, a plan may not need to establish a separate exceptions process, but cost-sharing limitations would still apply such that any nonformulary drug covered under the exceptions or appeals process would count towards an enrollee’s out-of-pocket maximum and the plan’s actuarial value.⁴³

Consumer Recommendations on Exceptions and Appeals Processes

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Require insurers and their designees to adopt standardized, easy-to-understand exceptions processes and request forms that allow enrollees to 1) request access to medically necessary nonformulary drugs; 2) request an exception to a plan’s tiered cost-sharing structure; or 3) waive UM restrictions that will unduly limit access to a medically necessary drug.
- Prohibit plans from imposing cost-sharing for drugs approved through the exceptions process that exceeds the level of cost-sharing for formulary drugs and count all cost-sharing for drugs approved through the exceptions process toward the plan’s annual maximum out-of-pocket limit.
- Require insurers and their designees to publicly post a clear, concise explanation of all of a plan’s exceptions processes, including electronic links to any required forms, a way to fill and submit those forms electronically, a timeline for each exceptions process, and contact information.
- Extend the notice requirements for coverage appeals in 45 C.F.R. § 147.136 to the exceptions process and require insurers and their designees to provide clear information to enrollees throughout these processes, including specific reasons for an adverse determination, the evidence or documentation used in making the adverse determination, notice of the right to appeal, and a referral to the appropriate independent review organization.
- Ensure that insurers and their designees process exception requests and appeals quickly and efficiently without undue burden on enrollees and providers, including a 24 hour expedited exceptions process for cases where an enrollee is suffering from a health condition that may seriously jeopardize the enrollee’s life, health, or ability to regain maximum function or an enrollee is undergoing a current course of treatment using a nonformulary drug.
- Collect and publicly report data on the use of the drug exceptions process, including how many requests are made, the drugs requested, approval and denial rates for drugs on each tier, and any cost-sharing restrictions on approved drugs.



CONSUMER
RECOMMENDATIONS

PHARMACY NETWORK ACCESS

Pharmacy networks operate similarly to provider networks: Plans enter into contracts with preferred pharmacies in exchange for lower drug prices or deeper discounts on prescription drugs and then offer lower enrollee cost-sharing to incentivize the use of preferred pharmacies. In return, preferred pharmacies receive an increase in the volume of consumers at their business. If a consumer cannot access a preferred pharmacy, they may pay higher cost-sharing and drug prices at an out-of-network pharmacy.

Pharmacy networks are increasingly common: The number of Medicare Part D and Medicare Advantage prescription drug plans with preferred pharmacies increased more than five-fold from 2011 to 2014.⁴⁴ Commercial plans also use pharmacy networks: The Pharmacy Benefit Management Institute found that nearly one-third of surveyed employers used a tiered pharmacy network in 2015, and 75 percent of surveyed employers had network-specific requirements for at least some and, in most cases, all specialty drugs.⁴⁵

Some studies have found that narrow pharmacy networks are associated with modestly higher drug adherence and limited effects on overall consumer access to pharmacies.⁴⁶ However, preferred pharmacies may not be convenient for all enrollees and are not always effective at lowering prices.⁴⁷ Critics have also raised concerns about pharmacy networks that heavily incentivize the use of mail-order pharmacies, which threatens consumer privacy, limits access to pharmacists that can help enrollees navigate their drug needs, and is not an appropriate pharmacy option for delivering all types of drugs, such as antibiotics or opioids.⁴⁸ Consumers may also be limited from accessing preferred pharmacies if, for instance, an enrollee does not drive, a preferred pharmacy is not accessible by public transportation, or an enrollee is undergoing treatment and cannot travel to the pharmacy.

In addition, many plans have adopted tiered pharmacy networks with a tier for **preferred cost-sharing pharmacies (PCSPs)**, which offer lower out-of-pocket costs compared to other in-network pharmacies. The use of PCSPs has increased dramatically: In 2015, 87 percent of Medicare Part D prescription drug plans had pharmacy networks that included PCSPs, up from only 7 percent in 2011.⁴⁹ Although little data is available for commercial coverage, CMS has raised concerns about tiered pharmacy networks under the Medicare Part D program (Figure 4).

Preferred pharmacies may include retail pharmacies, mail-order pharmacies, or specialty pharmacies. Although the use of mail-order pharmacies is common, many consumers depend on retail pharmacies to ensure timely access to medication, improve drug adherence through interaction with a pharmacist, or maintain privacy. Recognizing the importance of access to retail pharmacies, HHS requires new individual and small group plans to provide enrollees with access to in-network retail pharmacies, with some exceptions, for plan years beginning on or after January 1, 2017.⁵⁰ Under these rules, however, insurers can impose differential cost-sharing for drugs at retail pharmacies.

To ensure that consumers have access to the medications they need from a pharmacy of their choice, states should consider minimum quantitative access standards modeled after those used by the Medicare program and TRICARE. Regulators should also review pharmacy networks to ensure that these networks provide access to a variety of pharmacy options and are not designed in a way that unduly limits access to certain types of pharmacies or discourages the enrollment of individuals in certain geographic areas because of lack of access to

FIGURE 4:

Access to Preferred Cost-Sharing Pharmacies in Medicare Part D

Retail pharmacy networks offered by Medicare Part D and Medicare Advantage prescription drug plans must meet minimum quantitative access standards. These “convenient access standards” are the same as those established under TRICARE and vary based on whether a plan’s service area is defined as urban, suburban, or rural. For instance, plans must ensure that 90 percent of beneficiaries in urban areas have access to an in-network retail pharmacy within 2 miles of their residence (or 5 miles for suburban areas).

Plans are allowed to create “sub-networks” or tiers for preferred cost-sharing pharmacies (PCSPs) that do not have to meet convenient access standards. However, CMS has cautioned against PCSP networks with a cost-sharing differential “that is so significant as to discourage enrollees in certain geographic areas ... from enrolling in that Part D Plan.” In a 2015 study to understand beneficiary access to PCSPs, CMS made the following findings:

- PCSP networks included only 24 percent of available in-network pharmacies on average, but nearly half of PCSP networks—46 percent—fully met convenient access standards that apply to the entire pharmacy network.
- PCSP networks were far less likely to meet urban convenient access standards: Only 46 percent of PCSP networks met urban convenient access standards, compared to 87 percent and 95 percent for suburban and rural convenient access standards, respectively.
- PCSP networks that are largely comprised of only major retail chain pharmacies were less likely to meet convenient access standards compared to networks with a mix of chain and independent pharmacies, and PCSP networks with a single pharmacy chain account for most of the networks with the lowest access for beneficiaries in urban areas.

Source(s): 42 C.F.R. § 423.120; Centers for Medicare and Medicaid Services, *Analysis of Part D Beneficiary Access to Preferred Cost Sharing Pharmacies (PCSPs)* (Apr. 2015).

in-network pharmacies. In particular, regulators should ensure that differential cost-sharing requirements are not so significant as to discourage enrollment in a given plan and that enrollees are not required to fill prescriptions solely via mail-order pharmacies.

Plans should also disclose pharmacy network information to consumers. Publicly accessible formularies should specifically include any network-related limitations or restrictions for each covered drug. For more information on formulary-related disclosures, please see the section of this report on “Improving Transparency of Prescription Drug Coverage.”

State Action.

Although they vary in scope, about half of states have adopted standards that address pharmacy network access. These standards typically include “any willing provider” laws (which require plans to contract with all pharmacies that are willing to accept the plan’s terms and conditions) and “freedom of choice” laws (which require plans to reimburse non-network pharmacies for services).⁵¹ In many of these states—as well as the NAIC’s recently revised Health Benefit Plan Network Access and Adequacy Model Act—these laws define “health care providers” to include pharmacies under plan network adequacy

standards.⁵² Other states, like California, have modeled pharmacy network access requirements after federal standards under the Affordable Care Act.⁵³ And some states, like Arkansas and Maine, require (or will soon require) plans to disclose network-related information on formularies.



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Pharmacy Network Access

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Adopt minimum quantitative access standards for retail pharmacies, such as those used by Medicare and TRICARE, which require prescription drug plans to meet convenient access standards that vary by service area.
- Review pharmacy networks to ensure that these networks are not designed in a way that unduly limits consumer access to certain types of pharmacies or discourages the enrollment of individuals in certain geographic areas because of lack of access to in-network pharmacies.
- Allow enrollees to access prescription drug benefits at in-network retail pharmacies (unless a drug is subject to restricted distribution by the FDA or a drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy).
- Include any network-related limitations or restrictions in formularies and on an insurer's website in a publicly accessible manner.

CONTINUITY OF DRUG COVERAGE

Consumers often need continuous access to their medications, regardless of whether a plan year has ended or if a plan has changed its formulary. Many consumers—particularly those who are low-income—may churn between private marketplace coverage and Medicaid coverage or employer-sponsored coverage.⁵⁵ Others are actively exploring or changing their plan options during open and special enrollment periods.⁵⁶ Given ongoing transitions between plans, insurers and their designees should be required to adopt continuity of drug coverage requirements.

Continuity of drug coverage requirements would allow a consumer to access a medically necessary medication—even if not covered under a plan's formulary—for a limited period of time after enrollment. A consumer should, for instance, be able to obtain a one-time, temporary supply of a medically necessary nonformulary drug within the first 90 days of coverage. The temporary supply would be provided without UM and should include at least a 30-day supply of medication unless prescribed for less than 30 days. Consumers should also be able to obtain a one-time, temporary 30-day supply of a formulary drug without UM.

These protections can ensure that consumers in the middle of a course of treatment have continued access to the medication they need if their new plan does not cover that drug or covers the drug with UM restrictions. This temporary supply also gives a consumer time to request a drug exception if needed. The Medicare Part D program has adopted continuity standards for similar reasons: “to promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent drug or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated” (Figure 5).⁵⁷

FIGURE 5:

Medication Transition Policy in Medicare Part D

Medicare has recognized the importance of continuity of drug coverage protections under the Part D program. Key components of this policy include the following:

- Part D sponsors are required to adopt a transition process for nonformulary drugs and formulary drugs that require prior authorization or step therapy.
- The transition process is available to many enrollees, including all new enrollees, newly eligible Medicare enrollees, beneficiaries who switch plans after the start of the contract year, and current enrollees affected by formulary changes.
- Part D sponsors must ensure access to a one-time supply of drugs within the first 90 days of coverage under a new plan and include at least a 30-day supply of medication (or longer in long-term care settings), unless prescribed for less than 30 days.
- Part D sponsors must provide written notice to each affected enrollee within three business days after adjudication of the temporary fill and make reasonable efforts to notify prescribers.

Source(s): 42 C.F.R. § 423.120(b)(3).

Continuity protections should apply to all enrollees—including new enrollees and those who are automatically reenrolled in a plan—that are adversely affected by a plan’s formulary. Continuity of drug coverage should also apply to any drug approved under a drug exceptions process: If an enrollee maintains the same plan from one year to the next, they should not have to request another exception for coverage of the same medically necessary drug. We urge insurers to establish a clear, standardized process for enrollees to continue this coverage year-to-year so long as it is medically appropriate. As with exceptions and appeals processes, plans should be required to 1) limit plans from imposing cost-sharing that exceeds that imposed for formulary drugs; 2) count any nonformulary drug covered towards an enrollee’s out-of-pocket maximum and the plan’s actuarial value; and 3) inform consumers about these requirements in formularies, plan documents, and on an insurer’s website.

State Action.

Some states have adopted continuity of drug coverage requirements. In Virginia, for instance, enrollees can request access to a medically necessary nonformulary drug if the enrollee has been receiving that drug for at least six months prior and a formulary drug would be clinically inappropriate or present a significant health risk to the enrollee.⁵⁸ State law prohibits insurers from imposing cost-sharing that exceeds the level of cost-sharing for formulary drugs and requires insurers to act on this type of request within one business day.⁵⁹

Federal Standards.

The Medicare Part D program offers a strong model for commercial plans. Although HHS has also adopted some continuity of care requirements for qualified health plans (QHPs) sold through the federal marketplace, these protections apply only when a consumer loses access to an in-network provider in the middle of a course of treatment and do not offer similar protections for new enrollees or access to medication.⁶⁰

HHS also requires certain plans to establish drug exceptions processes that allow an enrollee to request access to a nonformulary drug in a new plan or because of a mid-year formulary change. While critical, exceptions processes cannot substitute for robust continuity of drug coverage protections: Although some enrollees may receive continued access to their medication through the plan's exceptions process, many are not aware of this option and not all exception requests are granted.



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Continuity of Drug Coverage

State and federal insurance regulators, marketplace officials, and state lawmakers should require insurers and their designees to provide a one-time, temporary supply of medically necessary nonformulary drugs (or formulary drugs subject to UM) within the first 90 days of coverage and meet the following requirements:

- Provide this temporary, transitional supply without UM and include at least a 30-day supply of medication, unless the drug is routinely prescribed for less than 30 days.
- Provide transitional coverage to all enrollees, including new enrollees and those automatically reenrolled in a plan, and collect and publicly report data on the use of continuity protections, including how many requests are made, the drugs requested, and any cost-sharing restrictions on approved drugs.
- Impose cost-sharing for a transitional supply that does not exceed the cost-sharing imposed for formulary drugs.
- Continue to provide coverage for a drug approved under a drug exceptions process if an enrollee remains enrolled in the same plan from one year to the next and establish a clear, standardized process for enrollees to continue this coverage year-to-year so long as it is medically appropriate.
- Inform consumers about continuity of drug coverage requirements in formularies, plan documents, and on an insurer's website that meets disability accessibility standards.

ADDRESSING HEALTH DISPARITIES

A significant body of research shows that health care access, utilization, and quality varies by gender, race, and ethnicity even when other factors—including insurance status, age, and income—are comparable.⁶¹ Similar disparities have been observed in underserved communities, such as the disability community and LGBT communities.⁶² As a result of these disparities, individuals are less likely to receive routine health care and experience a lower quality of health services when accessing care which, over time, can lead to overall worse health outcomes.

Health disparities are also observed in prescription drug coverage and medication use (Figure 6). Historically, people of color have been less likely to receive appropriate medications for cardiovascular disease or HIV/AIDS and are less likely to be prescribed appropriate medications even when insured. And many people with disabilities are living with chronic conditions that require access to prescription drugs: For instance, 4.6 percent of Deaf people are living with HIV/AIDS, and adults with disabilities have a 400 percent higher risk of developing Type II diabetes.⁶⁴ Health disparities are likely exacerbated for those who face multiple health barriers, such as people of color with disabilities.⁶⁵

Health disparities stem from a variety of factors that may include high cost-sharing; lack of access to convenient pharmacies; unintentional or intentional stereotyping, bias, or prejudice; inaccessible physical environments; failure to provide needed policy or procedural accommodations; or misperceptions of need by the enrollee.⁶⁶ Given these barriers, it may be unsurprising that adoption of the Medicare Part D program helped reduce some disparities (such as those observed between white and Hispanic Medicare seniors) but exacerbated others (such as those observed between white and black Medicare seniors).⁶⁷ Recognizing the importance of addressing disparities, expert organizations such as the American Society of Health-System Pharmacists have adopted policy statements on the role of pharmacists in eliminating racial and ethnic disparities.⁶⁸

FIGURE 6:
Health Disparities in Drug Coverage and Medication Use

Communities of color and people with disabilities have long faced health disparities in prescription drug coverage and medication use. At least some of these disparities appear to be continuing despite gains under the Affordable Care Act. Recent studies have shown that:

- Privately insured black and privately insured Hispanic adults and Medicaid enrollees are less likely to report taking a prescription drug than white counterparts.
- Latino children have lower adherence for asthma control medications compared to white children.
- Racial and ethnic minorities have lower rates of long-term adherence to statins even when controlling for income. The elimination of copays was shown to largely eliminate these disparities.
- People with physical disabilities have 85 percent higher odds of having unmet prescription drug needs.

Source(s): Samantha Artiga et al., "Racial and Ethnic Disparities in Access to and Utilization of Care Among Insured Adults (Aug. 2015); Elizabeth L. McQuaid et al., "Medication Adherence Among Latino and Non-Latino White Children with Asthma," *Pediatrics* (2012) 129(6): e1404-10; E. Mahmoudi & M.A. Meade, "Disparities in Access to Health Care Among Adults with Physical Disabilities: Analysis of a Representative National Sample for a Ten-Year Period," *Disabil. Health J.* (2015) 8(2): 182-90; Jennifer Lewey et al., "Medication Adherence and Healthcare Disparities: Impact of Statin Co-Payment Reduction," *Amer. J. Managed Care* (2015) 21(10): 696-704.

Given the need to reduce drug-specific health disparities, insurers and pharmacies should ensure that formulary design, materials, and outreach efforts are nondiscriminatory, culturally and linguistically appropriate, and equally accessible to individuals with disabilities and individuals with limited English proficiency. Insurers and their designees can also limit cost-sharing to help improve drug adherence among low-income communities, and pharmacists can ensure that all drug information, such as drug medication guides or inserts, is printed in an enrollee's preferred language, easily readable for older or visually impaired enrollees, and available in alternate formats such as Braille, sign language, or electronic formats for enrollees with disabilities.

Insurers should consider leveraging existing outreach and enrollment efforts and expertise developed by marketplaces and consumer assistance personnel to reach underserved communities. In particular, insurers could conduct consumer outreach and education campaigns that, for instance, help consumers understand the importance of drug adherence and disease management programs, educate consumers about plan incentives such as value-based insurance design, or improve health insurance literacy. These efforts should be culturally and linguistically appropriate and designed to reduce prescription-specific health disparities.

Federal Standards.

Federal standards include a number of mechanisms to reduce health disparities and improve cultural competency, although none are specific to drug coverage and medication use. First, insurers are required to provide certain disclosures and notices, such as Summaries of Benefits and Coverage (SBCs), in a culturally and linguistically appropriate manner under Sections 2715 and 2719 of the Public Health Service Act. In addition, insurers must provide information to applicants and enrollees in plain language and a manner that is accessible and timely to individuals with disabilities and individuals with limited English proficiency.⁶⁹ These requirements could be extended to include all drug-related benefit information, including medication guides and inserts.

Second, HHS has broadly prohibited discrimination on the basis of race, color, national origin, disability, age, sex, gender identity, sexual orientation, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or significant health need. In particular, Section 1557 of the Affordable Care Act prohibits individuals from being subject to discrimination, excluded from participation, or denied the benefits of health programs or activities based on race, color, national origin, sex, age, or disability.⁷⁰

Section 1557 applies broadly to any entity that operates a health program or activity that receives federal financial assistance from HHS, any entity established under Title I of the Affordable Care Act that administers a health program or activity (including the marketplaces in every state), and HHS itself. This includes many insurers (such as those that offer marketplace plans, Medicare Advantage plans, Medicare prescription drug plans, and Medicaid managed care plans), plans, providers, and consumer assistance personnel. These nondiscrimination protections are critical to helping address and eliminating health disparities among underserved communities. For more information on nondiscrimination requirements, please see the section of this report on “Nondiscrimination in Formulary Design.”

Finally, HHS has developed and updated National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care to help health care organizations understand and respond to the needs of diverse consumers with the ultimate goal of positive health outcomes that reduce health disparities. Insurers and their designees can draw from these standards or higher standards adopted by states at the legislative or regulatory level.⁷¹ The Affordable Care Act also includes several requirements designed to increase the collection of data on race, ethnicity, sex, primary language, and disability status, which can be used to identify and help eliminate disparities.⁷²

Consumer Recommendations for Addressing Health Disparities



CONSUMER
RECOMMENDATIONS

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Require insurers and their designees to adopt and comply with comprehensive nondiscrimination policies that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, gender identity, sexual orientation, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or significant health need.
- Require formularies and all drug-related benefit information, whether in electronic or print format, to be accessible to individuals with disabilities and individuals with limited English proficiency as defined in 45 C.F.R. Sections 92.201, 92.202, 92.204, and 155.205(c).
- Require pharmacies to use prescription medication guides or inserts with large fonts for older enrollees or those with visual impairments; print prescription labels in an enrollee's preferred language; and provide communication in plain language and alternate formats such as Braille, sign language, or electronic formats for enrollees with disabilities.
- Conduct consumer outreach and education campaigns on prescription drug access targeted to underserved communities in a way that is culturally and linguistically appropriate and designed to reduce health disparities.
- Encourage insurers and their designees to minimize cost-sharing or UM restrictions for medications that are disproportionately likely to be used in underserved communities, such as treatments for diabetes or cardiovascular conditions.
- Collect, analyze, and report data on drug access, utilization, adherence, and outcomes by gender, age, race, ethnicity, and functional disability status and measure progress toward reducing health disparities in prescription drug access.

Consumer Affordability of Prescription Drug Coverage

\$ The high price of prescription drugs combined with increasingly higher cost-sharing has shifted significant costs to consumers. This is particularly true for new therapies that, in some cases, exceed \$100,000 for a course of treatment or for other expensive drugs covered under a plan’s pharmacy or medical benefit that may be administered by a physician or require ongoing medical management.

Affordability is particularly concerning with respect to specialty drugs, which can range from several thousand dollars to hundreds of thousands of dollars annually. Although there is no standard definition of “specialty drug,” states that have defined this term typically include biologics, drugs prescribed to treat complex or rare medical conditions, or drugs that cost the plan more than \$600 per month. And only certain drugs—those where the price negotiated by the insurer and drug manufacturer exceeds a certain dollar-per-month amount (\$670 for 2017) that is updated on an annual basis—are allowed to be placed on a specialty tier under the Medicare Part D program.⁷³

Spending on specialty drugs could quadruple between 2012 and 2020, reaching about \$400 billion, or 9.1 percent of national health spending.⁷⁴ Specialty drugs alone can account for more than half of total annual health costs for many chronic conditions.⁷⁵ Affordability is especially important for millions of Americans living with multiple chronic conditions who may rely on more than one costly medication.

Key Recommendations for Consumer Affordability

- Limit the number of drug tiers
- Prohibit plans from placing all or most drugs for the same condition on any specialty tier
- Limit consumer cost-sharing by prohibiting coinsurance for prescription drugs, capping cost-sharing per drug and per month, and capping copays at a fixed amount
- Require prescription drug benefits to, at a minimum, meet the plan’s overall actuarial value level
- Ensure that value-based insurance design is evidence-based and includes robust consumer cost-sharing protections, such as low cost-sharing for prescription drugs and access to exceptions processes

High drug prices can also increase consumer costs through higher premiums, and plan features used to manage drug costs—such as cost-sharing, UM, and pharmacy network restrictions—can reduce drug adherence, potentially resulting in worse outcomes and higher health care costs. Recent studies show that high cost-sharing for specialty drugs to treat rheumatoid arthritis, multiple sclerosis, and cancer make enrollees more likely to fail to start, to abandon, or to delay treatment.⁷⁶ Consumers are also reducing the dosage and regularity of their prescription drug intake, asking providers to prescribe less-expensive medications, or using alternative therapies to offset high out-of-pocket costs.⁷⁷

Recent studies show that out-of-pocket prescription drug costs in average silver marketplace plans are twice as high as they are in average employer-sponsored plans, resulting in fewer prescriptions filled and refilled and in higher spending on other medical services; 26 percent of marketplace enrollees report that their plan either would not cover or required a very expensive copay for a prescribed drug.⁷⁸ Other studies have shown that about 10 percent of lowest-income marketplace enrollees—those with incomes below 200 percent of the federal poverty level in 2016—will spend nearly 20 percent of annual income on premiums and out-of-pocket medical costs, including prescription drugs.⁷⁹ State-specific analyses of marketplace formulary trends are available from Access Better Coverage and the Harvard Law School’s Center for Health Law and Policy.⁸⁰

This section discusses the ways that state and federal regulators, lawmakers, marketplace officials, industry representatives, and other stakeholders can address these issues and protect consumers from high prescription drug costs in the areas of **drug tiering, coinsurance and copays, drug deductibles, and value-based insurance design**. Each section includes background information, examples of state and federal approaches, and recommendations for consumer-protective policies.

COPAYS AND COINSURANCE

A copay (or copayment) is a fixed dollar amount that an enrollee pays when filling a prescription or receiving a health service. Coinsurance is the percentage of overall costs for a drug or health service that the enrollee must pay. Unlike copays, coinsurance is typically not required until after an enrollee has met their deductible.

In most cases, a drug’s “tier” will dictate the level of out-of-pocket costs (including copays and coinsurance) that the consumer must pay. Copays are relatively common in the lowest three tiers, with average copays in the employer market ranging from \$11 to \$54 per prescription in 2015.⁸¹ Copays are easier to understand and use than coinsurance because copays are fixed and predictable. Average copays continue to increase over time and can cost consumers hundreds of dollars per drug per month.

Coinsurance costs can be far more costly than copays and are nearly impossible for consumers to discern in advance. Because coinsurance is based on a percentage of the drug’s price, the amount an enrollee owes can vary significantly over time even for the same drug and dosage and is unknown prior to purchase, making it impossible for consumers to reliably budget. Coinsurance is particularly common on specialty tiers, which can result in consumers owing thousands of dollars until they reach their annual out-of-pocket maximum. A recent Pharmacy Benefit Management Institute survey found that the average coinsurance

for specialty drugs was 29 percent under the pharmacy benefit and 32 percent under the medical benefit.⁸² To address the potential for prohibitively expensive coinsurance for high-cost drugs, some plans will cap coinsurance by setting minimum or maximum amounts for each tier.

Although most likely to be used at higher-cost tiers, coinsurance is also used at lower tiers. In 2015, coinsurance averages for covered workers in plans with three or more tiers of were 17 percent for first-tier drugs, 27 percent for second-tier drugs, and 43 percent for third-tier drugs. For workers enrolled in plans with at least four drug tiers, the average coinsurance for fourth-tier drugs was 32 percent per prescription in 2015.⁸³ The level of coinsurance is also increasing: Plans have significantly higher coinsurance averages for second- and third-tier drugs compared to previous years.⁸⁴

Copays and coinsurance vary significantly in individual marketplace plans. Of plans sold through the federal marketplace in 2016, copays were the most prominent drug cost-sharing feature for generic and preferred brand tiers for silver, gold, and platinum plans.⁸⁵ Copays are significantly higher under marketplace plans compared to employer-based coverage for all formulary tiers other than generic drugs.⁸⁶ In contrast, coinsurance was widely used for nonpreferred brand and specialty tiers.⁸⁷ Although not all plans used these features, the average coinsurance and copay rates vary dramatically by tier and level of coverage (Figure 7).

FIGURE 7:
Average Coinsurance and Copay Rates in Individual Federal Marketplace Plans, 2016

TIER	BRONZE		SILVER		GOLD		PLATINUM	
	COPAY	COINS	COPAY	COINS	COPAY	COINS	COPAY	COINS
GENERIC	\$19	33%	\$12	25%	\$10	20%	\$8	38%
PREFERRED BRAND	\$67	36%	\$48	30%	\$39	27%	\$30	23%
NONPREFERRED BRAND	\$124	37%	\$98	34%	\$83	32%	\$66	37%
SPECIALTY	\$268	38%	\$258	34%	\$194	32%	\$193	34%

Sources(s): Matthew Rae et al., *Patient Cost-Sharing in Marketplace Plans, 2016*, Kaiser Family Foundation (Nov. 2015).

High cost-sharing disproportionately affects consumers with chronic conditions. A recent Avalere study on silver plans in all 50 states and the District of Columbia found that drugs for hepatitis, cancer, immune diseases, and multiple sclerosis were more likely than any other conditions to have coinsurance over 40 percent.⁸⁸ Specialty drugs accounted for nearly half of total drug spending in marketplace plans in 2015, with drugs for HIV/AIDS, hepatitis C, and inflammatory conditions contributing almost 65 percent of total specialty costs.⁸⁹

High cost-sharing deters enrollees from using the drugs they need, resulting in worse outcomes and higher health care costs. Among adults who purchased non-group coverage in 2014, 14.2 percent went without needed medications because they could not afford them.⁹⁰ And a study from the Colorado Department of Public Health and Environment on the impact of the Affordable Care Act on people living with HIV/AIDS noted that many marketplace plans had shifted HIV medications to a specialty tier, resulting in enrollees who were previously accustomed to paying a \$10 or \$20 copay now paying \$100 to \$200 or more in coinsurance.⁹¹

State Action.

Given these trends, many states have taken steps to limit copays and coinsurance for prescription drugs (Figure 8). California, Delaware, Louisiana, and Maryland cap monthly cost-sharing for all or certain drugs while Maine and Vermont cap annual cost-sharing for all drug coverage. Colorado requires insurers to offer at least one plan per metal level with a copay-only formulary structure that limits the highest allowable monthly copay for any drug to no more than 1/12 of the plan-specific annual out-of-pocket maximum (i.e., a plan with an annual out-of-pocket maximum of \$6,000 would be limited to maximum monthly copays of no more than \$500 for each drug on the highest cost tier).⁹² Additional states are likely to adopt similar requirements over time. Members of the Virginia Joint Commission on Health Care, for instance, have previously voted to introduce legislation that would cap copays for specialty drugs at \$150 per prescription and allow QHP enrollees to pay their out-of-pocket maximum in 12 equal installments over the course of the year.⁹³

FIGURE 8:
State Efforts to Limit Consumer Out-of-Pocket Costs for Prescription Drugs in the Individual and Small Group Markets, April 2016

STATE	COST-SHARING LIMIT	SCOPE OF COST-SHARING LIMIT
CALIFORNIA ¹	\$500/drug for 30-day supply (bronze) \$250/drug for 30-day supply (all others)	Applies to drugs on all tiers Applies to drug benefit only
COLORADO ²	Max copay/drug of no more than 1/12 of the plan-specific annual out-of-pocket maximum	Applies to drugs on all tiers Applies to drug and medical benefit
DELAWARE	\$150/drug for 30-day supply	Applies to specialty drugs only
LOUISIANA ³	\$150/drug for 30-day supply	Applies to specialty drugs only
MAINE	\$3,500/year out-of-pocket maximum	Applies to drugs on all tiers that are subject to coinsurance
MARYLAND ⁴	\$150/drug for 30-day supply	Applies to specialty drugs only
VERMONT ^{1,4}	\$1,000/year for self-only coverage \$2,000/year for family coverage	Applies to drugs on all tiers Applies to drug and medical benefit

¹ For high-deductible health plans, cost-sharing limits apply only after an enrollee has satisfied their deductible.
² In Colorado, insurers are required to offer a pre-deductible copay-only structure for all drug tiers in at least one plan design per metal tier. Insurers are also prohibited from using coinsurance for the highest-cost drug tiers in more than 75 percent of their filed plan designs for each metal tier in each service area.
³ Limit applies only after an enrollee has satisfied their deductible.
⁴ Amount increases each year. In Vermont, the annual out-of-pocket limit must be equivalent to the minimum deductible amount for a high-deductible health plan as defined under Internal Revenue Code § 26 U.S.C. 233(c)(2)(A).

Source(s): Sabrina Corlette et al., "State Efforts to Reduce Consumers' Cost-Sharing for Prescription Drugs," *Commonwealth Fund Blog* (Nov. 16, 2015); authors' analysis.

These types of caps have the potential to raise costs for all consumers through higher premiums—or result in plans shifting higher cost-sharing to other benefits, particularly when a plan's actuarial value is limited under the Affordable Care Act. Critics argue that such caps increase premiums; however, the impact, where studied, has been limited. In a 2015 report, Milliman found that most platinum and gold plans and about half of silver plans sold in

California could adopt fixed copay caps and an annual cap on drug costs while only increasing premiums by 0.5 percent.⁹⁴ Covered California estimates that its cost-sharing cap on prescription drugs will result in a premium increase of about one percent in 2016; external actuaries estimate that the same cap could be responsible for a three percent increase in premiums over the next three years based on expected new specialty drugs.⁹⁵

Aside from cost-sharing caps, standardized benefits can be a powerful tool to limit consumer copays and coinsurance for marketplace enrollees. About half of state-based marketplaces have adopted fixed copays for generic and preferred brand tiers and coinsurance for higher tiers for consumers enrolled in a standardized plan.⁹⁶ For instance, standardized silver plans sold through the Massachusetts Health Connector in 2016 have fixed copays that range from \$20 to \$225 per drug based on the drug’s tier and whether it is purchased at a retail pharmacy or via a mail-order pharmacy.⁹⁷ For its optional standardized plans, HHS adopted fixed cost-sharing amounts that vary based on metal level (Figure 9).

FIGURE 9:
Formulary Requirements for Federal Marketplace Standardized QHP Options

TIER	BRONZE	SILVER	SILVER CSR (73% AV)	SILVER CSR (87% AV)	SILVER CSR (94% AV)	GOLD
GENERIC	\$35	\$15	\$10	\$5	\$3	\$10
PREFERRED BRAND	35%*	\$50	\$50	\$25	\$5	\$30
NONPREFERRED BRAND	40%*	\$100	\$100	\$50	\$10	\$75
SPECIALTY	45%*	40%	40%	30%	25%	30%

*Coverage is subject to the deductible

Source(s): Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017, 81 Fed. Reg. 12204, 12291 (Mar. 8, 2016).

State insurance regulators can use their regulatory authority to require or encourage insurers to limit copays and coinsurance for certain drugs or tiers without setting an overall cap on cost-sharing. In Montana, for instance, the Commissioner for Securities and Insurance determined that certain cost-sharing plan designs discriminate against individuals with high-cost medical conditions.⁹⁸ Insurers are now required to offer at least one plan at the silver level or above with copays for all drug tiers. And, in Florida, after a complaint alleging that certain benefit designs discriminate against people living with HIV/AIDS, the Florida Office of Insurance Regulation established an HIV/AIDS benefit design safe harbor based on the state’s essential health benefits benchmark plan, which specifies maximum cost-sharing for each drug and tier in the form of fixed copays.⁹⁹

These types of actions underscore the need for ongoing monitoring of plan design and the regulatory flexibility that states have to address cost-sharing concerns. Insurance regulators in other states should similarly consider establishing benefit design safe harbors; soliciting feedback from external stakeholders, such as consumer and patient advocates; and applying and interpreting state laws on unfair trade practices to address potentially discriminatory cost-sharing requirements. States can also consider requiring plans to offer drug benefits that, at a minimum, meet the plan’s overall actuarial value level and to disclose the actuarial value of their prescription drug benefit coverage. Doing so would allow regulators to make more meaningful comparisons between plans and help ensure a level playing field based on benefit design.

State policymakers also recognize that efforts to address the burden of drug costs must occur in tandem with efforts to address the underlying cause of high drug manufacturer prices. Pending legislation in California would increase transparency of drug manufacturer prices by requiring insurers to report drug prices in conjunction with the rate review process and requiring manufacturers to provide advance notice of significant increases in wholesale acquisition prices to private insurers, PBMs, and public payers.¹⁰⁰ In Vermont, manufacturers of drugs with substantial price increases are required to submit reports that justify those increases.¹⁰¹

Federal Standards.

High copays and coinsurance may implicate the Affordable Care Act's nondiscrimination protections. This is particularly true if cost-sharing requirements are imposed in such a way that disproportionately burdens individuals with chronic conditions. For more information on discriminatory benefit design, please see the section of this report on "Nondiscrimination in Formulary Design."



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Copays and Coinsurance

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Prohibit or limit the use of coinsurance for drug coverage and/or adopt fixed copays for all drug tiers.
- Establish maximum levels of cost-sharing per prescription and per month and consider limiting monthly cost-sharing for any drug to no more than 1/12 of the plan-specific annual out-of-pocket maximum.
- Require formularies to disclose the actual dollar cost-sharing amount for a given medication under a particular plan.
- Require plans to offer drug benefits that, at a minimum, meet the plan's overall actuarial value level and disclose the actuarial value of their prescription drug benefit coverage.
- Encourage insurers that offer cost-sharing reduction plans to meet actuarial value targets by reducing cost-sharing for specialty drugs in addition to lowering deductibles and annual out-of-pocket maximums.

DRUG TIERING

The most common approach to addressing costs has been to assign covered drugs to a "tier" based on cost-sharing and other requirements, like prior authorization and step therapy. By varying cost-sharing based on tier, drug tiering incentivizes the use of lower-tier medications that are less expensive, more cost-effective, or of a higher value. The overall effect of drug tiering is that a consumer's costs and access vary dramatically based on the plan they are in, the drugs they need, and the tier on which each drug is placed.

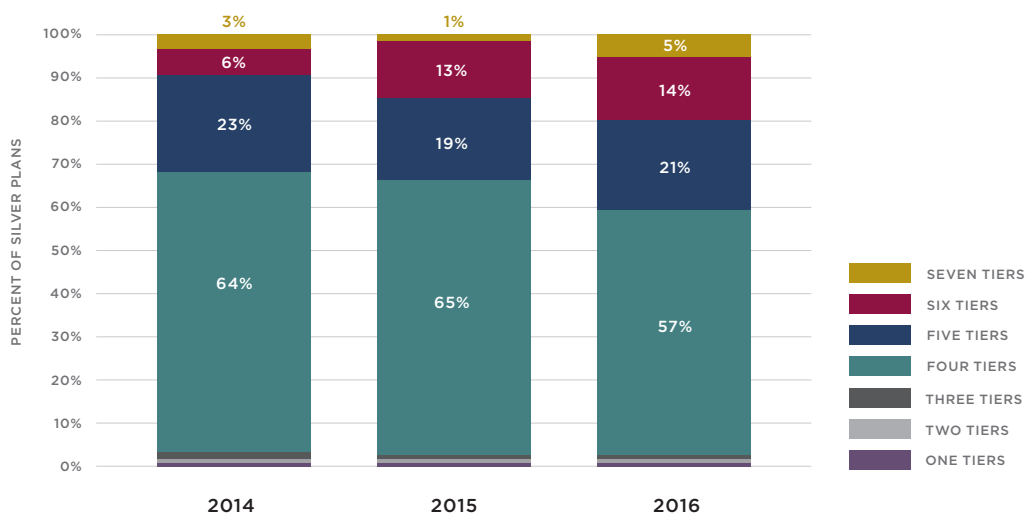
Drug tiering is common: In its most recent survey on trends in employer benefits, the Kaiser Family Foundation found that 88 percent of covered workers are in plans that use drug tiering.¹⁰² Drug tiering has also become increasingly complex. Many plans initially used a relatively simple two-tier design with generic drugs on the first tier and brand-name drugs on the second tier. However, by 2015, 81 percent of covered workers were enrolled in plans with three or more tiers (up from 68 percent in 2004), with 23 percent enrolled in a plan with four or more tiers (up from 3 percent in 2004).¹⁰³

Many plans place specialty drugs, however they define them, on the highest tier while others use a separate tier just for specialty drugs. The Pharmacy Benefit Management Institute found that the proportion of employers using a separate cost-sharing tier for specialty drugs increased from 23 percent in 2011 to 57 percent in 2015.¹⁰⁴ Of those not currently using a specialty tier, 31 percent of employers plan to do so in coming years.¹⁰⁵

Complex drug tiering is common in marketplace plans; nearly all silver plans sold through the federal marketplace have four or more drug tiers (Figure 10). The number of these plans using six or seven drug tiers also increased by 10 percent since 2014 as plans add additional specialty tiers as well as generic tiers (such as preferred and nonpreferred generic tiers).¹⁰⁶ And silver plans are more likely to place certain single-source drugs—brand-name drugs that do not have a generic equivalent or alternative—for hepatitis, multiple sclerosis, and cystic fibrosis on specialty tiers compared to employer plans.¹⁰⁷

Cost-sharing requirements vary significantly by tier. Although copays are relatively common in the first three tiers relative to coinsurance, coinsurance is applied much more often to fourth-tier drugs or higher.¹⁰⁸ Coinsurance has many downsides for consumers, including that the exact dollar amount of out-of-pocket costs can change frequently and is unknown

FIGURE 10:
Number of Formulary Tiers in Silver Plans, All Federally Facilitated Exchange States



Source(s): Avalere PlanScape®, a proprietary analysis of exchange plan features, December 2015. Avalere analyzed data from the FFE Individual Landscape File released October 2015. Note the case study analysis only includes silver plans. Plans that noted only pre-deductible cost-sharing amounts were excluded from the analysis; this explains why the total number of plans shifts across the analysis (2014 N = 754, 2015 N = 1231, 2016 N = 1060). Avalere did not include health plans in which there was no cost-sharing across service categories or that had deductibles that were equal to the out-of-pocket maximum.

prior to purchase, making it impossible for consumers to reliably budget. Despite these downsides, coinsurance is particularly common on specialty tiers compared to copays, which can result in consumers owing thousands of dollars each month for life-saving medication.

Although the Affordable Care Act protects against high prescription drug costs by limiting total annual out-of-pocket costs, this out-of-pocket maximum does not apply to all plans, such as grandfathered plans, and does not include premiums, balance billing amounts, or spending on non-essential health benefits. And consumers who are enrolled in plans that have a high deductible may have to pay thousands of dollars in cost-sharing for a drug, potentially in a single month, before reaching their deductible or out-of-pocket maximum.

Drug tiering can be used to discriminate against consumers who need high-cost medications, such as people living with HIV/AIDS or cancer. Consumer and patient advocates are particularly concerned about the use of adverse tiering and overly restrictive UM restrictions. Adverse tiering—the practice of placing most or all drugs that treat a specific condition on the highest cost-sharing tier—can have a dramatic financial impact on consumers and can result in adverse selection against plans that do not adopt this practice. Overly restrictive UM can similarly result in barriers to accessing medication, reduced drug adherence, and potentially worse health outcomes. For more information on adverse tiering and UM, please see the section of this report on “Nondiscrimination in Formulary Design.”

In addition, many plans change their formularies—including the placement of a drug on a higher tier—during the course of a plan year. These changes can have significant consequences for consumers, potentially rendering a drug unaffordable and thus unavailable. Because such changes do not result in eligibility for a special enrollment period, many consumers who lose access to a drug through a mid-year formulary change will remain locked in a plan that does not meet their health needs. Given the need for formulary transparency and stability, insurers and their designees should be prohibited from moving a covered drug to a higher-cost tier during the plan year. For more information on mid-year formulary changes, please see the section of this report on “Improving Transparency of Prescription Drug Coverage.”

State Action.

In response to these issues, states have prohibited specialty tiers altogether; defined “specialty tier” or “specialty drug”; limited the number of drug tiers through standardization; or capped cost-sharing on some or all drug tiers. The diversity of these approaches shows that states have significant flexibility in addressing drug tiering, and regulators should continue to monitor and evaluate the use of tiering and its impact on consumers and consider their options for regulatory action based on findings.

Some states prohibit specialty tiers altogether. In New York, plans have been prohibited from imposing cost-sharing on any drug that exceeds the cost-sharing level for nonpreferred brand drugs (or an equivalent tier) since 2010.¹⁰⁹ Other states, such as Delaware and Maryland, do not prohibit specialty tiers but have defined “specialty tier” or “specialty drug” to bring some standardization to which drugs are considered specialty drugs.¹¹⁰ These definitions vary by state but typically include biologics, drugs prescribed to treat complex or rare medical conditions, or drugs that cost the plan more than \$600 per month. These states may have adopted such definitions because the way that insurers classify prescription drugs often varies dramatically.¹¹¹

State-based marketplaces have also limited drug tiers in the individual market through plan standardization. Marketplaces in Massachusetts, New York, and Vermont, for instance, have limited plans to three formulary tiers.¹¹² Although these standardized plan requirements are helpful for consumers, insurers can offer plans in addition to the standardized options so consumers must continue to carefully consider their coverage options. As discussed in more detail in the previous section, HHS similarly established optional bronze, silver, and gold standardized plan designs for plans sold through the federal marketplace.¹¹³ These plan designs include four drug tiers, but HHS also allowed plans to include additional lower-cost tiers if desired, recognizing that more than half of proposed 2016 plans sold through the federal marketplace had more than four drug tiers.

Finally and as discussed in more detail in the previous section, several states have imposed caps on cost-sharing for specialty drugs. In Delaware, Louisiana, and Maryland, copays or coinsurance cannot exceed \$150 per month per specialty drug.¹¹⁴ Other states, such as California, Maine, and Vermont, similarly cap cost-sharing for prescription drugs but these caps are not specific to certain drugs or tiers.¹¹⁵ Still other states, such as Delaware, Pennsylvania, and Virginia, have commissioned legislative reports to study issues related to specialty drugs (Figure 11).¹¹⁶

FIGURE 11:

Impact of Specialty Tiers in Pennsylvania

In 2013, the Pennsylvania legislature asked the Legislative Budget and Finance Committee to study specialty tiers to determine their impact on access and patient care. The Committee's report—released in September 2014—included the following findings:

- Almost 60% of specialty drugs had annual out-of-pocket costs that exceeded 20% of a Pennsylvania household's median income.
- Over 40% of Pennsylvania specialty drug consumers delayed filling a prescription or skipped pills, injections, or dosages.
- 20% of Pennsylvania specialty drug consumers stopped taking a specialty drug because they could not afford it.
- High cost-sharing requirements resulted in economic hardship, with over 40% of specialty drug consumers reporting difficulty in buying food and groceries and 10 percent declaring bankruptcy.

Source(s): Pennsylvania Legislative Budget and Finance Committee, *Prescription Drug Specialty Tiers in Pennsylvania* (Sept. 2014).

Federal Standards.

Drug tiering may implicate the Affordable Care Act's nondiscrimination protections, particularly if a plan is designed to intentionally shift the cost of drugs to individuals in certain disease states or with chronic conditions. In particular, HHS has indicated that an insurer that places most or all drugs that treat a specific condition on the highest-cost tier, such as a specialty tier, effectively discriminates against individuals with that condition.¹¹⁷ For more information on discriminatory benefit design, please see the section of this report on "Nondiscrimination in Formulary Design."



Consumer Recommendations on Drug Tiering

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Limit the total number of drug tiers permitted in a plan.
- Define “specialty tier” or “specialty drug” to help bring some standardization to insurer tiering practices.
- Require or incentivize the adoption of standardized plans that limit the number of specialty, brand-name, and generic tiers.
- Prohibit insurers and their designees from placing all or most drugs that treat a specific condition and any generic drug on a specialty tier.
- Prohibit insurers and their designees from moving a covered drug to a higher-cost tier during the plan year.

DRUG DEDUCTIBLES

Most plans have a general annual deductible, which is the amount that a consumer must pay towards the cost of covered services before the plan pays for a portion of most covered services. Deductibles can vary significantly by plan but typically cannot exceed the annual out-of-pocket maximum established by the Affordable Care Act.¹¹⁸ In addition to general annual deductibles, insurers increasingly use separate drug deductibles, which apply only to prescription drug coverage and are typically lower than the general deductible.

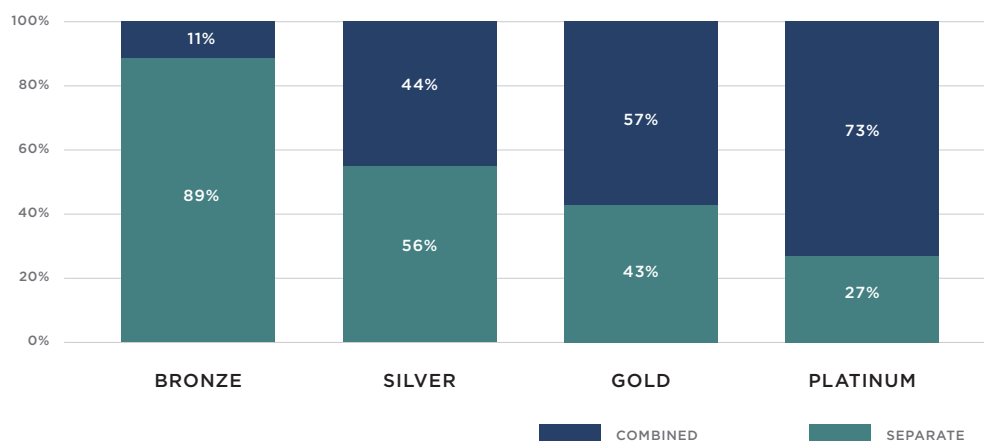
Drug deductibles operate in the same way as a general annual deductible: A consumer must meet the drug deductible before the plan pays for a portion of most covered drugs. As a result, a consumer may have to pay for the full cost of a drug until they reach their drug deductible. Drug deductibles can be structured differently: Some plans will impose a drug deductible on only a select number of tiers or cover certain medications, such as FDA-approved birth control methods, without requiring an enrollee to first meet the deductible.

Although drug deductibles add a layer of complexity to plans, they can be beneficial to consumers. In a plan with a low, separate drug deductible, for instance, a consumer will have lower out-of-pocket costs before their drugs are covered compared to a plan without a separate drug deductible that may require significant out-of-pocket costs—potentially thousands of dollars—to satisfy the general annual deductible before drugs are covered. With appropriate consumer protections, separate drug deductibles can be structured in a way that promotes appropriate access to medications.

The prevalence of drug deductibles varies significantly by type of plan. About 12 percent of covered workers were enrolled in plans with a separate drug deductible in 2015, with an average drug deductible of \$231.¹¹⁹ A recent Pharmacy Benefit Management Institute survey suggests that the use of drug deductibles is on the rise, noting that employers had increased the use of drug deductibles by 157 percent between 2014 and 2015, from 14 percent of employers in 2014 to 36 percent of employers in 2015.¹²⁰ Drug deductibles are even more

FIGURE 12:

Percent of Plans Where Medical Deductible is Combined with or Separate from the Prescription Drug Deductible



Source(s): Kaiser Family Foundation analysis of Marketplace plans in the 38 states with Federally Facilitated or Partnership exchanges in 2016 (including Hawaii, New Mexico, Oregon, and Nevada). Data are from Healthcare.gov health plan information for individuals and families available here: <https://www.healthcare.gov/health-plan-information/>; see also Matthew Rae et al., *Patient Cost- Sharing in Marketplace Plans*, 2016.

common in individual marketplace plans (Figure 12). Of plans sold through the federal marketplace in 2016, bronze plans had an average drug deductible of \$404 compared to \$12 for platinum plans.¹²¹

Despite these relatively low averages, drug deductibles vary considerably by insurer or state. A study commissioned by the Colorado Division of Insurance found that most separate drug deductibles in the individual market in 2014 and 2015 ranged from \$1,000 to \$2,000.¹²² A similar study found that drug deductibles in silver plans in Wisconsin varied widely across the state—ranging from \$400 to \$2,500—and that monthly out-of-pocket costs for an expensive cancer drug ranged from \$454 to \$5,375 depending on the plan.¹²³

To help consumers understand drug deductibles, each plan’s formulary and plan documents should identify whether the plan has a separate drug deductible and, if so, how this deductible applies, including which drugs are covered pre-deductible and any tier-specific differences. Plans should not apply drug deductibles to tier or drugs that have historically been covered pre-deductible, such as preventive medications.

State Action.

Some states are experimenting with drug deductibles in standardized plans. State-based marketplaces in California, Connecticut, and the District of Columbia include separate drug deductibles in their standardized plans.¹²⁴ These drug deductibles vary by plan level but are relatively low, ranging from \$25 in Connecticut to \$500 in California. California recently adopted new drug deductible standards that apply marketwide: Beginning in 2017, all new individual and small group plans will be prohibited from imposing a separate drug deductible for covered outpatient drugs that exceeds \$500 (\$1,000 for bronze plans).¹²⁵

Federal Standards

HHS does not require or prohibit drug deductibles, but insurers and employers are required to include information on drug deductibles in the SBC. In particular, insurers and employers must disclose whether there is a distinction between the general annual deductible and any other deductibles for specific services, including drug deductibles. This information will be listed on the first page of the SBC under “Are there other deductibles for specific services?” and should include the dollar amount of the drug deductible and any distinctions between individual and family coverage. Insurers and employers must also note the impact of separate drug deductibles in the Coverage Examples section of the SBC. And the Medicare Part D program allows, but does not require, plans to have drug deductibles but imposes a cap: For 2016, for instance, no Medicare drug plan may have a drug deductible of more than \$360.¹²⁶



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Drug Deductibles

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Require formularies and other plan documents to disclose whether a plan utilizes a separate drug deductible and how the drug deductible applies.
- Discourage drug deductibles from being applied to tiers or drugs that have historically been covered pre-deductible, such as preventive medications.
- Analyze drug deductibles along with other cost-sharing or tiering structures when reviewing plans for discriminatory formulary design.

VALUE-BASED INSURANCE DESIGN

Value-based insurance design (VBID) is a way of structuring health benefits to incentivize high-quality care and disincentivize low-value care.¹²⁷ To incentivize quality care, plans that use VBID often set cost-sharing requirements based on the clinical value of a health care service. For instance, a plan may cover a highly effective blood pressure medication without cost-sharing to promote its use among enrollees. Another hallmark of VBID is that “value” can vary based on clinical nuances and the needs of a particular enrollee. As a result, cost-sharing for a particular service or drug for one enrollee may differ from that of a different enrollee with a different risk profile.

Prescription drug use is similarly correlated with cost: As cost-sharing increases, initiation and adherence decreases.¹²⁸ VBID, often in conjunction with other interventions such as disease management, has been shown to be successful in improving drug adherence when targeted to medication classes for diabetes, congestive heart failure, asthma, and hypertension, among other conditions.¹²⁹ In most cases, plans reduced or eliminated cost-sharing for certain high-value drugs, and, on average, these efforts resulted in adherence improvement by three percent in one year (with some studies showing improvement of nine percent or more) and no statistically significant increase in total medical costs, despite increases in drug expenditures.¹³⁰ Drug-specific VBID has been adopted by a number of public and private payers and employers including CVS/caremark, Blue Cross Blue Shield of North Carolina, Blue Cross Blue Shield of Minnesota, and the State of Colorado, among others.¹³¹

VBID has not yet been applied to the use of specialty drugs. In expanding the VBID model to these drugs, payers should identify medications that are rarely used inappropriately and provide significant value, and then move these drugs to a lower tier to reduce cost-sharing.¹³² Plans should ensure that decisions about cost-sharing incentives are made based on strong clinical evidence and comparative effectiveness research. Plans should also adjust cost-sharing based on patient-specific clinical needs: For instance, determining what qualifies as high- or low-value treatment for a cancer patient will depend heavily on the patient's type of cancer (including the genetic mutations that drive a specific cancer), stage of chemotherapy, and biomarker, among other factors.¹³³

Furthermore, not all consumers have the same response to all drugs. A consumer may need access to a drug on a higher tier even when a value-based alternative is available at a lower tier—or a consumer may need a “lower value” drug that the plan has opted to disincentivize through higher cost-sharing. In these cases, plans should reduce cost-sharing for medically necessary medications for these enrollees.¹³⁴ Plans should ensure that a VBID program does not impose a one-size-fits-all standard that limits access to medications for those who need them and allows for flexibility in providing effective and efficient treatment.

Applying VBID to the use of specialty drugs may not be appropriate for all enrollees. This is particularly true for people with disabilities, people of color, and certain groups of patients, such as those with rare and orphan diseases, whose needs are routinely unaccounted for in comparative effectiveness research and other VBID data sources.¹³⁵ And many consumers, such as individuals with autism, depend on prescription drugs that are used on an “off-label” basis. Although off-label use may not have the same evidence base as “on-label” use, the use of drugs on an off-label basis can be medically necessary and life-saving or life-sustaining for many consumers, which should be recognized by plans when applying VBID to prescription drugs.

Federal Standards.

The Affordable Care Act includes a number of VBID-related provisions. First, all non-grandfathered plans are required to cover specified preventive services—such as those recommended by the U.S. Preventive Services Task Force—without cost-sharing. These services include immunizations, cancer screening, mental health screening, and blood pressure screening, among others. Second, the Affordable Care Act authorized federal regulators to issue guidelines to permit plans to use VBID, although regulations have not yet been issued. In addition, some state-based marketplaces, such as those in Oregon and Vermont, have explored the possibility of offering VBID plans in addition to standardized plans.¹³⁶



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Value-Based Insurance Design

State and federal insurance regulators, marketplace officials, insurers and their designees, and state lawmakers should ensure that plans that use VBID:

- Develop incentives informed by strong clinical evidence and comparative effectiveness research through a public, transparent process.
- Partner with state clinical advisory panels to shape permissible plan design and submit clinical evidence supporting VBID design to state insurance regulators during the form review process.
- Eliminate or reduce cost-sharing for high-value medications and incentivize value-driven decisions earlier rather than later in the disease stage.
- Establish a formal, standardized exceptions process that allows consumers to request a reduction in cost-sharing in accordance with patient- or disease-specific characteristics, including when an enrollee needs to waive VBID incentives for medically necessary care.
- Conduct consumer and provider outreach and education campaigns to effectively communicate plan incentives in a way that enables enrollees to fully understand VBID benefits.

Nondiscrimination in Formulary Design



Prior to the Affordable Care Act, insurers in most states could use underwriting to decline to cover an applicant, exclude coverage for certain treatments, or decline to cover prescription drugs at all. These types of discrimination—differentiation among individuals in designing and implementing private health insurance coverage—have long been accepted as legitimate market practice to shield insurers from the risk of adverse selection. These and other underwriting practices shift risk from an insurer to a consumer and help explain chronic levels of underinsurance, where even insured consumers face high out-of-pocket medical costs relative to their income.¹³⁷



Key Recommendations for Nondiscrimination

- Identify and prohibit specific examples of discriminatory formulary design
- Define adverse tiering as an example of discriminatory benefit design and prohibit plans from placing most or all drugs that treat a specific condition on the highest cost-sharing tiers
- Require UM and formulary composition to be based on accepted best medical practices or standards of care adopted by medical specialty societies
- Solicit feedback from external stakeholders to help identify concerns about discriminatory benefit design and to inform the formulary review process

To address this gap, the Affordable Care Act includes significant new protections that prohibit discrimination based on a variety of factors, including health status. Major reforms include guaranteed issue, a ban on preexisting condition exclusions, a ban on lifetime and annual limits, new rating reforms, and the coverage of essential health benefits, including prescription drugs. Insurers are also prohibited from offering or designing coverage in a way that discriminates based on race, color, national origin, disability, age, sex, gender identity, sexual orientation, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or significant health need.

Despite these reforms, some plans continue to limit adverse selection by adopting formulary designs that discriminate against high-risk populations. Plans have, for instance, placed most or all drugs that treat a specific condition on the highest cost-sharing tiers, refused to cover commonly prescribed treatments (such as single-tablet drug regimens), or required consumers to fill prescriptions solely via mail-order pharmacies or specialty pharmacies.¹³⁸ These design features disproportionately affect consumers with chronic conditions, may contravene accepted best medical practices and standards of care, and can result in adverse selection against plans with more generous drug coverage. Given its impact on consumers and the risk pool, discriminatory benefit design has been widely cited and discussed in administrative complaints, research and analysis, and media reports.

This section discusses the ways that state and federal regulators, lawmakers, marketplace officials, industry representatives, and other stakeholders can address these issues and reduce discrimination on the basis of health status in the areas of **comprehensive nondiscrimination protections**, **adverse tiering**, and **UM**. Each section includes background information, examples of state and federal approaches, and recommendations for consumer-protective policies.

COMPREHENSIVE NONDISCRIMINATION PROTECTIONS

Discrimination in private health insurance can occur in many ways, including at the point of enrollment, in the way that coverage is designed, and in the decisions that insurers make when administering benefits (Figure 13). The Affordable Care Act limits discrimination at each of these points through expansive new nondiscrimination protections. Given the significance of the changes, however, regulators must adopt a comprehensive, holistic approach to enforcing these benefit design protections.

FIGURE 13:
Select Benefit Design Features with the Potential to be Discriminatory

-
- | | |
|---------------------------------|--------------------------|
| • Cost-sharing | • Waiting periods |
| • Medical necessity definitions | • Service areas |
| • Exclusions | • Rating |
| • Narrow networks | • Visit limits |
| • Drug formularies | • Marketing of products |
| • Benefit substitution | • Utilization management |

Source(s): Katie Keith et al., *Nondiscrimination Under the Affordable Care Act*, Georgetown University Center on Health Insurance Reforms (July 2013).

Prior to the Affordable Care Act, federal and state law included some nondiscrimination protections but these laws had only a limited effect in ensuring that coverage met the needs of all consumers and few, if any, were specific to prescription drug coverage.¹³⁹ Most federal laws—such as the Health Insurance Portability and Accountability Act of 1996 and the Genetic Information Nondiscrimination Act of 2008—focused primarily on limiting discrimination in private health insurance at the point of enrollment.¹⁴⁰ Others—such as the Women’s Health and Cancer Rights Act of 1998, the Newborns’ and Mothers’ Health Protection Act of 2008, and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)—limited discriminatory benefit design by requiring insurers to cover certain benefits, but these requirements existed only where insurers already offered certain benefits, such as mastectomy coverage, hospital stays in connection with childbirth, or mental health coverage, respectively.¹⁴¹

States also had nondiscrimination protections prior to the Affordable Care Act. In addition to enforcement of federal requirements, states prohibited discrimination under their unfair trade practice statutes or through human rights laws.¹⁴² Many states also prohibited insurers from discriminating on the basis of domestic abuse, genetic information, sickle cell anemia, and HIV status; prohibited the use of premiums that are unfairly discriminatory; and adopted mandates that require insurers to cover certain benefits.¹⁴³

Although critical to promoting access to coverage, previous federal and state laws offered relatively limited protections against underwriting and other forms of discrimination. Given this history, the Affordable Care Act’s requirements ushered in substantial reforms. By prohibiting insurers from offering coverage that discriminates on a broad variety of factors (most notably health status), the Affordable Care Act marked a significant departure from past discriminatory practices to dramatically improve the quality of private health insurance.

Federal Standards.

The Affordable Care Act prohibits QHPs from adopting benefit designs—or implementing benefit designs (defined as coverage decisions, reimbursement rates, or incentive programs)—that discriminate based on age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.¹⁴⁴ HHS additionally prohibits QHP insurers from 1) adopting benefit designs that discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, or sexual orientation; and 2) utilizing discriminatory marketing practices or benefit designs that discourage the enrollment of individuals with significant health needs.¹⁴⁵ Finally, many plans must comply with mental health parity requirements in MHPAEA, which prohibits plans that cover mental health or substance use disorders from imposing less favorable benefit limitations on those benefits compared to medical or surgical benefits.¹⁴⁶

Section 1557 of the Affordable Care Act also applies existing federal civil rights protections to private health insurance and prohibits individuals from being subject to discrimination, excluded from participation, or denied the benefits of health programs or activities based on race, color, national origin, sex, age, or disability.¹⁴⁷ These protections are enforced by the HHS Office for Civil Rights and apply broadly to all health programs and activities that receive federal financial assistance and entities established under Title I of the Affordable Care Act (such as state-based marketplaces).

Federal financial assistance includes marketplace premium tax credits and cost-sharing reductions; as a result, Section 1557 applies to any insurer participating in any marketplace when advance premium tax credits or cost-sharing reductions are provided to any of the insurer's enrollees.¹⁴⁸ For insurers that offer marketplace coverage, Section 1557 applies to all of the insurer's health plans, offered both inside and outside the marketplace, as well as when the insurer acts as a third-party administrator for an employer-sponsored group health plan.¹⁴⁹ Section 1557 also applies to insurers that, for instance, offer Medicare Advantage plans, Medicare prescription drug plans, and Medicaid managed care plans.

Enforcement Challenges.

Regulators have reported some challenges in monitoring and enforcing the Affordable Care Act's nondiscrimination protections.¹⁵⁰ For instance, broad nondiscrimination standards—such as prohibiting discrimination based on “quality of life”—provide little guidance as to how regulators should undertake a systematic review for discriminatory benefit design. In addition, regulators report a lack of sufficient clinical expertise to determine whether certain design features might be discriminatory because this type of review requires an understanding of the latest drug treatments, patient needs, and evidence-based treatments. This type of review is made even more difficult by the fact that insurers change their formularies frequently.

State and federal regulators have largely declined to define “discriminatory benefit design” or identify examples of *per se* discrimination. Rather, HHS has identified various examples of potentially discriminatory practices, after “becom[ing] aware of benefit designs that we believe would discourage enrollment by individuals based on age or based on health conditions, in effect making those plan designs discriminatory.”¹⁵¹ In particular, HHS identified the following three examples of potentially discriminatory practices:

- Placement of most or all drugs that treat a specific condition on the highest cost tiers;
- Refusal to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal; and
- Attempts to circumvent coverage of medically necessary benefits by labeling the benefit as a “pediatric service,” thereby excluding adults.¹⁵²

HHS also issued guidance to regulators with examples of benefit designs, including drug-specific examples, which are potentially discriminatory (Figure 14). However, HHS has repeatedly declined to conclude that such designs are “definitively discriminatory” and, rather, provides plans with an opportunity to take corrective action to minimize potential discrimination or otherwise offer a justification for the chosen plan design. HHS affirmed this approach in its final rule implementing Section 1557. With the exception of prohibiting categorical exclusions or limitations for services related to gender transition, HHS declined to codify specific examples of discriminatory benefit design and noted that the Office for Civil Rights will analyze whether a design feature is discriminatory on a case-by-case basis.¹⁵³ HHS also declined to identify having a specialty tier as an example of discriminatory benefit design.¹⁵⁴ Despite these rules, many plans continue to fail to provide robust coverage of certain types of prescription drugs (Figure 15).

FIGURE 14:
Non-Exhaustive List of Examples of Potentially Discriminatory Benefit Design from HHS, 2015

TYPE OF FEATURE	EXAMPLE OF POTENTIALLY DISCRIMINATORY BENEFIT DESIGN
EXCLUSIONS	Bone marrow transplants are excluded from transplant coverage, regardless of medical necessity
COST-SHARING	Emergency room services with significantly increasing cost-sharing burden as the number of visits increases
MEDICAL NECESSITY DEFINITIONS	Medical necessity for rehabilitative speech therapy services that is defined with the use of restrictive phrases such as “recovery of lost function” or “restoration to previous levels of functioning” when habilitative speech therapy is not covered
DRUG FORMULARIES	Requiring consumers to receive specialty medications particularly for certain medical conditions from mail-order pharmacies and not allowing the use of retail pharmacies Placing expensive life-saving or life-prolonging drugs, for which there is no generic and/or less expensive comparable alternative treatment, in tiers with high consumer cost-sharing
VISIT LIMITS	The number of covered outpatient rehabilitation visits is limited without regard to best medical practices for a given condition
BENEFIT SUBSTITUTION	Chiropractor visit limit substantially reduced in comparison to the state benchmark plan benefit in order to substantially increase outpatient physical therapy visit limit
UTILIZATION MANAGEMENT	Requiring prior authorization and/or step therapy for most or all drugs in drug classes such as anti-HIV protease inhibitors, and/or immune suppressants regardless of medical evidence Covering mammography alone and not covering breast MRIs in combination with mammography, for individuals who would benefit from breast cancer evaluation that incorporates an MRI

Source(s): Center for Consumer Information and Insurance Oversight, *Non-Discrimination in Benefit Design*, available at: https://www.insurance.ohio.gov/Company/Documents/2015_Non-Discriminatory_Benefit_Design_QHP_Standards.pdf.

FIGURE 15:

Significant Gaps in QHP Coverage of Antiretrovirals

In 2016, the National Alliance of State and Territorial AIDS Directors released a groundbreaking report documenting the coverage of antiretroviral therapy (ARV)—key treatment for many people living with HIV—in over 91,000 QHPs available through the federal marketplaces. The analysis found that many QHPs failed to provide robust ARV coverage. Key findings include:

- 20% of plans only covered one single-tablet regimen, Atripla, the oldest and least-recommended regimen
- One-third of plans place all covered single-tablet regimens on the specialty tier
- Over 45% of bronze plans subject all covered single-tablet regimens to coinsurance
- 15% of plans do not cover any HIV drugs introduced since 2013
- 34% of plans place Truvada, which can prevent HIV infection as Pre-Exposure Prophylaxis (PrEP), on a specialty tier
- 29% of plans require patients to “fail first” on another HIV drug before taking Stribild, a leading single-tablet regimen
- Cost-sharing reduction plans have the same high levels of coinsurance as silver plans
- Increases in drug list prices lead to increased frequency of coinsurance at statistically significant levels

Source(s): National Alliance of State and Territorial AIDS Directors, *Discriminatory Design: HIV Treatment in the Marketplace* (Jul. 2016).

Other examples of potentially discriminatory benefit design include the adoption of UM practices based on sobriety or disease progression or drug coverage decisions that do not reflect the unique needs of people with disabilities. For example, regulators should be aware of the risk that certain drugs or therapies may be wholly excluded or subject to inappropriately restrictive UM since many medical studies and standards of care do not include people with disabilities and thus may not reflect the needs of those with developmental or intellectual disabilities.¹⁵⁵ We urge state and federal regulators to actively monitor and address these potentially discriminatory issues as they arise and to issue guidance defining these practices as potentially discriminatory.

Given continued incentives for plans to limit adverse selection, regulators must remain vigilant in monitoring, investigating, and correcting potentially discriminatory benefit design. Doing so is particularly important as insurers adjust to the Affordable Care Act’s market reforms and experiment with new plan design features.

Enforcement Tools.

Regulators have developed new processes and tools to address discriminatory formulary design. HHS has developed a suite of tools that include a category class drug count review, a nondiscrimination formulary outlier review, and a nondiscrimination clinical appropriateness review.¹⁵⁶ While valuable, some state regulators have noted the need for more robust regulatory tools that allow holistic reviews of the categories and classes of covered drugs, UM criteria, differential cost-sharing, heightened administrative requirements, and incentive programs for drugs used to treat high-cost conditions.¹⁵⁷

State regulators also increasingly rely on feedback from external stakeholders, including consumer advocates, sister agencies, ombudsmen, and providers, to help identify discriminatory formulary design. Regulators at DC Health Link, for instance, quickly took corrective action after external stakeholders alerted regulators to discriminatory HIV/AIDS design that had previously been missed by regulators.¹⁵⁸ The Montana Commissioner of Securities and Insurance similarly limited high coinsurance requirements after receiving a complaint from the National Multiple Sclerosis Society.¹⁵⁹ And the Pennsylvania Department of Insurance solicits external feedback from interested parties through proactive outreach to other state agencies and consumer organizations to discuss concerns and solicit complaints.¹⁶⁰

Given enforcement challenges, regulators should also solicit ongoing feedback from external stakeholders with clinical expertise to help regulators identify concerns about discriminatory formulary design and to inform regulators' formulary review process. For more information on enforcement tools, please see the section of this report on "Meaningful Oversight and Regulation of Prescription Drug Benefits."



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Comprehensive Nondiscrimination Protections

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Define "discriminatory benefit design" and "discriminatory UM restrictions" and identify and prohibit specific examples of discriminatory benefit design, including:
 - Placing most or all drugs that treat a specific condition on the highest cost tiers;
 - Refusing to cover a single-tablet drug regimen, extended-release product, or combination therapy that is customarily prescribed and just as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen; and
 - Adopting UM practices based on sobriety or disease progression.
- Develop more sophisticated review templates and tools to identify and address potentially discriminatory plan design and any other limitations that are inconsistent with federal and state law or nationally recognized clinical guidelines and medical evidence before a plan is approved for market.
- Solicit feedback from external stakeholders—including consumer and patient advocates, consumer assistance programs, state clinical advisory panels, other state agencies, ombudsmen, and independent medical experts—to help identify concerns about discriminatory formulary design and to inform the formulary review process.

ADVERSE TIERING

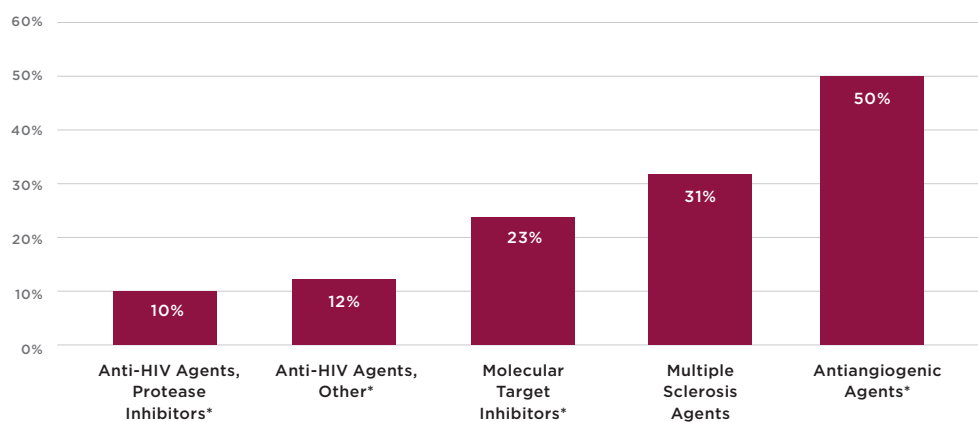
Drug tiering—assigning covered drugs to a “tier” based on cost-sharing and UM requirements—has become increasingly complex over time. Many plans have at least three drug tiers with a separate tier just for specialty drugs.¹⁶¹ Coinsurance is particularly common on the highest-cost tiers compared to copays, which can result in consumers owing thousands of dollars each month for life-saving medication.

Because the most expensive drugs are often placed on the most expensive tiers, drug tiering disproportionately affects consumers with costly chronic conditions like cancer, multiple sclerosis, depression, HIV/AIDS, cystic fibrosis, hemophilia, diabetes, mood or anxiety disorders, and hepatitis. These increased costs can result in higher health care costs since higher out-of-pocket costs have been shown to cause consumers to skip doses or discontinue a drug entirely.¹⁶²

As drug tiering has become increasingly common, so too has adverse tiering. Adverse tiering—the practice of placing most or all drugs that treat a specific condition on the highest cost-sharing tier—has been observed in employer and marketplace plans and often affects single-source medications used to treat chronic conditions.¹⁶³ One analysis found adverse tiering of HIV medications in 25 percent of 2015 marketplace plans in 12 states while another found that most cancer drugs in 2015 marketplace plans in 5 states and DC were placed on the highest cost-sharing tiers.¹⁶⁴

A 2016 study on marketplace plans in all 50 states found evidence of less adverse tiering in 2016 compared to previous years. However, some silver plans continue to place all covered drugs in a class on a specialty tier (Figure 16). Fifty percent of silver plans placed all covered antiangiogenic agents—drugs used to fight cancer—on a specialty tier, and 31 percent of these plans placed all covered multiple sclerosis agents on a specialty tier.¹⁶⁵

FIGURE 16:
Percentage of 2016 Silver Plans Placing All Covered Drugs in the Class on a Specialty Tier



* There are no generic drugs available in the class. All products are single-source.

Source(s): Access Better Coverage, “New Avalere Study: Health Plan Formularies Continue to Suggest Bias Against Individuals with Certain Health Conditions,” Pharmaceutical Research and Manufacturers of America (Apr. 2016); Avalere PlanScape Analysis of Prescription Drug Tier Placement and Cost Sharing in Exchange Plans, 2016.

There may have been lower levels of adverse tiering in 2016 marketplace plans because of recent HHS guidance on discriminatory benefit design. In late fall 2014, HHS identified adverse tiering as an example of a potentially discriminatory practice.¹⁶⁶ Under federal guidance, adverse tiering could be discriminatory based on specific facts and circumstances and thus may require additional investigation and justification by a plan to explain why the practice is not discriminatory.¹⁶⁷

Although marketplace plans showed some expanded coverage for HIV/AIDS medicines in 2016, about 10 percent of silver plans continue to place all covered single-source HIV/AIDS medicines on a specialty tier or impose coinsurance requirements of more than 30 percent.¹⁶⁸ Copays were more common than coinsurance across HIV classes, but average coinsurance requirements were 35 percent and ranged from 10 percent to 70 percent. This was true despite a high-profile complaint filed with the HHS Office for Civil Rights alleging discriminatory formulary design for HIV/AIDS medications in Florida (Figure 17).

FIGURE 17:
Discriminatory Formulary Design and HIV/AIDS Medications

In 2014, The AIDS Institute and the National Health Law Program filed a complaint with the HHS Office for Civil Rights alleging that four Florida insurers adopted unlawful discriminatory benefit designs by:

- Requiring inordinately high copays and coinsurance for HIV treatments, such as 40 percent coinsurance;
- Placing all HIV drugs on the highest cost-sharing tier, including generic versions of widely prescribed antiretrovirals; and
- Imposing restrictive UM, such as prior authorization for all refills.

The Florida Office of Insurance Regulation ultimately entered into agreements with the insurers and established an HIV/AIDS benefit design safe harbor. However, the HHS Office for Civil Rights has not yet resolved the complaint, which is still pending.

Source(s): National Health Law Program & The AIDS Institute, *Discriminatory Pharmacy Benefits Design in Select Qualified Health Plans Offered in Florida, Administrative Complaint to HHS Office for Civil Rights (May 29, 2014)*.

Adverse tiering can have a dramatic financial impact on consumers: A person with HIV in a marketplace plan with adverse tiering pays more than \$3,000 for treatment annually even after accounting for premium tax credits and an out-of-pocket maximum.¹⁶⁹ In addition to the significant financial burden that adverse tiering places on consumers, this practice is likely to result in adverse selection against plans that do not adopt this practice.¹⁷⁰ By placing most or all drugs that treat a specific condition on the highest cost-sharing tier, plans may be intentionally discouraging high-risk consumers from enrolling in their plan, resulting in a competitive disadvantage to plans with more generous drug coverage.

Standardized Plans.

Plan standardization also presents an opportunity to limit adverse tiering. A recent analysis comparing the coverage of HIV/AIDS medications in standardized plans in California, New York, and Massachusetts to non-standardized plans in Colorado, Maryland, and Washington found that “[p]lan standardization appeared to eliminate adverse tiering completely.”¹⁷¹

Of the 45 plans analyzed, none of the 19 standardized plans had adversely tiered HIV/AIDS medication while six of the 26 non-standardized plans did. (Adverse tiering was defined as the placement of all drugs on tiers with coinsurance or copay levels of at least 30 percent.) Plan standardization also led to significant savings for those with HIV: Drug costs were about three and a half times higher in non-standardized plans, which were an average of \$2,550 more expensive than standardized plans for HIV-positive beneficiaries even after accounting for premiums, deductibles, and out-of-pocket maximums.

Despite its promises, plan standardization is only effective if it includes meaningful cost-sharing limits. California, for instance, limited specialty drug cost-sharing to 20 percent while Massachusetts and New York adopted fixed maximum copays for their most expensive tiers. These relatively low cost-sharing limits effectively mitigated adverse tiering and reduced consumer costs.

Although HHS established standardized plan options, coinsurance requirements range from 25 to 45 percent for specialty tier drugs at all metal levels (and 35 to 45 percent for lower tiers in bronze plans).¹⁷² Given these levels of coinsurance, HHS should consider adjusting its standardized options to better limit the risk of adverse tiering for drugs used to treat chronic conditions.

State Action.

States have adopted a variety of approaches to addressing adverse tiering in addition to plan standardization. Delaware, for instance, prohibits plans from placing all drugs in a given class on a specialty tier.¹⁷³ California similarly prohibits plans from designing formularies in a way that 1) discourages the enrollment of individuals with health conditions, or 2) reduces the generosity of benefits for enrollees with a particular health condition in a way that is not based on clinical indicators or reasonable medical management practices.¹⁷⁴

Other states, such as Colorado, issued guidance to incorporate HHS standards, noting that the placement of most or all drugs to treat a specific condition on the highest cost-sharing tiers may be considered discriminatory against those with chronic conditions.¹⁷⁵ Still others—including Delaware, Louisiana, Maine, and Maryland—have capped cost-sharing for prescription drugs on a per drug or monthly basis. For more information on state cost-sharing requirements, please see the section of this report on “Consumer Affordability of Prescription Drug Coverage.”

Finally, state regulators have developed new processes and tools to aid in the identification of adverse tiering. In Florida, for instance, the Office of Insurance Regulation created a drug-specific “chronic conditions template” that requires plans to identify the number, name, and tier of covered drugs used to treat certain conditions, such as breast cancer, bipolar disorder, hepatitis C, and rheumatoid arthritis, among others.¹⁷⁶ For more information on tools for monitoring and enforcement, please see the section of this report on “Meaningful Oversight and Regulation of Prescription Drug Benefits.”



Consumer Recommendations on Adverse Tiering

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Define adverse tiering as an example of discriminatory benefit design and prohibit insurers and their designees from placing most or all drugs that treat a specific condition on the highest cost-sharing tiers.
- Require prior approval of mid-year formulary changes (where permitted) that negatively affect enrollee access to drugs (such as moving a drug to a higher formulary tier) to ensure that such changes do not result in adverse tiering.
- Evaluate the potential for adverse tiering through outlier analyses and by reviewing the categories and classes of covered drugs, UM criteria, differential cost-sharing, heightened administrative requirements, and incentive programs for drugs used to treat high-cost conditions.
- Adopt standardized plans with meaningful cost-sharing limits to mitigate the risk of adverse tiering.

UTILIZATION MANAGEMENT

UM is a set of review criteria and techniques used by plans to evaluate and determine whether a particular health service, procedure, or facility is medically necessary, appropriate, and efficient for a given enrollee. UM is commonly applied to prescription drug benefits, particularly for high-cost or specialty medications. Although UM varies by insurer and plan, common techniques include prior authorization, step therapy, quantity limits, and mandatory generic substitution (Figure 18).

When applied appropriately based on accepted best medical practices or standards of care adopted by medical specialty societies, UM helps ensure that drugs are prescribed effectively and efficiently. Examples of such standards include the American Association for the Study of Liver Disease's guidelines on hepatitis C and federally approved HIV/AIDS medical practice guidelines.¹⁷⁷ UM can also be used to control or limit the use of low-value prescription drugs, such as expensive treatments that provide minimal clinical benefit or that result in negative side effects. At the same time, overly restrictive UM can result in barriers to accessing medication, reduced drug adherence, and potentially worse health outcomes and higher health care costs.

Many employer plans use UM as a way to control specialty drug costs. In 2015, 31 percent of surveyed large employers reported using UM to contain the cost of specialty drugs, with 30 percent reporting the use of step therapy and 25 percent imposing quantity limits.¹⁷⁸ UM was even more common in a recent survey on trends in specialty drug benefits in 2015 where 93 percent of surveyed employers used prior authorization, 78 percent used step therapy, 69 percent imposed 30-day quantity limits, and 35 percent limited an enrollee's first prescription fill to a one- or two-week supply to test the clinical response before filling a longer supply.¹⁷⁹ Similar surveys show that step therapy requirements are most often applied to drug classes used to treat rheumatoid arthritis, high cholesterol, and attention deficit disorder.¹⁸⁰

FIGURE 18:

Prescription Drug Utilization Management

UM TECHNIQUE	DEFINITION
PRIOR AUTHORIZATION	A requirement that a provider or enrollee get permission from the plan before a drug is covered
STEP THERAPY ("FAIL FIRST")	A requirement that an enrollee try a lower-cost medication for a period of time before a higher-cost medication will be covered
QUANTITY LIMITS	A limit on the quantity of a given drug that can be dispensed at one time (such as a 30-day supply of a particular medication per month)
MANDATORY GENERIC SUBSTITUTION	A requirement that an enrollee that chooses a brand-name drug over an equivalent generic drug must pay the difference in cost between the two drugs (in addition to cost-sharing for the brand-name drug)

Source(s): American Cancer Society Cancer Action Network, *Just the Facts: Prescription Drug Utilization Management* (Feb. 25, 2014).

Marketplace plans impose UM at higher rates than employer plans, particularly for single-source drugs in selected classes.¹⁸¹ For instance, UM restrictions for the coverage of single-source mental health drugs occur in 40 percent of silver marketplace plans compared to only 24 percent of employer plans. The use of UM is also increasing over time: In 2016, UM was more prevalent for single-source drugs for HIV/AIDS, hepatitis, mental health, cancer, immune diseases, and diabetes compared to previous years.

Although UM can be beneficial when used properly, excessive or overly restrictive UM can impede access to appropriate, timely prescription drug coverage and result in adverse selection against plans that impose less burdensome UM restrictions. For instance, overly restrictive UM requirements were part of a complaint filed by The AIDS Institute and the National Health Law Program alleging that four Florida insurers adopted unlawful benefit designs that discriminated against people with HIV/AIDS after CoventryOne, Cigna, and Humana placed all HIV drugs on the highest cost-sharing tier, required prior authorization for widely used antiretrovirals, and imposed 30-day quantity limits.¹⁸² Other examples of potentially discriminatory UM design include:

- Applying prior authorization requirements without transparent criteria for review and approval;
- Adopting UM practices that contraindicate treatment guidelines adopted by specialty medical organizations or the federal government that are recognized as setting the standard of care for a condition, such as step therapy or quantity limits on antiretrovirals or requiring antiretrovirals to be prescribed by an infectious diseases physician;
- Requiring prior authorization for all drug refills;
- Refusing to accept a patient assistance program card for a medically necessary drug;
- Covering intravenous anti-cancer treatment but not oral anti-cancer treatment (or covering oral anti-cancer treatment after increasing cost-sharing for intravenous therapies);

- Adopting UM practices based on sobriety or disease progression unless based on accepted best medical practices or standards of care adopted by medical specialty societies; and
- Restricting the overall number of prescriptions allowed to be filled in a given time period.

In conjunction with or as an alternative to UM, many plans offer clinical and educational programs to help enrollees understand and comply with prescription drug protocols. These programs—which include disease management programs, complex case management, or therapy adherence—are common among employers,¹⁸³ and insurers and their designees should be encouraged to use clinical and educational programs rather than UM whenever possible to reduce health care costs and patient disruption. In offering clinical and educational programs, plans should ensure that these programs are fully accessible to individuals with limited English proficiency as well as individuals with disabilities by, for example, offering written materials available in alternative formats such as in Braille or in a large font.

Plans should also disclose UM information to consumers in plain language. Formularies should be publicly accessible and specifically include any UM-related limitations or restrictions for each covered drug, including drugs covered under the medical benefit. These types of requirements are critical to identifying potentially discriminatory UM design. As with adverse tiering, such public information—combined with ongoing feedback from enrollees and external stakeholders, such as providers and advocates—can help regulators identify concerns about potentially discriminatory UM design. For more information on formulary-related disclosures, please see the section of this report on “Improving Transparency of Prescription Drug Coverage.”

State Action.

Nearly all states have adopted some UM standards, with many states adopting laws similar to the NAIC’s model act on utilization review and benefit determination.¹⁸⁴ California, for instance, explicitly requires insurers and their designees to develop and maintain written UM policies and procedures to “ensure that decisions based on the medical necessity of proposed health care services are consistent with criteria or guidelines that are supported by clinical principles and processes.”¹⁸⁵ These policies and procedures must be filed with state regulators and disclosed to enrollees, providers, and the public upon request.

Some states have developed standardized processes for prior authorization or step therapy, expanded exceptions and appeals processes to include UM, and improved the transparency and availability of UM information. These changes help limit the potential for discriminatory UM design by providing clarity, promoting transparency, and enabling data collection. However, many states have not explicitly addressed discriminatory UM design or imposed UM-specific standards in the context of prescription drug benefits.

Standardized requirements.

Many states—such as California, Colorado, Illinois, Iowa, Mississippi, and Oregon—have adopted standardized prior authorization processes that are specific to prescription drugs and require insurers to respond to a prior authorization request within a certain period of time. Mississippi, for example, require insurers to respond to prior authorization requests within two business days after the receipt of such requests while other state requirements vary from one to five days.¹⁸⁶

States also require the use of standardized prior authorization forms. These forms are typically developed by state insurance regulators or working groups and informed by national standards, such as those developed by the National Council for Prescription Drug Programs.¹⁸⁷ In some states, such as Arkansas, Louisiana, and Mississippi, prior authorization forms and any amendments must be filed with state regulators.¹⁸⁸

Other states allow enrollees (or their providers) to request an exception to a plan's UM. Although some states already allowed these exceptions processes for prior authorization, some—such as California, Connecticut, Illinois, Kentucky, and Mississippi—are allowing enrollees to request an “override” of step therapy requirements.¹⁸⁹ Requirements vary by state but some laws specify that insurers must respond to override requests within a certain period of time, such as 48 hours.¹⁹⁰

Connecticut and Maryland also recently adopted step therapy-specific requirements. In Connecticut, insurers are prohibited from requiring the use of step therapy for more than 60 days.¹⁹¹ In Maryland, step therapy and fail first protocols are prohibited if 1) the step therapy drug has not been approved by the FDA for the medical condition being treated; or 2) a prescriber submits supporting medical information that the prescribed drug was ordered for an enrollee within the past 180 days and, based on professional medical judgment, is more effective in treating the enrollee's condition.¹⁹²

Increased transparency.

States are also requiring plans to disclose information about UM to enrollees and the public. Arkansas, California, Connecticut, Maine, South Dakota, and Texas, for instance, require or will require some or all plan formularies to publicly disclose UM information—including prior authorization, step therapy, or any other protocol requirements—for each covered drug or category.¹⁹³ Other states—such as Colorado, Virginia, and Washington—require insurers or utilization review entities to publicly post some or all UM requirements and restrictions on their websites.¹⁹⁴ Oregon also requires insurers to file an annual summary of all UM policies and document the insurer's procedures for monitoring delegated UM activities.¹⁹⁵

Federal Standards.

Federal regulations require that UM be regularly reviewed by P&T committees and provided in a nondiscriminatory manner.¹⁹⁶ In particular, insurers that offer QHPs cannot adopt plan designs, including UM, that discriminate on the basis of a variety of factors including health status or that discourage the enrollment of individuals with significant health needs.¹⁹⁷

HHS has recognized that UM could be designed in a discriminatory way.¹⁹⁸ In guidance on nondiscrimination in benefit design, HHS noted that a plan that required UM for most or all drugs in drug classes such as anti-HIV protease inhibitors or immune suppressants regardless of medical evidence “may discriminate against individuals with conditions for which those drug classes are applicable . . . and cause undue burden to receive necessary therapies.” The guidance goes on to note that a plan could minimize the potential for discrimination by “[u]sing current medical evidence to establish clinically appropriate prior authorization, step therapy, or unrestrictive coverage for drugs in a given drug class.” HHS also developed tools to help identify potentially discriminatory UM design. This includes a formulary outlier review tool, which regulators use to identify plans with an unusually small number of drugs without prior authorization or step therapy requirements.¹⁹⁹

Plan formularies are also required to note any restrictions on the manner in which a drug can be obtained, including UM restrictions, in a manner that is easily accessible to enrollees, potential enrollees, states, marketplaces, HHS, and the public.²⁰⁰ We urge regulators to identify a systematic way to list UM in the SBC, which only requires the disclosure of plan details related to prior authorization.

Consumer Recommendations on Utilization Management



CONSUMER
RECOMMENDATIONS

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Encourage insurers and their designees to prioritize clinical and educational programs—such as disease management programs and therapy adherence programs—over UM wherever possible to reduce health care costs and patient disruption and design these programs to be fully accessible to individuals with disabilities and individuals with limited English proficiency.
- Require insurers and their designees to only use UM techniques that are transparent and based on accepted best medical practices or standards of care adopted by medical specialty societies.
- Review plan UM design for discrimination and define the following UM techniques as examples of discriminatory benefit design:
 - Restricting coverage through prior authorization requirements, step therapy requirements, fail first protocols, dose or dose strength restrictions, or non-medical switching in a way that is inconsistent with accepted best medical practices or standards of care adopted by medical specialty societies;
 - Covering intravenous anti-cancer treatment but not oral anti-cancer treatment (or covering oral anti-cancer treatment after increasing cost-sharing for intravenous therapies);
 - Adopting UM practices based on sobriety or disease progression unless based on accepted best medical practices or standards of care adopted by medical specialty societies; and
 - Restricting the overall number of prescriptions allowed to be filled in a given time period in a way that prevents enrollees from obtaining all of the medically necessary medications they need for their health condition(s).
- Develop uniform standards for prior authorization requirements including 1) standardized request forms; and 2) a requirement that plans respond to urgent medical needs subject to utilization review within 24 hours and within 72 hours for all other medical needs.
- Require insurers and their designees to adopt a standardized, transparent process to request an exception to UM restrictions and to appeal UM determinations.

Improving Transparency of Prescription Drug Coverage



Despite recent strides in improved access to drug formularies, more can be done to make formularies more accessible, comprehensive, accurate, and consumer-friendly. Standardized, easy-to-understand formularies are critical to allowing consumers to make informed decisions about their coverage options. This is true for all consumers but particularly the millions of Americans living with chronic conditions that need to secure access to life-sustaining or life-saving medications.

Key Recommendations for Improving Transparency

- Require electronically accessible, accurate, up-to-date formularies to be available prior to enrollment that include comprehensive information about tiering structures, cost-sharing, UM, drug deductibles, and exceptions processes
- Prohibit mid-year formulary changes that negatively affect enrollee access to drugs, including the removal of a drug from a formulary (except for safety reasons which should be allowed as needed), moving a drug to a higher formulary tier or otherwise imposing higher cost-sharing, or imposing new or more restrictive UM
- Require formulary information to be submitted in standardized, machine-readable formats to aid in the development of consumer support tools

At a minimum, consumers should be able to easily find and understand whether a plan will cover the drugs they need, how much they will pay in out-of-pocket costs for each drug, if they will face any UM or network limitations, and whether the drugs they need are covered under the pharmacy or medical benefit. This information should be available to all enrollees, potential enrollees, states, marketplaces, HHS, and the public prior to enrollment. Consumers should also be informed about a plan's policy on mid-year formulary changes and the process for requesting drug exceptions and appealing a drug denial.

Transparency is equally important for regulators and policymakers. Standardized formulary requirements can help regulators more easily review formularies and identify discriminatory formulary design. This information can be analyzed by researchers to better understand the quality of drug coverage and inform policy reforms that consumers need. Standardization can also enable the development of robust consumer support tools, with the ultimate goal of allowing consumers to make informed plan choices based on health need, quality, cost, and personal preferences.

This section discusses the ways that state and federal regulators, lawmakers, marketplace officials, industry representatives, and other stakeholders can increase the level of transparency of prescription drug coverage in the areas of **access to formularies**, **mid-year formulary changes**, and **consumer support tools**. Each section includes background information, examples of state and federal approaches, and recommendations for consumer-protective policies.

ACCESS TO COMPREHENSIVE, ACCURATE FORMULARIES

Many plans have made formularies more accessible under the Affordable Care Act. New plans in the individual and small group markets are required to publish up-to-date, accurate plan-specific formularies, including any tiering structures and restrictions on accessing a drug prior to enrollment so that consumers can consider this information while shopping for coverage and selecting a plan.²⁰¹ Formularies must be easily accessible and identifiable on an insurer's website, and plans must include a direct link to the plan-specific formulary on the SBC.²⁰² Finally, QHPs sold through the federal marketplace are required to submit formulary information to HHS in a standardized format established by federal regulators.²⁰³

Many of these changes, however, did not go into effect until recently, and many formularies were unavailable or inaccurate in 2014 and 2015. According to an Avalere analysis of plans sold in 17 states, drug formularies were not available in 38 percent of plans in 2014.²⁰⁴ In a 2015 analysis of coverage in six states, the American Cancer Society found that the availability of links to formularies had improved since 2014, but significant gaps remained.²⁰⁵ For instance, most plans did not directly link to their formulary and there were inconsistencies between the information listed on the marketplace and the formulary itself: Of the formularies reviewed, cost-sharing information in the formulary matched the cost-sharing information displayed on the marketplace only about 50 percent of the time.²⁰⁶ Other studies—such as those by the National Partnership for Women and Families and The Urban Institute—had similar findings for 2015 marketplace plans.²⁰⁷ These gaps in marketplace information and on insurer websites suggest that ongoing monitoring and oversight of formularies will continue to be critical for consumers and regulators.

In addition to ensuring that consumers can access formularies, there is a significant need to make formularies more consumer-friendly (Figure 19). Consumer understanding of commonly used drug benefits terms—even the word “formulary”—is limited. And, because there is currently no consistent formulary display format used across plans or insurers, standardization of drug-specific terms and formulary displays would be particularly helpful for consumers. Benefits of standardization include:

- Allowing consumers to make apples-to-apples comparisons amongst plans and more easily select the plan that suits their health needs and budget.
- Ensuring a level playing field by allowing regulators to better compare plans and develop more sophisticated oversight tools to ensure compliance with regulatory requirements.
- Enabling marketplaces, developers, and other stakeholders to develop and design consumer-facing support tools, such as formulary search tools or other “smart tools” with interactive features.
- Aiding external stakeholders in monitoring drug coverage trends and alerting regulators to the potential for discriminatory formulary design.

FIGURE 19:

Improving Formularies for Consumers

In 2015, the California HealthCare Foundation released a report on consumer experiences accessing drug coverage information. To improve the consumer-friendliness of formularies, the report made the following recommendations:

- Use the term “prescription drug list” instead of “formulary”
- Use consumer-friendly medical terms for drug categories (i.e., “high blood pressure” instead of “hypertension”)
- Standardize formulary terminology and abbreviations
- Display copay information, tier placement, and step therapy requirements
- Clearly differentiate between brand-name drugs and generics (i.e., all capital letters for brand drugs and all lowercase letters for generic drugs)
- Provide information on the exceptions process prominently in the formulary introduction and throughout the directory
- Publish formularies in Spanish and other languages and ensure translations are accurate, understandable, and standardized

Source(s): HSM Group, *Hidden from View: How Consumers Find Information About Prescription Coverage*, California HealthCare Foundation (Aug. 2015).

Formularies should also be expanded to reflect the full scope of information that consumers want to consider when selecting a plan (Figure 20). Without access to comprehensive information, some consumers may be forced to pay thousands of dollars more for drug coverage or be unable to access the medication they need because of limitations they were unaware of when they enrolled in coverage.

In particular, formularies should disclose whether each covered drug is covered under the pharmacy benefit, the medical benefit, or both depending on the plan’s design. A drug, particularly a specialty drug, might be covered under the medical benefit if, for instance, it is administered by a provider or in a medical setting, such as a hospital or doctor’s office. Such coverage is fairly common: Of the \$457 billion spent on prescription drugs in 2015, about \$328 billion was spent on retail drugs—drugs purchased through a pharmacy—and about \$128 billion was spent on non-retail drugs, such as physician-administered drugs covered under a plan’s medical, rather than pharmacy, benefit.²⁰⁸ Experts estimate that non-retail drugs account for nearly 30 percent of all drug spending.²⁰⁹

FIGURE 20:

Drug Coverage Features to Disclose to Consumers

- Tiering structures
- Cost-sharing
- Utilization management
- Drug-specific deductibles
- Deductible-free drug coverage
- Network restrictions
- Medical versus pharmacy drug benefits
- Exceptions and appeals processes

Many plans do not currently list drugs that are covered under the medical benefit on plan formularies. As a result, it often appears to a consumer that these drugs are not covered at all, requiring much more extensive research to determine whether and how a drug will be covered.²¹⁰ Insurers and their designees should be required to disclose any drugs covered under the plan’s medical benefit, including cost-sharing, UM restrictions, and any distinctions between drug coverage under the medical versus the pharmacy benefit.

Finally, plans should do more to inform consumers that an exceptions process exists and how to utilize it. This is particularly important because many consumers are not familiar with and struggle to find information about exceptions processes.²¹¹ Formularies should include a clear explanation of the plan’s drug-related exceptions processes—including the expedited exceptions process, the standard exceptions process, the contraception exceptions process, and external review process—in the formulary introduction and plan documents. This explanation should include how and where consumers can request an exception, links to any required forms, and a timeline for each process. Plan-specific exceptions information should also be publicly accessible on an insurer’s website. For more information on exceptions and appeals processes, please see the section of this report on “Improving Access to Comprehensive Prescription Drug Coverage.”

State Action.

Many states have taken steps to improve formulary transparency. Arkansas, California, Connecticut, Maine, and Texas, for instance, recently required plans to make formularies publicly available and to disclose information on tiering structures, cost-sharing, utilization management, exclusions, and/or network restrictions for each covered drug.²¹² Texas adopted broad disclosure standards to “promote consistency and clarity in the disclosure of formularies to facilitate comparison shopping among health benefit plans” (Figure 21).²¹³

FIGURE 21:
Formulary Disclosure Requirements in Texas

In 2015, the Texas legislature enacted formulary disclosure standards that require plan formularies to disclose the following information:

- Cost-sharing amount for each drug expressed as the dollar amount of a copay, the dollar amount of coinsurance, or a specified range for coinsurance (such as \$501-\$1000);
- Prior authorization, step therapy, or other protocol requirements for each drug;
- The specific tier for each drug listed in the formulary; and
- Descriptions of how drugs will be included or excluded from the deductible and any out-of-pocket costs that would not apply to the deductible.

The law allows the commissioner to develop a publicly available web-based tool to display cost-sharing information as an alternative to these disclosures.

Source(s): *Tex. Ins. Code § 1369.0543*

Most of these states require formularies to be publicly available on an insurer’s website in a way that is accessible and searchable by applicants, enrollees, providers, and the public. Some states—such as Connecticut—also require this information to be posted on the marketplace website in addition to the insurer’s website.²¹⁴

Although each of these states requires plans to disclose certain formulary information, most do not specify how plans must do so or otherwise impose standardized display requirements (although state regulators could consider doing so by issuing regulations or guidance). In contrast, California’s law directs state regulators—with public input—to develop a standard formulary template that insurers will be required to use beginning in 2017.²¹⁵

Still other states, such as South Dakota, do not require marketwide standardization but require each insurer to adopt a standardized formulary format for every plan that it offers “so that comparison of the attributes of the plans is facilitated.”²¹⁶ Like the states noted above, South Dakota requires the disclosure of cost-sharing, UM, exclusions, and network restrictions for each covered drug.

Finally, federal and state-based marketplaces have enhanced features to help consumers more easily consider their prescription drug needs when shopping for coverage. The state-based marketplace in Colorado, for instance, features a prescription drug directory that allows consumers to enter the names of their medications into a search tool, which then displays available plans that cover those specified medications.²¹⁷ The federal marketplace similarly features a “prescription drug lookup” tool to allow consumers to search for their prescription drugs when shopping for coverage.²¹⁸ These tools are discussed in more detail below.



Consumer Recommendations on Access to Comprehensive, Accurate Formularies

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Require the use of and develop standardized formulary display requirements to enable consumers to make apples-to-apples comparisons across plans.
- Require insurers and their designees to publish up-to-date, accurate, and complete formulary lists that include the following information and are electronically accessible to enrollees and the public:
 - Tiering structures and cost-sharing requirements for each tier, including the dollar amount of any copay or coinsurance;
 - Any restrictions on the manner in which a drug can be obtained including, but not limited to, quantity limits, dose restrictions, prior authorization requirements, step therapy requirements, and any other UM restrictions;
 - Any drugs covered under the plan's medical benefit, including cost-sharing, UM restrictions, and any distinctions between drug coverage under the medical versus the pharmacy benefit;
 - Any drugs that are covered as a preventive service without cost-sharing;
 - Whether the plan has a separate drug deductible or whether the medical deductible applies to prescription drugs;
 - Any network-related limitations or restrictions, including differential cost-sharing, on the location from which a prescription can be filled;
 - The process to secure a drug exceptions or external review request; and
 - Coverage of over-the-counter medications.
- Ensure that insurers and their designees provide direct links to searchable formularies for each plan and include this direct link in the plan's SBC.
- Require formularies and all drug-related benefit information, whether in electronic or print format, to be written in plain language and accessible to individuals with disabilities and individuals with limited English proficiency as defined in 45 C.F.R. Sections 92.201, 92.202, 92.204, and 155.205(c).
- Require insurers and their designees to update their formularies at least weekly and periodically audit a reasonable sample of formulary data for accuracy.

MID-YEAR FORMULARY CHANGES

Although access to comprehensive, accurate formularies is particularly important when consumers are shopping for coverage, formulary transparency remains important throughout the year since consumer health needs change over time. Despite the need for ongoing transparency and formulary stability, many plans change their formularies during the course of a plan year. Changes may be made as new drugs are added to the market or as utilization, pricing, and medical knowledge evolves over time.

Mid-year formulary changes can have significant consequences for consumers. This is particularly true when plans remove a drug from a formulary altogether, move a drug to a higher level tier, otherwise increase cost-sharing for a drug, or impose more restrictive UM than what was originally in place when a consumer selected a plan. Because a change in drug coverage does not result in eligibility for a special enrollment period, many consumers who lose access to a drug through a mid-year formulary change will remain locked in a plan that does not meet their health needs. Some enrollees may receive continued access to their medication through the plan's exceptions process, but many enrollees are not aware of this option and not all exception requests are granted.

Mid-year formulary changes are occurring in marketplace plans. According to an Avalere study of formularies in all 50 states and DC, nearly half of analyzed plans revised their formularies between October 2013 and September 2014.²¹⁹ Although the study did not find widespread negative mid-year changes in 2014, some plans dramatically reduced drug coverage for at least four classes of medication used to treat cancer, diabetes, multiple sclerosis, and asthma. Of the 41 plans that changed their formularies, 33 reduced drug coverage for at least one of these four classes of medication.²²⁰ Six of these plans—18 percent—made significant drug coverage reductions, removing between 15 and 57 products during the plan year, and five of these plans saw drug coverage fall in at least one class by more than 15 percent.²²¹ Given these findings—and continued incentives for plans to limit adverse selection—regulators should remain vigilant in monitoring mid-year formulary changes.

Plans should have flexibility to make some mid-year formulary changes, such as adding newly approved drugs or biologics, removing drugs from a formulary after the FDA deems a drug unsafe, or eliminating UM requirements. These formulary changes have the potential to enhance consumer coverage, rather than detract from it, and should be allowed at any time.

However, plans should not be able to reduce the generosity of coverage after a consumer has enrolled. In particular, plans should be prohibited from making mid-year formulary changes—changes made between the date on which open enrollment begins and the end of the plan year—that negatively affect enrollee access to drugs. Such negative changes include:

- Removing a covered drug from a formulary except when the FDA deems a drug unsafe or a manufacturer removes a drug from the market;
- Moving a drug to a higher formulary tier or otherwise imposing higher cost-sharing;
or
- Imposing more restrictive UM.

Although we strongly recommend that regulators prohibit mid-year formulary changes that reduce drug coverage, states that continue to allow this practice should adopt additional consumer protections. First, if a plan is removing a drug from its formulary, the plan should be required to continue covering that drug for all affected enrollees at the same cost-sharing level for the remainder of the year, a requirement adopted in Medicare Part D (Figure 22). Alternatively, states should allow a special enrollment period for enrollees who lose access to a needed drug due to a mid-year formulary change. Second, state insurance regulators should review and approve any mid-year formulary change that negatively affects enrollee access prior to the change being implemented to ensure that it does not discriminate against enrollees with significant health conditions or on other bases that are prohibited under the Affordable Care Act. In addition, insurers and their designees should be required to provide at least 60 days advance notice to enrollees, prescribers, and in-network pharmacies when making a mid-year formulary change. In particular, notices should include easy-to-understand information about the plan's drug exceptions processes and how a consumer can begin the process of securing an exception.

FIGURE 22:

Mid-Year Formulary Changes in Medicare Part D

Medicare has recognized the importance of formulary stability and imposes a number of limitations on mid-year formulary changes for drugs covered under Medicare Part D. Key components of the policy include the following:

- Part D sponsors can expand coverage at any time by adding drugs, reducing cost-sharing, or deleting UM.
- Part D sponsors must seek CMS approval for negative formulary changes, including removal of a drug from a formulary, higher cost-sharing, or new or more restrictive UM. Even if approved, affected enrollees are exempt from the change for the remainder of the plan year.
- Part D sponsors must provide 60 days advance written notice of an approved negative change to affected enrollees, pharmacies, and other stakeholders.

Source(s): Centers for Medicare and Medicaid Services, Chapter 6: Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual (Rev. 18, Jan. 2016).

State Action.

A number of states have prohibited or limited mid-year formulary changes or required insurers that do make such changes to notify consumers. Texas, for instance, enacted legislation to prohibit most mid-year formulary changes except at the time of coverage renewal (Figure 23). Even then, insurers must comply with additional requirements, such as notifying each affected enrollee and group sponsor and ensuring that the change is made uniformly across all identical or similar plans.

Nevada similarly prohibits most mid-year formulary changes but did so through the regulatory process. In 2015, the Nevada Division of Insurance promulgated regulations to prohibit insurers in the individual market from removing a drug from a formulary during the plan year except in limited circumstances.²²² Insurers are similarly prohibited from moving a drug to a tier with higher cost-sharing unless the insurer adds a generic alternative at the same tier or a lower tier during the plan year. The regulations allow insurers to add a drug to a formulary at any time.

FIGURE 23:

Texas Limits Mid-Year Formulary Changes

Individual and group health benefit plans in Texas have been prohibited from making mid-year formulary changes since January 1, 2012. Prohibited changes include:

- Removing a drug from a formulary;
- Adding a requirement that an enrollee receive prior authorization for a drug;
- Imposing or altering a quantity limit for a drug;
- Imposing a step-therapy restriction for a drug; and
- Moving a drug to a higher cost-sharing tier unless a generic alternative is available.

Under Texas law, these changes can only be made at renewal and must be adopted uniformly for all individuals or groups covered by identical or substantially identical plans. Insurers must also provide at least 60 days advance notice to state regulators and each affected enrollee before the change goes into effect.

Source(s): Tex. Ins. Code §§ 1369.0541, 1501.108

In promulgating these regulations, the Nevada Division of Insurance cited its authority to review and approve policy forms and develop standards on fair marketing and health plan availability. Since many states have comparable protections, other states could consider a similar regulatory approach to limiting mid-year formulary changes.

Other states have limited but not prohibited mid-year formulary changes. In New Mexico, plans cannot make most mid-year formulary changes within 120 days of any previous changes.²²³ Such changes include removing a drug from a formulary, reclassifying a drug to a higher tier, imposing higher cost-sharing, or adopting or modifying certain UM restrictions. Insurers that make such changes have to notify affected enrollees at least 60 days in advance of the change.

Arkansas, Oklahoma, and Virginia have adopted similar notice requirements. In Arkansas, insurers and their designees must provide affected enrollees with at least 60 days advance written notice of a mid-year formulary change that increases an enrollee's financial responsibility.²²⁴ Oklahoma imposes similar requirements but only when a drug is being removed from a formulary.²²⁵ And Virginia requires insurers to provide at least 30 days advance written notice when moving a drug to a tier with higher cost-sharing requirements.²²⁶ Virginia also requires insurers to establish a process for enrollees to obtain continued access to drugs that they have been receiving for at least six months prior to a formulary change at a cost-sharing level that is no higher than the level imposed on formulary drugs.²²⁷ For more information on continuity of drug coverage, please see the section of this report on "Improving Access to Comprehensive Prescription Drug Coverage."

Federal Standards.

HHS has indicated that it is concerned about mid-year formulary changes, especially those that negatively affect enrollees.²²⁸ Although HHS has not prohibited mid-year formulary changes for QHPs, federal regulators have noted that insurers "generally may not make plan design changes, including changes to drug formularies, other than at the time of plan renewal" under guaranteed renewability requirements.²²⁹

In addition, HHS has required plans to provide a standard drug exceptions process, which allows an enrollee to request and potentially gain access to a medically necessary drug that is no longer covered under the formulary.²³⁰ This presents an opportunity for some enrollees to receive continued access to their medication; however, not all enrollees are aware of this option and not all exception requests are granted. For more information on exceptions and appeals processes, please see the section of this report on “Improving Access to Comprehensive Prescription Drug Coverage.”

Some mid-year formulary changes may implicate the Affordable Care Act’s nondiscrimination protections. This is particularly true if changes are imposed in a way that disproportionately burdens individuals with chronic conditions. For more information on discriminatory benefit design, please see the section of this report on “Nondiscrimination in Formulary Design.”



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Mid-Year Formulary Changes

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Allow insurers and designees to add new products—including drugs, biologics, and biosimilars—at any time during the plan year.
- Prohibit insurers and their designees from making mid-year formulary changes—changes made between the date on which open enrollment begins and the end of the plan year—that negatively affect enrollee access to drugs, including:
 - Removing a covered drug from a formulary except when the FDA deems a drug unsafe or a manufacturer removes a drug from the market;
 - Moving a drug to a higher formulary tier or otherwise imposing higher cost-sharing; or
 - Imposing new or more restrictive UM requirements.

CONSUMER SUPPORT TOOLS

Consumer-facing support tools—such as formulary search tools or other “smart tools” with interactive features—can increase consumer knowledge, satisfaction with the decision process, and selection of a plan that aligns with the consumer’s needs and preferences.²³¹ These tools can help fill significant gaps in consumer knowledge and highlight the need to consider certain plan elements, such as prescription drug coverage, to a consumer who might be unaware that benefits can vary dramatically by plan (Figure 24). Such tools may also be critical to attracting and retaining young people who expect to use consumer support tools to simplify their options and make a coverage decision.

Although decision support tools can be very valuable to consumers, the quality of these tools depends on the availability of meaningful and relevant content.²³² One consistent barrier to developing effective consumer support tools is a lack of relevant and standardized content. This barrier is particularly relevant to the development of drug-specific support tools since there are few standardized machine-readable formats or reporting requirements for formularies.²³³

FIGURE 24:

Gaps in Consumer Knowledge

Consumers have significant gaps in knowledge about prescription drug coverage. In 2015, a report commissioned by the California HealthCare Foundation found that consumers were unfamiliar with common drug-specific coverage terms and highlighted the following examples:

- Most consumers did not know the term “formulary” and those who did were uncertain of its definition.
- Coinsurance was often mistaken for being secondary insurance.
- Drug tiers were often confused with metal level tiers.
- Consumers assumed that a preferred drug (compared to a nonpreferred drug) indicated a better drug rather than one with reduced cost-sharing.
- Consumers were unfamiliar with exception or appeals processes and could not find this information.

Source(s): HSM Group, Hidden from View: How Consumers Find Information About Prescription Coverage, California HealthCare Foundation (Aug. 2015).

Given the need for standardization, state and federal regulators can play a key role in requiring all plans to submit accurate, comparable formulary data. Marketwide data collection is particularly important because most consumers—57 percent of the individual market and 95 percent of the small employer market—are enrolled in plans sold outside the marketplaces.²³⁴ State regulators, in particular, can leverage their form review processes to require the submission of comparable formulary data and can ensure that State Electronic Rates and Forms Filing System data is accurate, reported consistently across plans and states, and submitted in a standardized machine-readable format.²³⁵

Marketplaces can use the data they have to develop prescription drug tools, as the federal marketplace and some state-based marketplaces have already done. The federal marketplace has, for instance, developed an integrated prescription drug directory that allows a consumer to enter the names of their medications and select the appropriate dosage amounts. The resulting plan options then identify whether each drug is covered by a given plan or not. The state-based marketplace in Colorado similarly developed a “medication look-up” tool where a consumer can enter the names of their medications. The marketplace then shows plans that cover those medications and links to a summary of each plan’s formulary and coverage of that medication, including cost-sharing requirements, the availability of mail-order prescription filling, and whether a generic drug is available. Such tools can allow consumers to easily and quickly see which plans cover their medications.

Marketplaces can also ensure that other tools—even where not drug-specific—incorporate information about covered medications, cost, and other information that consumers need to know to make an informed decision. These other tools may include cost calculators or the health condition consumer support tool used by the state-based marketplace in Connecticut. This tool allows a consumer to select options from a drop-down list about their health condition (e.g., asthma), any planned surgeries (e.g., total hip replacement), and the severity of their condition (e.g., low, moderate, or high). The tool then provides total cost ranges for plans on each metal level tier and projected premiums and out-of-pocket costs, including medical and pharmacy services.

FIGURE 25:

Importance of Consumer Testing

Consumer support tools are only as useful as their design and functionality. Tool design and presentation should account for consumer needs and preferences as well as consumer literacy, the intended use of the tool, and the complexity of the information.

Testing throughout the development process—including initial and post-launch focus groups, beta testing, and interviews with consumers—helps ensure that data displays, interactive features, and other design elements meet consumer needs. Given the importance of testing to ensuring that tools are well-understood and valued by consumers, we strongly encourage the use of consumer testing throughout any consumer support tool development process.

Consumer support tools are used in other federal health programs and the private sector. A prominent example is the Medicare Plan Finder, which allows Medicare-eligible consumers to enter the name of a drug as well as the dosage, quantity, frequency, and pharmacy type for each individual drug. This information is then used to sort various plan options and can be saved, edited, and compared across plans. In recent consumer testing, the Medicare Plan Finder was praised by consumers, even as compared to the Colorado marketplace tool and existing California marketplace displays, and could be a helpful example upon which to base future formulary tools.²³⁶ For more information on the importance of consumer testing, see Figure 25. Private sector examples of consumer support tools include the Consumers' Checkbook, Stride Health, and Clear Health Analytics, among others.²³⁷ Most of these tools allow for the consideration of drug-specific information.




CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Consumer Support Tools

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Require insurers to use standardized formulary display requirements and submit formulary information in machine-readable formats so that designers of consumer tools and apps have full access to the data necessary to develop robust consumer support tools.
- Ensure that all plans in the individual and small group markets submit data on prescription drug benefits in the same machine-readable standardized formats at least 60 days prior to open enrollment each year and make this data available to the public.
- Develop electronically searchable, consumer-tested plan comparison tools that allow consumers to search for plans that cover their drugs and accurately calculate out-of-pocket costs.
- Promote the availability of consumer support tools among consumers, consumer and patient advocates, enrollment assisters, producers, and other stakeholders.

Meaningful Oversight and Regulation of Prescription Drug Benefits

 Regulators play a critical role in ensuring that consumers receive the full benefits and protections of state and federal law. Given the new changes ushered in by the Affordable Care Act, robust monitoring and enforcement has never been more important for consumers. This is particularly true as prescription drug coverage has increased in complexity and as insurers experiment with new plan design features.

Despite its importance, monitoring and enforcement is not without its challenges, and not all regulators have the resources they need to fully enforce state and federal requirements. Regulators may, for instance, lack clinical expertise or the technical tools needed to review and monitor formulary design. These challenges may be exacerbated for state insurance departments that are limited in terms of staff time, capacity, and financial resources. We recognize these barriers and urge policymakers to prioritize capacity building and funding for state insurance regulators.

Data collection and analysis can be a powerful tool to help address regulatory gaps. The collection of meaningful data about, for instance, the number of formulary changes in a



Key Recommendations for Meaningful Oversight and Regulation

- Collect comprehensive, standardized plan-level data on prescription drug benefits during form and rate review processes, data calls, analysis of MCAS data, and marketplace reporting requirements and make this information available to the public
- Analyze collected data and issue public reports about trends, challenges, and potential areas of concern in formulary design and the regulation of drug-specific benefits
- Solicit regular feedback from external stakeholders to inform the formulary review process and help identify concerns about potentially discriminatory formulary design
- Actively regulate PBMs to ensure state-level oversight and establish uniform standards that protect all consumers and define PBMS as designees of health insurers for purposes of state law and the NAIC Health Carrier Prescription Drug Benefit Management Model Act
- Limit the incorporation of drug utilization into risk adjustment models to a very small number of diagnosis-drug pairs that result in significant improvements in overall predictive accuracy

given year or the type of drug-specific complaints received can be invaluable in informing regulators' review of formularies during the form and rate review process and the development of new standards that better protect consumers.

In addition to collecting standardized information, regulators should consistently report about trends, challenges, and potential areas of concern in the regulation of drug-specific benefits. These reports are valuable for many stakeholders, can illustrate for legislators the need for changes in state law, and can help illuminate the need for state insurance regulators to build capacity and expertise in regulating pharmacy benefits.

This section discusses the ways that state and federal regulators, lawmakers, marketplace officials, industry representatives, and other stakeholders can address these issues in the areas of **tools for monitoring and enforcement, data collection and analysis, regulation of PBMs, and risk mitigation programs**. Each section includes background information, examples of state and federal approaches, and recommendations for consumer-protective policies.

TOOLS FOR MONITORING AND ENFORCEMENT

Effective monitoring and evaluation requires regulators to have access to the information and expertise they need. Regulators should require insurers to submit comprehensive information about prescription drug benefits and utilization; use and develop tools to aid in review and analysis of plans; and partner with external stakeholders to inform the formulary review process.

First, regulators can monitor and enforce drug-specific requirements through the **regulatory review process**. Doing so is particularly important since many consumers are unaware of their rights to file a complaint with a state insurance department and unlikely to do so (Figure 26). In particular, plans should be required to submit comprehensive, standardized formulary information during the form review process that includes tiering, cost-sharing, UM, and network restrictions for each covered drug (including drugs covered under a plan's

FIGURE 26:
Need for Robust Regulatory Review

Many regulators rely on complaint and other post-market enforcement mechanisms to alert them to consumer concerns. However, doing so likely underestimates the extent of health insurance issues because many consumers are unaware of their rights or reluctant to assert them. A 2015 study from Consumer Reports found that:

- Two-thirds of privately insured Americans were uncertain about which state entity is responsible for resolving issues with health insurance billing.
- 87 percent did not know the state agency or department tasked with handling health insurance complaints.
- 83 percent have never complained to a government agency about any issue.
- 72 percent were unsure if they have the right to appeal to the state or an independent expert if they receive a claim denial.

Given this lack of awareness, regulators should thoroughly review and analyze plans before they are marketed to best protect consumers.

Source(s): Consumer Reports National Research Center, Surprise Medical Bills Survey: 2015 Nationally-Representative Online Survey (May 2015).

medical benefit). As discussed in the section of this report on “Improving Transparency of Prescription Drug Coverage,” a number of states have already adopted similar formulary disclosure standard that could be replicated for use by regulators.

State regulators can use this information to require corrective action before consumers are impacted (Figure 27). We also urge marketplaces to collect, analyze, and publicly report data on trends in drug coverage for marketplace plans. This information could aid policymakers and marketplace staff in better understanding plan complexity and illuminate the need for plan standardization or additional consumer support tools to help consumers make meaningful comparisons among plans.

FIGURE 27:
Monitoring Formulary Design: Spotlight on State Regulators

State insurance regulators can use their regulatory authority to require or encourage insurers to limit copays and coinsurance for certain drugs or tiers without setting an overall cap on cost-sharing.



Montana.

The Montana Commissioner of Securities and Insurance limited high coinsurance requirements for specialty tier drugs after receiving a complaint from the National Multiple Sclerosis Society. Given dramatically different cost-sharing among plans (with some imposing coinsurance of up to 90 percent for specialty drugs), Montana regulators determined that such plan designs discriminate against individuals with high-cost medical conditions and risk adverse selection against plans that offer fixed copays for all drug tiers. Following this determination, insurers are now required to offer at least one plan at the silver level or above with copays for all drug tiers. In addition, copay amounts must be proportionally related between the tiers: For example, an increase in copays from \$75 to \$500 between a nonpreferred brand-name tier and a specialty tier may be unacceptable.



Florida.

The Florida Office of Insurance Regulation (FLOIR) addressed a similar issue after some insurers placed all HIV/AIDS drugs—including generic versions of widely prescribed antiretrovirals—on specialty drug tiers and imposed restrictive UM, such as prior approval for all refills for HIV/AIDS medications. Following a complaint by The AIDS Institute and the National Health Law Program alleging that these benefit designs discriminate against people living with HIV/AIDS, the FLOIR issued consent orders to insurers who agreed to limit cost-sharing and drop UM for HIV/AIDS drugs. The FLOIR also established an HIV/AIDS benefit design safe harbor based on the state’s essential health benefits benchmark plan, which specifies maximum cost-sharing for each drug and tier in the form of fixed copays.

Insurance regulators in other states should consider establishing similar benefit design safe harbors; soliciting feedback from external stakeholders, such as consumer and patient advocates; and applying and interpreting state laws on unfair trade practices and unfair competition to address burdensome and potentially discriminatory cost-sharing requirements.

Source(s): Sally McCarty, “Regulatory Activity in Two States Restricts How Plans Structure Specialty Drug Coverage,” CHIRBlog (Jan. 21, 2015); Montana Office of the Commissioner of Securities and Insurance, *Montana Review: Specialty Tier Drugs*, Presentation for Northwest Health Law Advocate (Nov. 7, 2014); Florida Office of Insurance Regulation, *Humana Agrees to Consent Order Regarding HIV/AIDS Medications and Conduct of Exams* (Feb. 17, 2016); Florida Office of Insurance Regulation, *PPACA Guidance to Insurers - 2016 Filings HIV/AIDS Drugs Safe Harbor*; Ron Hurtbise, “State Tells Insurers to Limit Co-pays for HIV/AIDS Drugs,” *Florida Sun Sentinel* (Jul. 1, 2015).

Second, regulators should **develop and use tools** to aid in monitoring and enforcement. Regulators can, for instance, monitor complaints associated with the prescription drug appeals process for drugs included (and not included) on formularies; request complaints data on prescription drugs from all insurers; and build a database to track specific benefits—including drug formularies—to help ensure that plans do not steer high-risk individuals to other products.²³⁸

In Florida, for instance, the Office of Insurance Regulation created a drug-specific “chronic conditions template” for insurers to complete as part of their filings.²³⁹ Insurers must enter the number and name of covered drugs at each tier that are used to treat bipolar disorder, breast cancer, diabetes, hepatitis C, HIV, multiple sclerosis, prostate cancer, rheumatoid arthritis, and schizophrenia. Regulators have also developed internal databases and other tools to identify potential concerns about formulary adequacy or discriminatory formulary design.²⁴⁰

HHS similarly developed a suite of tools to assist state regulators and insurers in reviewing and designing nondiscriminatory formularies. Current tools include a category class drug count review, a nondiscrimination formulary outlier review, and a nondiscrimination clinical appropriateness review.²⁴¹ The formulary outlier review tool, for instance, assists regulators in identifying plans with an unusually small number of drugs without prior authorization or step therapy requirements.²⁴²

While valuable, some state regulators have noted the need for more robust regulatory tools. In particular, regulators note the need for tools that allow holistic reviews of the categories and classes of covered drugs, UM criteria, differential cost-sharing, and incentive programs for drugs used to treat high-cost conditions.²⁴³ At a minimum, regulators should have sufficient review tools and processes to identify plans where most or all covered drugs used to treat a specific condition are placed on a specialty tier and where exclusions, cost-sharing, UM, and network restrictions are inconsistent with federal and state law or nationally recognized clinical guidelines and medical evidence.

Third, regulators should **partner with external stakeholders** to inform the formulary review process and fill gaps in expertise. State insurance regulators can, for instance, partner with state clinical advisory panels or independent medical experts to help identify concerns about plan design, such as adverse tiering. Regulators can also coordinate with other state agencies (such as the office of the attorney general or ombudsman offices for worker’s compensation programs); consumer support entities (such as consumer assistance programs); federal agencies (such as HHS); and state opioid addiction task forces to share data and help identify consumer concerns. The Pennsylvania Department of Insurance, for instance, solicits external feedback from interested parties through proactive outreach to other state agencies and consumer organizations to discuss concerns and solicit complaints.²⁴⁴ State insurance regulators can also coordinate with one another through the NAIC or by forming multistate or regional collaborations to identify or develop new regulatory review tools, share data and best practices, and monitor insurer activity to better identify multistate trends and concerns.

State regulators also increasingly rely on feedback from advocates and providers to help identify discriminatory formulary design. Regulators at DC Health Link, for instance, took corrective action after external stakeholders alerted regulators to a discriminatory HIV/AIDS design that had previously been missed by regulators.²⁴⁵ Montana regulators similarly limited high coinsurance requirements after receiving a complaint from the National Multiple Sclerosis Society.²⁴⁶ Ongoing feedback from external stakeholders can help regulators identify concerns about formulary design and inform the formulary review process.

Finally, regulators should conduct **consumer outreach and education campaigns** to solicit complaints and raise awareness of prescription drug benefit requirements, nondiscrimination protections, exceptions processes, and appeals rights. Although many state insurance departments already conduct consumer outreach efforts, we encourage regulators to diversify these efforts and partner with consumer assistance personnel to reach underserved communities. All education and outreach efforts should be culturally and linguistically appropriate.



CONSUMER
RECOMMENDATIONS

Consumer Recommendations on Tools for Monitoring and Enforcement

State and federal insurance regulators and marketplace officials should:

- Collect comprehensive, standardized plan-level data on prescription drug benefits during form and rate review processes, data calls, analysis of MCAS data, and marketplace reporting requirements and make this information available to the public.
- Develop more sophisticated review templates and tools—including those that go beyond outlier analyses—to identify and address potentially discriminatory plan design before a plan is approved for market.
- Coordinate with regulators in other states and on a regional basis to identify or develop new regulatory review tools, share data, and monitor insurer activity to better identify multistate trends and concerns.
- Solicit feedback from external experts—including consumer and patient advocates, consumer assistance programs, state clinical advisory panels, other state agencies, ombudsmen, and independent medical experts—to inform the formulary review process and help identify concerns about discriminatory formulary design.
- Conduct consumer outreach and education campaigns to solicit complaints and raise awareness of drug coverage requirements, nondiscrimination protections, exceptions processes, and appeals rights.

DATA COLLECTION AND ANALYSIS

Regulators can collect data in a variety of ways, including pre- and post-market regulatory processes (Figure 28). Regulators can, for instance, review and collect information on drug coverage during regular and targeted market conduct examinations. For best practices on conducting efficient, effective market conduct exams, please see “Strengthening the Value and Performance of Health Insurance Market Conduct Examination Programs: Consumer Recommendations for Regulators and Lawmakers.”²⁴⁷ This report—commissioned by the consumer representatives to the NAIC in 2013—identified best practices and recommendations for regulators in performing market conduct examinations.

Regulators can also distribute surveys directly to consumers or link regulatory data with all payer claims database data for a more robust analysis of plan design and cost. In Colorado, for example, the Division of Insurance commissioned a study using pharmacy claims data from the state’s all payer claims database and specialty drug information provided to the Division in regulatory filings to assess the impact of imposing a pre-deductible, \$150 copay cap on specialty drugs in commercial markets.²⁴⁸

FIGURE 28:

Select Opportunities for Regulators to Collect Data on Prescription Drug Coverage

- Form review process
- Rate review process
- Market conduct exams
- Analysis of MCAS data
- Drug-specific data calls
- Marketplace reporting requirements

Understanding the need for data, the NAIC Market Regulation and Consumer Affairs (D) Committee has long worked to improve the collection, storage, and reporting of publicly available data on a nationwide basis. As part of this effort, the Market Analysis Procedures (D) Working Group recently developed and tested the first-ever Market Conduct Annual Statement (MCAS) template for health insurance products (Figure 29). The MCAS is a mandatory filing that collects data on a state-specific, industry-wide basis. As a result, insurers in most states will be required to report health data using the Health MCAS template. We strongly encourage regulators to make this information available to the public as well as analyze and report this information to inform oversight and plan design.

FIGURE 29:

Drug-Specific Data Collected through the NAIC Health MCAS

In 2016, the NAIC Market Regulation and Consumer Affairs (D) Committee adopted a Health Market Conduct Annual Statement (MCAS) reporting template and definitions. Insurers in most states will be required to report the following pharmacy-specific data beginning in fall 2017:

- Number of pharmacy claims received and paid;
- Number of denials for both in-network and out-of-network pharmacy claims;
- Number of paid claims for in-network and out-of-network pharmacy services; and
- Consumer cost-sharing requirements (including copays, coinsurance, and deductibles) related to pharmacy benefits.

Insurers will also have to submit data on the total number of internal and external reviews (such as the number of requested appeals) that include any drug-specific requests.

Source(s): National Association of Insurance Commissioners, Market Conduct Annual Statement, available at: http://www.naic.org/mcas_2016.htm.

The Health MCAS fills a critical need for state-based market analysis and market regulation. Although the data that insurers must report on the Health MCAS will provide a significant amount of new information, we urge the NAIC and regulators to collect additional pharmacy-specific information by metal level, rather than in aggregate, to allow for a more detailed review and understanding of potential concerns for enforcement. Additional information that should be collected through the Health MCAS includes:

- Amount that the insurer paid for pharmacy claims;
- Number of formulary exception requests;
- Number of pharmacy-related appeals and the outcome of those appeals;
- Number of drugs dispensed at a preferred pharmacy, nonpreferred pharmacy, specialty pharmacy, or other type of network tier;
- Number of drugs filled under the medical benefit versus the pharmacy benefit;

- Number of drugs and percent of approved drugs within a category or class on the formulary and the number and percent of drugs on the highest cost-sharing tier;
- Number of drugs subject to a formulary change (including a change in UM or moving a drug to a higher cost-sharing tier) in a given quarter; and
- Number of drugs subject to UM and number of pharmacy prior authorizations requested, approved, and denied.

Regulators also collect, analyze, and report data on consumer inquiries and complaints. Many state insurance departments issue annual reports on the number and type of consumer complaints they received. In California, the Office of the Patient Advocate released the nation’s most robust multi-departmental report on health care complaint data, which includes a summary of complaint data from the state’s four primary health agencies in California (Figure 30). Other states, like Missouri, maintain a “complaint index” that measures how many complaints an insurer has received relative to premiums, including pharmacy-specific complaints.²⁴⁹

**FIGURE 30:
Consumer Health Care Complaints in California**

In 2014, the California legislature directed the Office of the Patient Advocate (OPA) to produce a multi-departmental baseline report on health care complaint data. The report includes a summary of complaint data from the state’s four primary health agencies—the Department of Managed Health Care, the Department of Health Care Services, the Department of Insurance, and Covered California—which are, collectively, responsible for regulating private health insurance, managing the state’s marketplace, and administering Medi-Cal coverage.

Reported data includes demographic information, type of coverage, the reason for a complaint, and the time it took to resolve a complaint. OPA made the following findings in its inaugural report:

- There were more than 27,000 consumer health care complaints closed in 2014. The most common reasons for a consumer complaint included claim denials, quality of care, denial of medical necessity, and cost-sharing issues.
- Agencies varied in the amount of time it took to resolve a complaint, ranging from 37 days to 157 days.
- 40% of the resolutions of consumer complaints were in favor of the consumer while 16% were decided in favor of the health plan.
- Previously, these agencies did not use similar tracking mechanisms and used different data and complaint categories, and this was the first time a state was able to do comparative analysis of public program and commercial complaint data.

Source(s): California Office of the Patient Advocate, *Annual Health Care Complaint Data Report: Baseline Report to the Legislature* (May 2016).

State insurance regulators also voluntarily submit data to the NAIC’s Complaints Database System which is used to develop reports with aggregate information about complaints. Although state regulators have reported nearly 1,000 complaints about pharmacy benefits to the NAIC’s Complaints Database System since 2014,²⁵⁰ little else is known about the content of these complaints and how they were resolved. We urge the NAIC and state regulators to release more detailed information about complaints. Doing so will help policymakers better understand and assess the frequency, type, and resolution of consumer complaints about prescription drug coverage. We also urge state insurance regulators, including marketplace officials, to coordinate with other state and federal agencies and opioid task forces to address complaints through shared data, joint investigations, and enforcement action as needed.

Federal Standards.

Federal regulators have significant authority to collect, analyze, and report health insurance data under the Affordable Care Act. Under Section 2715A of the Public Health Service Act and Section 1311(e) of the Affordable Care Act, many insurers are required to submit a range of data to marketplaces, state regulators, and HHS. This data includes claims payment policies and practices, periodic financial disclosures, data on enrollment and disenrollment, data on the number of claims that are denied, and other information as determined appropriate by the Secretary.²⁵¹

Despite these robust data collection requirements, implementation and enforcement has largely been delayed.²⁵² Although some data is being collected for the 2018 plan year, these requirements are limited to certain states and data. Marketplaces are also required to collect data from QHP insurers on plan quality and enrollee satisfaction, but implementation of these requirements has similarly been delayed. We strongly urge marketplaces, state regulators, and HHS to fully implement these data collection requirements and collect as much plan- or product-level data as possible.

Consumer Recommendations on Data Collection and Analysis

State and federal insurance regulators and marketplace officials should:

- Analyze and publicly report data obtained through the Health MCAS and update the Health MCAS to collect additional pharmacy-specific information by metal level, rather than in aggregate.
- Release more detailed information to the public about consumer complaints to help policymakers better understand and assess the frequency, type, and resolution of consumer complaints about prescription drug coverage.
- Coordinate with all payers claims databases, other state and federal agencies, and multi-disciplinary state opioid addiction task forces to identify, track, report, and investigate complaints regarding drug coverage through shared data, joint investigations, and enforcement action as needed.
- Fully enforce Section 2715A of the Public Health Service Act and Section 1311(e) of the Affordable Care Act to require plans to make plan- or product-level information on drug coverage—such as pharmacy claims denied—available to the public.
- Collect and analyze robust data from QHP insurers and PBMs pursuant to Section 6005 of the Affordable Care Act and 45 C.F.R. § 156.295 and provide this information to state-based marketplace officials to inform marketplace oversight and policymaking.



CONSUMER
RECOMMENDATIONS

REGULATION OF PHARMACY BENEFIT MANAGERS

PBMs administer prescription drug benefits for more than 253 million Americans.²⁵⁴ A PBM is an organization that administers prescription drug programs on behalf of a public or private payer or employer. The role of PBMs has expanded dramatically over time: most PBMs create and manage formularies, negotiate discounts with drug manufacturers, create pharmacy networks, and conduct UM reviews.²⁵⁵ Many also own and operate their own mail-order pharmacies.

Because PBMs represent millions of consumers, they are able to negotiate significant price reductions from drug manufacturers and can reduce administrative burdens on plan sponsors. Use of PBMs has resulted in savings: Consumers with PBM-administered drug coverage paid 15 percent less for certain brand-name drugs compared to consumers without a PBM.²⁵⁶

Critics, however, argue that PBMs do not always pass along these savings to plan sponsors; that these deals incentivize PBMs to favor certain drugs over others for financial gain; and that PBMs face limited direct oversight and regulation. Others note that the PBM industry is highly concentrated: In 2014, just four PBMs—Express Scripts, CVS/caremark, OptumRx, and Catamaran (acquired by OptumRx in 2015)—administered benefits for more than 78 percent of Americans that had coverage through a PBM.²⁵⁷ While the PBM industry argues that it remains competitive, critics have expressed concern that limited competition among the three largest PBMs contributes to higher drug prices and that savings are not passed along to consumers.²⁵⁸ Still others raise concerns about the potential for self-dealing through payment structures that steer consumers to PBM-owned mail-order pharmacies. For these and other reasons, PBMs and drug manufacturers have been the subject of numerous investigations and settlements under laws such as the federal False Claims Act.²⁵⁹

Given the significant role that PBMs play, consumers should have access to information regarding how PBMs are managing their prescription drug benefits. PBMs should also provide drug coverage that meets the same formulary standards that apply to commercial insurers, such as standards for P&T committees, exceptions processes, and formulary transparency. This is particularly important for consumers who may not know or understand the difference between a PBM and traditional prescription drug coverage through their insurer.

We urge the NAIC and state policymakers to define PBMs as designees of health insurers for purposes of state law and the NAIC Health Carrier Prescription Drug Benefit Management Model Act. Doing so will continue state-level oversight by insurance regulators and establish uniform standards that protect all consumers, regardless of how an insurer decides to design its formulary. Even if PBMs are not explicitly defined as designees, insurers should actively enforce these standards through their contract with a PBM, which should be available to state insurance regulators.

PBMs should also be accredited by a recognized accreditation organization, such as URAC, to help augment state regulation of prescription drug programs. Although we support accreditation, it is not sufficient for meaningful oversight of prescription drug coverage and formulary design by state regulators.

Data Collection and Transparency.

Consumers need greater transparency about how PBMs are managing their prescription drug benefits. We urge regulators to collect and publicly report robust data about PBM pricing, rebates, and conflicts of interest. Some of this information can be collected by federal regulators under Section 6005 of the Affordable Care Act, which requires many plans to provide certain data to HHS (Figure 31). This information should be aggregated and released to the public. In general, we encourage the collection and reporting of data that allows stakeholders to better monitor prevailing, average, and actual pricing so there is additional access to pricing information to judge the effectiveness of PBM price negotiations.

Policymakers should also collect PBM data with a higher degree of granularity. Key information includes maximum allowable cost lists for pharmacy reimbursement, transparency regarding pharmacy network design, reporting of a dispensing rate for when a lower cost drug could have appropriately been dispensed, reporting of prompt payment rates, and reporting of how patient data is used and disclosed. We encourage regulators to make as much data as possible available to the public.

States can also commission studies and surveys on PBM management practices and policies. In Texas, for instance, state insurance regulators studied PBM policies and practices on generic substitution, therapeutic interchange, and formulary changes.²⁶⁰ In doing so, regulators sought input from stakeholders such as the Board of Pharmacy and the Texas Medical Association and surveyed PBMs, insurers, and physicians to inform policy recommendations. The Arkansas Bureau of Legislative Research issued a similar report on PBM practices and procedures that included recommendations for new legislation.

FIGURE 31:

Collecting PBM Data Under the Affordable Care Act

Section 6005 of the Affordable Care Act allows the Secretary of HHS to request information from insurers and PBMs that provide pharmacy benefits for a QHP, a Medicare Advantage prescription drug plan, or a Medicare Part D prescription drug plan. This data includes the:

- Total number of prescriptions dispensed
- Percentage of all drugs provided through retail pharmacies compared to mail-order pharmacies
- Percentage of drugs for which a generic drug was available and dispensed, broken down by pharmacy type
- Aggregate amount and type of rebates, discounts, or price concessions that are attributable to patient utilization
- Aggregate amount and type of rebates, discounts, or price concessions that are passed through to the insurer
- Difference between the amount the insurer pays the PBM and the amount the PBM pays retail and mail-order pharmacies for drugs

The information submitted by a plan or PBM is confidential, but HHS can, under certain circumstances, disclose aggregated information. This information can also be disclosed to states, such as state-based marketplaces, to carry out Section 1311 of the Affordable Care Act.

Source(s): 42 U.S.C. § 1320b-23; 45 C.F.R. § 156.295; 42 C.F.R. § 423.514.

One area that merits additional study by regulators and policymakers is the increased use of price protections in insurer contracts with PBMs. In some cases, insurers are including inflationary cap provisions or other price protection arrangements that cap the amount a manufacturer can increase the cost of a medication during the life of the rebate contract with the PBM.²⁶² Additional study is needed to better understand this trend and protections that can be put in place to ensure that consumers benefit from these price protections.

State Regulation of PBMs.

States have adopted diverse approaches to regulating PBMs.²⁶³ Some of these efforts have resulted in litigation about the extent to which states have the authority to regulate PBMs and which, if any, state requirements are preempted under federal law.²⁶⁴ This section summarizes some approaches that states have taken to regulating PBMs (Figure 32).

First, almost all states require PBMs to **register with the insurance department or become licensed as a third-party administrator.**²⁶⁵ In doing so, a PBM may have to file business information and pay a fee, among other requirements. Some states, such as Connecticut, additionally allow state regulators to revoke a PBM’s license because of unfair or deceptive business practices.

Second, some states require PBMs to provide plan sponsors with **access to PBM data and information** that might otherwise be claimed to be proprietary. In North Dakota, for instance, all contracts with PBMs must include a provision that allows the plan sponsor to audit a PBM’s records to confirm that the PBM is appropriately sharing any savings.²⁶⁷ In Maryland and South Dakota, disclosure requirements extend to data on revenue, utilization discounts, and manufacturer rebates.²⁶⁸ These types of standards help ensure that plan sponsors can request and access information that they might not have otherwise received.

Third, PBMs in some states are required to disclose information about **drug pricing and fee arrangements.** These requirements were adopted in part to address concerns that PBMs were retaining, rather than “passing through,” potential savings to plan sponsors. In Maryland, for instance, PBMs are required to inform the plan sponsor that pass-through pricing will depend upon the terms of the contract between the PBM and the insurer or employer.²⁶⁹ In other cases, a PBM may charge a flat fee or a transaction fee for services. Because of this variation in fee arrangements, Vermont requires PBMs to use pass-through pricing unless the contract with the plan sponsor states otherwise.²⁷⁰ And North Dakota requires PBMs to offer a pass-through pricing option, a transaction fee option, and a combination of these two options to plan sponsors.²⁷¹

FIGURE 32:
Select Areas of State Regulation of PBMs

-
- | | |
|--|--------------------------------|
| • State licensure | • Formulary changes |
| • Audit of PBM records | • Drug pricing arrangements |
| • Fiduciary duty to enrollees or plans | • Fee arrangements |
| • Drug substitution | • Pharmacy reimbursement rates |
-

Fourth, some states have imposed **formulary requirements** with respect to PBMs. Under these standards, a PBM may be restricted from, for instance, making mid-year formulary changes or drug substitutions. In South Dakota, PBMs can only request a more costly substitution drug if there are medical reasons that benefit the enrollee and their prescriber has approved the substitution.²⁷² Although Vermont does not limit a PBM's ability to substitute a more expensive drug for a prescribed drug, PBMs must disclose to the plan sponsor the price of both drugs and the benefit or payment that the PBM receives as a result of the substitution.²⁷³

Finally, some states, such as the District of Columbia and Maine, have imposed a **fiduciary duty** on PBMs to act in the best interest of enrollees or plans. Although the District of Columbia's requirement was found to be preempted under ERISA in 2010 and Maine repealed this requirement in 2011, many states have considered legislation to impose a fiduciary duty on PBMs.²⁷⁴ Critics argue that these duties would increase legal and administrative costs and deter PBMs from cost-reducing practices, such as directing consumers to mail-order pharmacies.²⁷⁵ However, consumer advocates, such as Consumers Union, support fiduciary duties for PBMs and have developed model legislation for consideration by states.²⁷⁶

We urge state and federal policymakers to actively regulate PBMs and ensure that consumers have access to the prescription drug coverage they need. These efforts may include adopting policies on licensure, disclosures, drug pricing, and fiduciary duties; conducting state-level studies of PBM practices and policies; or soliciting comments from external stakeholders, as the Oregon Department of Consumer and Business Services has done in creating a Pharmacy Benefit Manager Rulemaking Workgroup to gather input on new rules on PBM compliance.²⁷⁷

Consumer Recommendations on Regulation of Pharmacy Benefit Managers

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Actively regulate PBMs and consider adopting policies related to licensure, information disclosure, accreditation, drug pricing, and fiduciary duties.
- Ensure that PBMs provide drug coverage that fully meets formulary standards that apply to insurers and plans by:
 - Defining PBMs as designees of health insurers for purposes of state law and the NAIC Health Carrier Prescription Drug Benefit Management Model Act; and
 - Requiring insurers to enforce compliance with these standards under their contract with the PBM, which should be accessible to state regulators.
- Collect robust data about PBM pricing, rebates, and conflicts of interest through Section 6005 of the Affordable Care Act and state-level studies and surveys on PBM management practices and policies.



CONSUMER
RECOMMENDATIONS

RISK MITIGATION PROGRAMS

Prior to the Affordable Care Act, many consumers with health conditions faced significant challenges in obtaining health insurance coverage. This is, in part, because insurers that enrolled less healthy individuals, such as those with chronic conditions, faced much greater risk than those that enrolled relatively healthy individuals.

To avoid this increased risk, insurers often cherry picked the healthy while avoiding the sick. To address this barrier, the Affordable Care Act ushered in significant reforms that included risk adjustment, reinsurance, and risk corridors.²⁷⁸ These risk mitigation programs are designed to reduce incentives for insurers to avoid higher-risk enrollees. Consumers may not be aware of these programs, but they are critical to ensuring that markets remain stable.

Despite risk mitigation programs, some insurers have continued to limit their risk of adverse selection through design features that may discourage the enrollment of individuals with significant health needs. This is especially true in formulary design where some plans have consistently used adverse tiering or overly restrictive UM for single-source drugs or selected drug classes.

At the same time, there have been challenges to fully funding the risk mitigation programs. For 2014, HHS was able to pay out only about 12 percent of the \$2.87 billion in requested risk corridor payments.²⁷⁹ This shortfall had a dramatic effect on some insurers, contributing to significant losses and the ultimate closure of some new health insurance cooperatives.²⁸⁰ To reduce incentives for insurers to cherry pick healthy enrollees, we urge HHS to fully fund outstanding and risk corridor payments and continue to strengthen program oversight.

Risk Adjustment.

Risk adjustment, in particular, is intended to limit adverse selection, establish a level playing field, and promote competition based on quality and price, rather than avoiding higher-risk enrollees. Risk adjustment is a permanent program that transfers premium revenue from plans with below-average risk to plans with above-average risk.

HHS, in consultation with states, must establish criteria and methods to be used in risk adjustment methodology (or states can submit an alternative methodology to HHS for approval).²⁸¹ In reviewing its risk adjustment model for the 2018 plan year, HHS discussed the possibility of adding prescription drug utilization as a risk marker to its model to create a hybrid drug-diagnosis model.²⁸² To the extent that HHS incorporates this model, we recommend doing so on only a limited basis. This would mean incorporating a very small number of diagnosis-drug pairs that meet the strict criteria outlined in HHS' proposal and that result in significant improvements in overall predictive accuracy.

We are concerned that a broad-based approach could result in gaming, perverse incentives, or distorted prescribing patterns. If these strict criteria are not met, insurers could, for instance, encourage providers to prescribe more costly drugs or choose prescription drug treatments over less-costly alternatives like behavioral modification. Drug utilization could also reduce predictive accuracy where enrollees use a drug on an “off-label” basis rather than for the condition for which the drug was originally approved.

Consumer Recommendations for Risk Mitigation Programs

Federal insurance regulators and marketplace officials (and state regulators using an alternative risk adjustment methodology) should:

- Limit the incorporation of prescription drug utilization into risk adjustment models to a very small number of diagnosis-drug pairs that result in significant improvements in overall predictive accuracy.
- Fully fund outstanding and future risk corridor payments and continue to strengthen program oversight.



CONSUMER
RECOMMENDATIONS

Addressing Emerging Therapies



Rapid advances in science and technology are leading to clinical breakthroughs and groundbreaking new drugs, therapies, devices, and diagnostic tools. Pharmaceutical innovation is vital for consumers: new products offer fewer side effects, improved quality of life, and the possibility of living a longer, more productive life.



Key Recommendations for Addressing Emerging Therapies

- Require insurers to review newly approved therapies or indications within 90 days of approval by the FDA and make a coverage determination within 180 days of release onto the market
- Ensure that routine patient costs are approved for qualified enrollees participating in approved clinical trials
- Encourage the use and study of new payment models that incentivize risk-sharing with drug manufacturers, such as value-based pricing
- Actively participate in the development of value frameworks to assess the value of new treatments and support patient-centered clinical decision-making

New breakthrough therapies include targeted cancer treatments, cures for diseases like hepatitis C, or improved treatment to lower cholesterol. These types of advances are only expected to continue through the power of personalized medicine, multi-disciplinary approaches like the National Cancer Moonshot Initiative, and large-scale, open-source genome sequencing, among other efforts.

Yet, emerging therapies—which save lives and improve the quality of life for millions of consumers—can come at a very high price. There is typically no generic alternative or equivalent to help moderate prices, and many new products are expensive or complicated to administer or produce. Drug manufacturers also set prices to recoup costly investments in research and development or to otherwise maximize exclusivity protections.

High prices for emerging therapies can strain health care budgets and put treatment out of reach for many consumers. Although some drug manufacturers offer patient assistance programs to offset consumer cost-sharing, these programs may not result in significant enough out-of-pocket reductions or be available to all consumers and critics argue that they distort the market and contribute to high drug costs.²⁸³

A comprehensive approach to addressing high prices for emerging therapies—a challenging and complex public policy issue with no single, simple solution—is beyond the scope of this report. However, private and public payers, PBMs, and policymakers can help address drug costs for new therapies and support innovative payment models with drug manufacturers.

This section discusses the ways that state and federal regulators, lawmakers, marketplace officials, industry representatives, and other stakeholders can address these issues in the areas of **new therapies**, **value-based pricing**, and **value frameworks**. Each section includes background information, examples of private sector and government approaches, and recommendations for consumer-protective policies.

NEW THERAPIES

The FDA approves new drugs and therapies on an ongoing basis. Some of these newly approved products are truly novel while others are similar or related to existing, previously approved products. In 2015 alone, the FDA approved more than 110 drugs in areas such as cardiology, gastroenterology, infectious disease, neurology, and oncology.²⁸⁴ Of these, nearly half—45 drugs—were approved as new molecular entities or new therapeutic biologics, meaning that the drug serves previously unmet medical needs or otherwise offers unique clinical advantages over existing therapies.²⁸⁵ Ten of these drugs were designated as “breakthrough therapies,” meaning they had the possibility to substantially improve clinical results over other available therapies, leading to fast-track review by the FDA.²⁸⁶ As of June 2016, the FDA had already approved 13 novel drugs and biologic products for 2016, a number which is expected to grow throughout the year.²⁸⁷

Expedient Review of New Therapies.

Health insurers consider a variety of evidence when determining whether and how to cover a newly approved drug or therapy. This evidence may include medical literature, clinical trial data, clinical practice guidelines, and FDA-approved package inserts, among other information. This information is typically reviewed by an insurer or PBM’s P&T committee which assesses whether a given drug should be added to a formulary and, if so, what tier it should be placed on and whether any UM should be applied.

Few standards dictate how and when a newly approved drug or indication must be reviewed by an insurer. Some plans follow the standards set by Medicare Part D (Figure 33). Others have built upon these standards to require an expedited review of 90 days for certain drug classes, such as new anticonvulsants, antidepressants, antipsychotics, chemotherapies, HIV medications, and immunosuppressants.²⁸⁸ Some plans also allow providers and enrollees to submit a formal request for a P&T committee to consider adding new drugs or otherwise making formulary changes.²⁸⁹ Still others will delay their formulary evaluation until a drug is already available on the market but allow a provider to request access to the drug through the medical review process.²⁹⁰

PBMs also use different strategies for reviewing new-to-market drugs and therapies. CVS/caremark has a P&T subcommittee that meets monthly to review newly approved drugs and makes recommendations to its national P&T committee.²⁹¹ The national P&T committee of Express Scripts meets at least quarterly to evaluate formulary additions or removals.²⁹²

FIGURE 33:

New Drug Review Process in Medicare Part D

Medicare has recognized the importance of ongoing formulary management and established specific requirements for Medicare Part D plans in considering newly approved drugs and indications. Key components of the policy include the following:

- P&T committees are required to review new FDA-approved drug products and indications for potential inclusion on formularies.
- P&T committees must make a reasonable effort to review new products and indications within 90 days of its release onto the market and make a decision on each new product within 180 days of its release onto the market. P&T committees must consider a drug’s therapeutic advantage in terms of safety and efficacy in selecting formulary drugs and deciding on tier placement.
- Clinical decisions must be based on scientific evidence and standards of practice, including peer-reviewed medical literature, well-established clinical practice guidelines, and pharmacoeconomic studies.

Source(s): Centers for Medicare and Medicaid Services, Chapter 6: Part D Drugs and Formulary Requirements, Medicare Prescription Drug Benefit Manual (Rev. 18, Jan. 2016).

Although the committee may use mail ballots to approve new clinical designations between meetings, Express Scripts has not otherwise imposed a specific timeframe for the review and approval of new drugs or therapies.

To ensure that all consumers have timely access to newly approved products, insurers should be required to review a newly approved therapy or indication within 90 days of approval by the FDA and make a coverage determination within 180 days of the therapy’s release onto the market. All coverage decisions should be based on clinical appropriateness, therapeutic advantage, safety, and efficacy. Express Scripts notes, for instance, that its P&T committee does not have access to or consider information on rebates, negotiated discounts, or a drug’s net cost when considering formulary management.²⁹³

Generic Substitution of Biosimilars.

Biologic drugs are medical products derived from living organisms that are often used to treat complex conditions. Examples include immunotherapies that stimulate the body’s immune system to act against cancer cells or neurotoxins that help relieve muscle spasms for people with multiple sclerosis. Like traditional drugs, biologics must be approved by the FDA before they can be marketed and sold in the United States.

Biologics have revolutionized medicine but are often extremely expensive. Most are placed on specialty tiers and can cost hundreds of thousands of dollars per year. High prices may reflect the fact that biologics are more complex than traditional drugs, and production must be tightly controlled to prevent contamination and produce a consistently safe, pure, and potent product.

Prices are also high because there is little competition among biologics. There are few “generic” versions of biologics, known as biosimilars, to compete with brand-name biologics and ultimately reduce costs. Biosimilars are not identical copies of brand-name biologics and, thus, are not considered to be generic versions but are highly similar to a reference product biologic.

Without biosimilars, brand-name biologics do not face competition even after exclusivity protections have expired, thus extending high prices indefinitely.²⁹⁴ Although the FDA has had a process in place to approve generic drugs since 1984, biosimilars were not recognized until 2010 when the FDA was granted the authority to approve and regulate biosimilars and interchangeable biosimilars under the Affordable Care Act.²⁹⁵

Interchangeable biosimilars are a type of biosimilar that must produce the same clinical result as the reference product in any given patient.²⁹⁶ Under federal law, a pharmacist can automatically substitute an interchangeable biosimilar for a reference product even if, and without the intervention of, a provider that prescribed the reference product.²⁹⁷

Biosimilars and interchangeable biosimilars have the potential to dramatically reduce costs for life-saving or life-sustaining therapies, with savings estimates ranging from \$44 billion to \$250 billion by 2024.²⁹⁸ The FDA approved its first biosimilar product, Zarxio, in March 2015 to treat leukemia and has since approved another biosimilar, Inflectra, to treat inflammatory diseases.²⁹⁹ The FDA has not yet approved an interchangeable biosimilar.

Although the FDA has not yet finalized its standards, many states have already enacted new legislation regulating the substitution of biologics with biosimilars or interchangeable biosimilars (Figure 34).³⁰⁰ As of late 2015, 21 states had enacted laws restricting biosimilar substitution with many more states considering similar bills.³⁰¹

FIGURE 34:

Common Features of State Biosimilar Substitution Laws

Many states—21 as of 2015—have enacted laws restricting biosimilar substitution. Although the new laws vary by state, common features include:

- Giving the prescriber the option to prevent automatic substitution by noting “dispense as written” or “brand medically necessary.”
- Requiring the pharmacist to notify the prescriber and the enrollee about the substitution (and, in some cases, obtain an enrollee’s consent).
- Requiring pharmacists to retain records of substituted medications.
- Requiring the state to maintain a list of permissible interchangeable products.

Source(s): Richard Cauchi, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars* (Jun. 2016), *National Conference of State Legislatures*.

Proponents of such laws argue that state-level substitution restrictions protect consumers by safeguarding the physician-patient relationship and promoting patient access, quality, and transparency.³⁰² Critics note that similar arguments and restrictions have been used to discourage substitution of traditional generic drugs and are designed to restrict access to biosimilars in favor of costly brand-name biologics.³⁰³ Such restrictions may also be premature since the FDA has not yet finalized its standards on how it will determine and define “interchangeability.”

The policies being considered by states may, indeed, restrict access to biosimilars. One study found that requiring patient consent before generic substitution of traditional drugs reduced substitution rates by 25 percent and that state Medicaid programs could save over \$100 million in a single year by eliminating patient consent requirements for just three drugs.³⁰⁴ Another study found that limiting a provider’s ability to preemptively override generic substitution could reduce health system costs by as much as \$7.7 billion.³⁰⁵

Transparency is critical for consumers, especially in the context of access to medications. In contemplating restrictions on biosimilar substitution, state policymakers should consider the burdens being placed on prescribers, providers, and enrollees; the potential for savings to the health care system and for consumers in the form of out-of-pocket costs; and the fact that federal requirements have not yet been finalized in this emerging area of science and medicine.

Access to Clinical Trials.

Insurers can help promote innovation by improving coverage for clinical trials, which can provide consumers with access to the newest, most cutting-edge treatments, facilities, and physicians as well as ongoing monitoring and evaluation. Randomized, well-controlled clinical trials are also essential to testing the effectiveness of new drugs and therapies while providing an evidence base for FDA approval. Participation in cancer clinical trials has been shown to increase overall survival with minimal increase in cost.³⁰⁶

Despite the benefits of clinical trials, enrollment remains low in part because insurers prefer not to cover certain costs associated with clinical trials, such as complications or other health services that arise as a result of participation in a clinical trial. Given the potential that an insurer would deny coverage not only for the clinical trial but for all associated health needs, many patients are forced to choose between paying out-of-pocket or forgoing participation altogether.

Recognizing the need for access to clinical trials, most states enacted laws requiring the coverage of routine costs for enrollees participating in clinical trials.³⁰⁷ Beginning in 2014, the Affordable Care Act prohibited many plans in all states from 1) denying a qualified enrollee from participating in an approved clinical trial; 2) denying or limiting the coverage of routine patient costs in connection with a clinical trial (such as hospital stays, diagnostic tests, and treatment for complications from trial participation); and 3) discriminating against an enrollee based on trial participation.³⁰⁸

Although these protections have been in effect since 2014, implementation and enforcement has been mixed, with some cancer centers reporting continued denials of routine costs or delays in approval that discourage enrollees who otherwise want to participate in a trial.³⁰⁹ To address some of this confusion, HHS recently issued additional guidance to insurers to clarify the scope of coverage for clinical trials (Figure 35). State and federal regulators should actively monitor and enforce state and federal laws and issue additional guidance as needed to clarify these requirements.

FIGURE 35:

Clarifying Coverage Requirements for Clinical Trials

HHS considers Section 2709 of the Affordable Care Act to be self-implementing, and plans and insurers are expected to implement these requirements using a good faith, reasonable interpretation of the law. To inform these efforts, HHS issued additional guidance in April 2016 to clarify the scope of coverage and prohibit insurers from:

- Limiting the coverage of chemotherapy due to the fact that it is provided in connection with participation in an approved clinical trial for a new anti-nausea medication; or
- Denying coverage of items and services to diagnose or treat certain complications or adverse events (such as side effects) due to the fact that such treatment is in connection with participation in an approved clinical trial.

Source(s): U.S. Departments of Labor, Health and Human Services, and the Treasury, *FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women's Health and Cancer Rights Act Implementation* (Apr. 20, 2016) at 6-8.



Consumer Recommendations on New Therapies

State and federal insurance regulators, marketplace officials, and state lawmakers should ensure that:

- P&T committees review newly approved therapies or indications within 90 days of approval by the FDA and make a coverage determination within 180 days of release onto the market.
- Insurers and their designees make coverage decisions regarding new drugs and therapies based on clinical appropriateness, therapeutic advantage, safety, and efficacy.
- Pharmacists can substitute an interchangeable biosimilar with a brand-name drug without the intervention of a prescriber as required under federal law.
- Plans cover routine patient costs for qualified enrollees participating in an approved clinical trial.

VALUE-BASED PRICING

As payers and other stakeholders continue to search for ways to control ever-increasing drug prices, many insurers and PBMs have looked to plan design, such as drug tiering, cost-sharing, UM, and network design. However, these efforts alone—focused largely on controlling utilization—do little to address the actual expense of covering costly single-source and other drugs.

An increasingly explored cost control alternative is value-based pricing. Value-based pricing is a payment methodology—typically in the form of an agreement between a payer and a drug manufacturer—where prices, rebates, and other financial incentives are determined based on a drug’s clinical value.³¹⁰ By tying financial incentives to clinical performance, payers can slow growth in drug costs without compromising patient access. At the same time, drug manufacturers can secure formulary access and preferred tier placement, which can increase the volume of prescriptions. Other potential benefits of value-based pricing include:

- Increased alignment between payers and drug manufacturers to inform the development of future therapies that deliver value;
- Greater transparency of the value of each medication, allowing payers to pay premium pricing only for high-value products; and
- Improved exchange of health information among providers, pharmacists, payers, and drug manufacturers to monitor outcomes, reduce the cost of post-market surveillance, facilitate expedited clinical trial recruitment, and strengthen these foundations for better outcomes research.³¹¹

Although value-based contracts are not yet widely adopted, these risk-sharing arrangements have been in use since at least the 1990s in the United States and are common in European countries.³¹² One of the first U.S. value-based pricing agreements was between Cigna and Merck for two diabetes drugs in 2009 (Figure 36).³¹³

FIGURE 36:

How Successful is Value-Based Pricing?

In April 2009, Cigna and Merck entered into a value-based partnership for two brand-name diabetes drugs, Januvia and Janumet. Merck agreed to reduce the price for its two drugs and offered a rebate when enrollees with type 2 diabetes reached certain benchmarks for drug adherence and lowered blood sugar. By December 2010, the 165,000 enrollees taking the two drugs exhibited the following:

- Blood sugar levels improved by more than 5 percent on average.
- Blood sugar lab testing increased by 4.5 percent.
- Medical adherence rose to 87 percent.

These results were widely hailed as promising although some stakeholders noted the need for additional clinical and financial data to fully assess the success of the initiative.

Source(s): Steve Davolt, "CIGNA-Merck Outcomes Contract Hailed as 'First Step,' but Some Want More Data," AISHHealth (Dec. 17, 2010).

Value-based pricing is particularly important because of the unique market for emerging drugs and therapies. In some cases, the entry of a new drug or generic onto the market results in substantial price reductions or competition.³¹⁴ However, these situations are relatively rare, and at least one recent study showed that competition—specifically the addition of new oral anti-cancer treatments to the market—was not effective at reducing drug prices.³¹⁵ This lack of elasticity, even if just for some types of drugs, suggests that value-based contracting and other risk-sharing agreements can play a significant role in reducing costs even where traditional competition may not.

Given the significant attention paid to the high price of drugs, value-based pricing is expected to increase in use (Figure 37). In addition to addressing concerns about cost, such efforts mirror other “pay for performance” initiatives that have been widely adopted or explored in other parts of the health care system through, for instance, accountable care organizations, bundled payments, quality incentives, or comparative effectiveness research. Medicare, for instance, plans to test the use of value-based payments for medications covered under Medicare Part B including many treatments for cancer, among others.³¹⁶

Despite the promise of value-based pricing, there are a number of challenges with this approach.³¹⁷ It can be difficult for payers and drug manufacturers to identify and agree upon appropriate outcomes that are meaningful, measurable, and can be achieved within a reasonable timeframe. Success may be limited by access to data and fragmented infrastructure: A recent survey of stakeholders found that access to clinical data was a significant barrier to value-based pricing.³¹⁸ Drug manufacturers may be reluctant to share the risk or assume the responsibility for positive clinical outcomes when they are unable to control how a drug is prescribed or used. Finally, drug manufacturers can only negotiate reimbursement contracts for FDA-approved indications, meaning that value-based pricing is of limited value for off-label indications that many consumers depend on.³¹⁹

Although the primary focus of value-based pricing is on payers and drug manufacturers, regulators can encourage these new payment models and ensure that such arrangements have appropriate consumer protections. Regulators can, for instance, address and clarify state or federal regulatory barriers that may exist as HHS recently did in a notice to encourage states to consider entering into value-based purchasing arrangements as a means to address and

offset Medicaid's high-cost drug treatments.³²⁰ Regulators and lawmakers can require post-market surveillance data to be collected by a variety of stakeholders—including insurers, PBMs, physicians, pharmacists, and other providers—to monitor the safety and efficacy of new therapies and advance clinical decision-making to inform value-based contracting. Regulators can also support the development of robust data collection infrastructure and urge insurers and PBMs to disclose as much information as possible about these new payment models to better inform policymaking in this arena.

FIGURE 37:

Examples of Value-Based Pricing of Pharmaceuticals

The use of value-based pricing and other risk-sharing arrangements with drug manufacturers has the potential to reduce costs while also ensuring that health care dollars are well spent. Recent examples of value-based pricing include:

Rebates based on performance

- **Harvard Pilgrim Health Care** and **Cigna** agreed to give preferred formulary placement to **Amgen's** new PCSK9 inhibitor, Repatha, and to receive an enhanced rebate if Repatha fails to reduce cholesterol levels to levels observed during clinical trials. **Cigna** also entered into an agreement with **Sanofi/Regeneron** for Praluent, a similar PCSK9 inhibitor, making Cigna the first company to reach value-based agreements for an entire new class of cholesterol drugs.
- **Aetna** and **Cigna** inked similar agreements with **Novartis**, the manufacturer of Entresto, a drug approved in 2015 to treat chronic heart failure that costs about \$4,500 per year. Under these agreements, the level of rebates from Novartis will vary based on how effective Entresto is at reducing hospitalization and death. If the drug meets clinical targets, the rebate is reduced.
- **Humana** and **Eli Lilly & Co.** have agreed to tie the level of reimbursement for Effient, a drug that treats cardiac conditions, to the rate of hospitalization for patients who take the drug.

Indication-specific pricing for cancer therapies. In January 2016, **Express Scripts** launched the **Oncology Care Value program** with the goal of paying for drugs based on their clinical effectiveness, which often varies by indication. Express Scripts developed adjusted price proposals per drug and indication for prostate cancer, lung cancer, and renal cell carcinoma. Price points for each were set using clinical parameters, cost analyses, and feedback from external stakeholders such as the Institute for Clinical and Economic Review. The program is part of Express Scripts' broader **SafeGuardRx** initiative which has adopted a number of value-based pricing efforts for medication classes that pose significant budgetary threats to payers.

Source(s): Bob Herman, "Harvard Pilgrim Cements Risk-Based Contract for Pricy Cholesterol Drug Repatha," *Modern Healthcare* (Nov. 9, 2015); Stephen Barlas, "Health Plans and Drug Companies Dip Their Toes Into Value-Based Pricing," *Pharmacy & Therapeutics* (2016) 41(1): 39-53; Peter Loftus & Anna Wilde Mathews, "Health Insurers Push to Tie Drug Prices to Outcomes," *Wall Street Journal* (May 11, 2016); Cigna, "Cigna's Two New Value-Based Contracts with Pharma for PCSK9 Inhibitor Cholesterol Drugs Tie Financial Terms to Improved Customer Health," (May 11, 2016); Julie Appleby, "How Medicare Drug Plans Hope to Follow Private Sector Lead," *Kaiser Health News* (Mar. 18, 2016); Caroline Humer, "Novartis Sets Heart-Drug Price with Two Insurers Based on Health Outcome," *Reuters* (Feb. 9, 2016); Lauren Flynn Kelly, "Express Scripts Leads Indication-Specific Pricing with Launch of OCV Program," *AISHealth* (Feb. 5, 2016); *Express Scripts, SafeGuardRx Improves Affordability and Access to Budget-Busting Drugs* (Dec. 15, 2015).

Other Cost-Saving Efforts.

Other efforts place more of an emphasis on cost control than ensuring quality care. Some payers, such as the California Public Employees Retirement System, have adopted benchmarks or reference prices for services where cost varies widely and then cap provider payments at these levels.³²¹ Medicare plans to experiment with reference pricing payment rates for a group of therapeutically similar drug products covered under Medicare Part B.³²²

Some payers and PBMs are negotiating lower prices by entering into exclusive agreements with drug manufacturers: Express Scripts, for instance, entered into an exclusive deal with AbbVie for Viekira Pak—an expensive breakthrough treatment for hepatitis C that competes with Gilead’s Sovaldi and Harvoni—and negotiated a significantly lower price in the process.³²³ Although such exclusive deals can drive price reductions, consumers may be at risk if a formulary refuses to cover a drug that has clinically better outcomes for a patient. This may be why Express Scripts agreed to make exceptions to cover Sovaldi or Harvoni for patients who would not benefit or would face adverse effects from taking Viekira Pak.

Other types of risk-sharing arrangements have not been widely tested but may include contracts with a maximum cost per patient (where a drug manufacturer caps drug costs for a specific patient) or a capitation amount per member per month (where an insurer or designee pays a single payment for an unlimited supply of medications).³²⁴ We encourage further testing of these and other risk-sharing arrangements via pilot programs before such arrangements are adopted more broadly to better understand their impact on consumer access.

Consumer Recommendations for Value-Based Pricing

State and federal insurance regulators, marketplace officials, and state lawmakers should:

- Encourage insurers and their designees to consider new payment models with appropriate consumer protections that incentivize risk-sharing with drug manufacturers.
- Release guidance and clarify concerns regarding any federal or state regulatory barriers to value-based pricing and other new payment models for drug coverage.
- Require post-market surveillance data to be collected by a variety of stakeholders—including insurers, PBMs, physicians, pharmacists, and other providers—to monitor the safety and efficacy of new therapies and advance clinical decision-making and inform value-based contracting.



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VALUE FRAMEWORK

While many treatments can and do save lives, others do not, perhaps only prolonging an individual's life by a few months or having little or no benefit to overall survival. It is increasingly difficult to determine whether and how such drugs should be covered and at what cost to an insurer, a consumer, and the health system as a whole. In an environment where drug prices are ever-increasing, decision-makers are in need of evidence-based, transparent decision-making tools to assess, compare, and quantify the value of new drugs and therapies.

Given this need to develop clear guidelines on value, a variety of nonprofits and medical societies—including the American College of Cardiology and the American Heart Association, the American Society of Clinical Oncology (ASCO), the Institute for Clinical and Economic Review (ICER), the Memorial Sloan Kettering Cancer Center (MSKCC), and the National Comprehensive Cancer Network—have developed value frameworks. Value frameworks are tools to help providers, payers, and consumers understand the value of new therapies and make better choices about their use.³²⁵

Value frameworks are particularly helpful in identifying the factors that stakeholders should consider when making treatment, coverage, and policy decisions (Figure 38). Some of the models, like the one developed by ASCO, focus solely on the value of cancer drugs while others, like the one developed by ICER, are broader and extend even beyond pharmaceuticals. In response to the development of these models, other stakeholders, such as Pharmaceutical Research and Manufacturers of America, have made recommendations about principles that should be used when developing value frameworks.³²⁶

FIGURE 38:
Common Considerations in Value Frameworks

Although each value framework is unique, most frameworks include the following value factors in assessing value to consumers:

- Quality of clinical data for each therapy
- Magnitude of a therapy's treatment effects
- Likelihood of severe adverse events
- Cost and effects on the health system budget
- Cost-effectiveness and ancillary benefits

Source(s): Peter J. Neumann & Joshua T. Cohen, "Measuring the Value of Prescription Drugs," *New Engl. J. Med.* (2015) 373: 2595-97.

Despite consensus in some areas, frameworks vary in their definition of "value" and the way it is calculated and scored. The ICER framework, for instance, assesses value based on cost-effectiveness and budget impact and then includes additional factors, such as clinical effectiveness, the severity of the condition, and whether other treatments are available.³²⁷ In contrast, the MSKCC framework enables users to adjust the weight given to many of the factors, such as toxicity, to develop a price based on their own prioritization of the factors.³²⁸

Most value frameworks provide an important starting point for considering value and cost in a transparent and consistent way. The ASCO framework, for instance, considers factors that include cost per month while the ICER framework assesses budget impact, among other factors.³²⁹ However, critics have argued that these factors do not go far enough by not including costs as part of an overall score or go too far by adjusting a drug's price benchmark to reach certain cost-effective requirements.³³⁰

The ICER framework, in particular, includes a budget impact assessment and cost-effectiveness ratio where an intervention that exceeds \$150,000 per quality-adjusted life year is considered low-value care. In a recent analysis of the price of new PCSK9 inhibitors—new drugs that are effective at reducing high cholesterol and cost more than \$14,000 per year—ICER used its framework to conclude that such drugs should be no more than \$4,811 based on clinical value in preventing heart attacks and death.³³¹ The analysis then went one step further to recommend a price of \$2,177 so as not to strain health care budgets. ICER has performed similar analyses for treatment for multiple myeloma, a type of cancer, among others.³³²

Despite the importance of broadly applicable value frameworks, not all patients will respond to all therapies in the same way and not all benchmarks, such as quality-of-life years, are appropriate for all individuals, such as people with disabilities. For example, some benchmarks may underestimate the value of, and need for, many habilitative services, which have treatment goals that necessarily fluctuate and deviate based on individual needs and cannot easily be measured against a baseline for an average healthy individual. As a result, it may be inappropriate for payers to rely solely on this approach when developing and applying clinical guidelines or coverage policies. Key considerations in limiting treatment choices should include when, for instance, patients with the same disease vary in the symptoms they experience or patients are likely to have different responses to available treatments.³³³

Consumer Recommendations for Value Frameworks

State and federal insurance regulators, marketplace officials, insurers and their designees, and state lawmakers should ensure that a diverse group of stakeholders—including regulators, insurers, PBMs, physicians, pharmacists, researchers, consumer and patient advocates, and consumers—participate in developing meaningful value frameworks and tools that help assess the value of new treatments and support patient-centered clinical decision-making.



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