

# An Advocate's Guide to Appealing Prescription Drug Denials

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## Medicare Rights Center

Based in New York, the Medicare Rights Center is a national, nonprofit consumer service organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Since 1989, Medicare Rights has helped people with Medicare understand their rights and benefits, navigate the Medicare system, and secure the quality health care they deserve. Medicare Rights is committed to:

- Serving as a kind and expert health insurance counselor, educator, and advocate for those who need it most;
- Providing independent, timely, and clear information on Medicare, Medicaid for dually-eligible individuals, and related topics to communities nationwide;
- Fostering diverse partnerships and points of view; and
- Finding lasting solutions to systemic problems that prevent older adults and people with disabilities from accessing needed health coverage and care.

## Key Lessons

- 1. Identify the type of prescription access problem your client is facing and the reason for the denial.** A person may believe that coverage for their drug has been denied when the problem actually has to do with going to the wrong pharmacy or affordability issues in the deductible period. If there is a denial, understanding the reason will help you and the beneficiary decide on the correct next steps.
- 2. Learn how to assist beneficiaries with the appeals process.** The administrative appeals process can seem complicated, and there are different types of appeals to address different reasons for a denial. Understanding the different levels of appeal and how beneficiaries can get relief if they continue to appeal can help ensure your clients get access to coverage they are entitled to.
- 3. Problem solve to find strategies for accessing needed drugs in a situation where an appeal is unlikely to be successful.** Some types of denials are unlikely to be resolved through the appeals process. Learn about alternative avenues to coverage.

## Background: Understanding the Part D Benefit

U.S. spending on prescription drugs in 2020 was estimated at approximately \$350 billion,<sup>1</sup> while Medicare beneficiaries are expected to be paying out-of-pocket for 35% of the cost of their prescription drugs.<sup>2</sup> Medicare's prescription drug program, Part D, covers more than 47 million people and, on average, pays for over \$2,000 worth of prescription drugs per enrollee.<sup>3</sup> The Part D benefit is operated by private insurance companies that make initial decisions on claims at the pharmacy about whether a beneficiary's prescription will be covered. These Part D insurance companies deny payment for millions of prescriptions every year.<sup>4</sup> Many of these denials are improper and, as a result, nearly three quarters of the denials that are appealed are overturned or partially overturned.<sup>5</sup>

Part D is offered through private companies either as a stand-alone prescription drug plan (for those enrolled in Original Medicare), or a set of benefits included with a Medicare Advantage Plan (MA Plan). Each Part D plan is different, offering varying premiums, deductibles, copayments/coinsurance, and formularies (the drugs they cover and any restrictions they put on those drugs). Within this flexibility, however, there are certain drugs that Part D plans cannot cover.<sup>6</sup> These excluded drugs include:<sup>7</sup>

- Drugs used to treat anorexia, weight loss, or weight gain (however, Part D may cover drugs used to treat physical wasting caused by AIDS, cancer, or other diseases)
- Fertility drugs
- Drugs used for cosmetic purposes or hair growth
- Drugs that are only used to treat cough or cold symptoms
- Drugs used to treat erectile dysfunction
- Drugs that have not been approved by the Food and Drug Administration (FDA)
- Prescription vitamins and minerals, except for prenatal vitamins and fluoride preparations
- Most over-the-counter drugs

## Turned Away at the Pharmacy—What Next?

Since Medicare does not cover over-the-counter medication, all Part D appeals start with a prescription from a medical provider. That prescription contains important information that will be relevant throughout the appeals process, including the name of the medication, dispensing instructions (i.e., quantity, dosage, and number of refills), and sometimes the condition or illness for which the medication is being prescribed. It can be worth the time to check that the prescription is correct, as an erroneous prescription cannot be corrected through the appeals process.

### **PRACTICE TIP: RECEIVING A BILL DURING THE APPEALS PROCESS**

While this is not as common in Part D appeals, sometimes a provider or pharmacy will supply the medication and then bill the individual for it. If this happens during the appeals process, the individual should contact the provider or pharmacy and ask them to pause billing until the appeals process is complete. This is a common request and should be accepted as a matter of practice. Ideally, the pharmacy will send the claim to the Part D plan rather than the individual (since that is faster, more accurate, and does not require the individual to front the entire cost of the drug while awaiting a coverage decision). However, if an individual does pay out-of-pocket, they can be reimbursed by their Part D plan if the appeal is successful.<sup>8</sup>

## Notice of Non-coverage

When the pharmacist tries to run the prescription and the plan does not authorize coverage, the pharmacist should provide a form called Medicare Prescription Drug Coverage and Your Rights.<sup>9</sup> This notice provides instructions on filing an exception request with the plan, which is the first step of the appeal process. Note: this initial notice is not a formal denial; an individual must file an **exception request** first before they get an appealable denial.<sup>10</sup>

## ADVOCACY TIP: KEEP COPIES AND NEVER SEND ORIGINALS

It can be helpful to keep a copy of all documents sent and received during the appeals process. Medicare Rights advises its clients to never send the original copies of important documents.

### Contact the Plan

Once an individual knows the plan did not authorize coverage, the next step is to contact the plan and determine why. Often the pharmacist can do this quickly through the plan's pharmacy help desk. If not, the individual can also call their plan (the phone number should be on their insurance card). Sometimes, the plan made a mistake that can be fixed at this stage. If not, the individual should ask the plan exactly why they are not covering the drug and what information they would need in order to change that decision (see the following section on exception requests for reasons why a plan might not authorize coverage for a drug).

At this step it is also a good time to ensure that the pharmacist correctly coded the request and submitted it to the right plan. While it can be difficult for individuals and their advocates to know how to code a request, by calling the plan and asking for information on the decision they should be able to hear whether the request the plan received was the same one prescribed by the doctor. If it was not, then the individual should consider checking with the pharmacy to make sure the claim is entered correctly.

### Start the Appeal: Get an Initial Decision (File an Exception Request)

Once the individual is at the pharmacy and knows their plan is refusing to cover the medication, the individual needs to file a formal exception request to ask the plan to cover their drug. There are many different types of exceptions to ask for. In general, though, a few pieces of advice apply across the various types of exceptions:

1. Most importantly, an individual should ask their prescribing doctor for help. Specifically, the doctor should complete a generic Coverage Determination Request form (or contact the plan for a plan-specific version of the form).<sup>11</sup> It can be filled out by the individual if the doctor will not. Practice Tip: Using this particular form is not required, but it is recommended since it prompts for required information and is easily processed by Part D plans.<sup>12</sup>
2. It is often necessary (or at least helpful) to include additional documentation with the exception request, such as proof of medical need.<sup>13</sup> The prescribing doctor should write a letter of support to send to the individual's plan along with the request. This letter should explain why the individual needs the drug and, if possible, how other medications to treat the same condition are dangerous or less effective for them. If the individual and their doctor do not include necessary medical information, the plan is required to make one attempt to request it before making a decision.<sup>14</sup>

The plan should issue a decision within 72 hours of the request, but the individual can request a fast exception request if they or their doctor feel that the individual's health could be seriously harmed by waiting the standard timeline for a decision.<sup>15</sup> If the plan grants the request to expedite the process, they should send a decision within 24 hours of the initial request.<sup>16</sup> The decision is called a coverage determination and provides the individual with appeal rights and more information about the reason for the denial.<sup>17</sup>

### What Kind of Denial is This?

Most commonly, when a Medicare drug plan denies coverage for a prescription drug, it does so because it believes that the request does not match the plan's formulary. The formulary is the list of drugs the plan covers and when it will cover them. Plan formularies can change from year to year and plans can have very different

formularies. In fact, enrolling in a plan with a formulary that matches their prescription drug needs is one of the most important things to do in order to make the most of Medicare's prescription drug benefit. Some coverage requests are denied because the medication is not on the plan's formulary at all (an off-formulary denial).<sup>18</sup> Other times, the plan puts certain restrictions on the medication, called utilization management, and a person needs to meet or seek an exception from those rules. Other times, a medication is excluded from Part D coverage as discussed above.

### Off-Formulary

CMS gives plans leeway in deciding what drugs they cover, what dosages they cover, and for what conditions the drugs can be prescribed. When an individual wants a drug that does not match their plan's list of covered drugs, the drug is called off-formulary.<sup>19</sup> When faced with this type of off-formulary denial, the individual can access their drug by requesting a formulary exception, which puts the drug they want, the dosage they want, and the usage of the drug on the plan's formulary just for them. To be successful, the individual (through, ideally, their prescribing doctor) needs to support the request with documentation explaining why the individual needs the drug and, if possible, how other medications to treat the same condition are dangerous or less effective.

## PRACTICE TIP

One issue with off-formulary situations is that when a plan places a drug on their formulary as a result of a formulary exception, they almost always place the drug on the plan's highest cost-sharing tier.<sup>20</sup> As a result, individuals often have very high cost-sharing even after they win their appeal and get their drug placed on the plan's formulary.

### Quantity Limits

Plans can limit their coverage by a certain amount over a particular period of time.<sup>21</sup> Information about whether a plan places quantity limits on certain drugs is available in Medicare's Plan Finder, so individuals should consider this when shopping around for a Part D plan. To appeal a quantity limits denial, individuals should get assistance from the prescribing doctor in explaining and documenting why a larger quantity of the drug than the plan normally allows is needed.

### Prior Authorization

Plans can require that they authorize a claim ahead of time.<sup>22</sup> In other words, that they approve a prescription before the individual is at the pharmacy. How to request prior authorization differs by plan, so individuals may want to ask their plan how to do that. In Medicare Rights' experience, prescribing doctors can often call the plan and request prior authorization on behalf of the individual. This strategy is helpful because the prescribing doctor can also ensure the plan gets any medical documentation they need. It is also important to remember that prior authorization is usually a hurdle to overcome rather than a helpful benefit.

### Step Therapy

Plans can also require an individual to try a different drug (almost always a less expensive one) first before they cover the prescribed drug. This utilization management restriction is called step therapy.<sup>23</sup> To request an exception, it is absolutely vital that the prescribing doctor provide documentation showing that the individual has either tried the other drug(s) or that it would be unsafe for them to do so.<sup>24</sup>

### Tiering Exception

Medicare drug plans have a tiering system that determines how much of the cost of a drug a plan member will have to pay. Generally, the higher the tier, the more expensive the medication will be to the individual. Typically, the lowest tiers are for generic drugs, the highest tiers are for specialty drugs,

and the middle tiers are for common brand-name drugs.<sup>25</sup> Each plan sets its own tiers, and plans may change their tiers from year to year. That being said, most plans have the same five-tiered structure, but differ in what drugs they put on each tier and the plan member cost-sharing responsibilities for the different tiers. When faced with high costs because of the tier their medication is placed on, individuals can request a tiering exception from their drug plan.<sup>26</sup> A tiering exception is a formal request asking the plan to move the drug to a lower tier so that it will be more affordable for the individual.<sup>27</sup>

### Off-Label

Under federal law, Part D plans must only cover FDA-approved Part D drugs that are prescribed for “medically-accepted indications.”<sup>28</sup> CMS has interpreted this narrowly to mean a use that is either: 1) FDA-approved; or 2) supported by at least one of the two approved compendia.<sup>29</sup> In other words, for a Part D plan to cover a drug, both the drug itself and the prescribed use of the drug have to be approved by the FDA unless the use is found in one of the compendia. Off-label means any use of a drug that is not expressly approved by the FDA. This can mean using a drug to treat an illness or condition for which it is not FDA approved, or using a drug to treat an on-label condition but at a dose not recommended by the FDA. This narrow interpretation of Part D coverage has had a huge impact on individuals with Part D coverage, since around 20% of all prescriptions are for off-label use.<sup>30</sup> There is, though, an exception for cancer drugs. Besides the use being approved by the FDA or being listed in the approved compendia, treatments for cancer can also meet the “medically-accepted indication” requirement if they have support in peer-reviewed literature or in two other compendia.<sup>31</sup> Part B drugs also have a different, more generous standard.<sup>32</sup>

## PRACTICE TIP: RESOLVING AN OFF-LABEL DENIAL

Determine whether the drug use is off label. Get a copy of the FDA label for the drug to ensure the drug is, in fact, not approved by the FDA for the prescribed use.

Check the compendia. Ask the prescribing doctor to look for support for the use of the drug in the approved compendia. If the doctor does not have access to the compendia, individuals can contact their local teaching hospitals, libraries (especially medical school libraries), or submit the appeal asking for the plan to review the compendia.

Include supplemental information when possible. Most commonly, off-label appeals are only successful when there is an FDA on-label use or there is support in the compendia. Therefore, it is vital to include supplemental information showing that support (e.g., a copy of the compendia entry indicating support for this specific use of the drug). If an individual does not have any support and cannot take an alternative drug with an on-label use, then there are also several legal arguments that can be made (most commonly at the OMHA and Federal District Court levels). These legal arguments are beyond the scope of this guide. Please contact us at the Medicare Rights Center for more help with these cases.

## Keep Going! Further Appeal Steps

After filing an exception request, there are further levels of appeal. If an individual’s exception request is denied, they can begin the appeals process by requesting a redetermination from the plan. The following chart provides an overview of the appeal process, the entities involved, and the deadlines for filing appeals and receiving decisions.

Before Filing Appeal	Pharmacist Tells Beneficiary That Plan is Not Covering Their Drug
First Level of Appeal	Appeal to plan <b>Deadline to file:</b> 60 days <b>Deadline for standard decision:</b> 7 days <b>Deadline for expedited decision:</b> 72 hours
Second Level of Appeal	Appeal to Independent Review Entity (IRE) <b>Deadline to file:</b> 60 days <b>Deadline for standard decision:</b> 7 days <b>Deadline for expedited decision:</b> 72 hours
Third Level of Appeal	Appeal to Office of Medicare Hearings and Appeals (OMHA) <b>Deadline to request hearing:</b> 60 days <b>Deadline for standard decision:</b> 90 days <b>Deadline for expedited decision:</b> 10 days
Fourth Level of Appeal	Appeal to Medicare Appeals Council (Council) <b>Deadline to request review:</b> 60 days <b>Deadline for standard decision:</b> 90 days <b>Deadline for expedited decision:</b> 10 days
Final Level of Appeal	Appeal to Federal District Court <b>Deadline to request review:</b> 60 days <b>No deadline for decision</b>

## Accessing Drugs Outside of the Appeals Process

### Transition Refills

Sometimes individuals may find themselves enrolled in a Part D plan that does not provide coverage for, or imposes restrictions on, medication they have been taking. There may be a short-term fix for this problem called transition refills (also called transition fills).<sup>33</sup>

A transition refill is usually a one-time, 30-day supply of a prescribed drug that Part D plans are required to cover and allow access to even if it is not on their formulary or even if there is a plan restriction on the drug.<sup>34</sup> The transition refill policy only extends to drugs that a beneficiary has been taking since before they changed their Part D coverage or since before their existing Part D plan changed its coverage rules.<sup>35</sup> That is, transition refills are not for new prescriptions. The purpose of the refill “is to promote continuity of care and avoid interruptions in drug therapy,” while an individual either finds a new drug or requests an exception.<sup>36</sup> Thus, transition refills can only be requested within the first 90 days of coverage under a new plan.<sup>37</sup> Keep in mind, though, that the cost sharing for transition refills (for off-formulary drugs) will often be higher,<sup>38</sup> and the plan does not have to provide a transition refill when there are certain safety concerns (e.g., the refill would go beyond the FDA recommended quantity limit for the drug).<sup>39</sup>

To access a transition refill, an individual must submit an exception request to the plan. In most cases, the pharmacist should be able to do this for them (the prescribing physician may also be able to help). So as not to confuse their plan members, Part D plans are required to provide them with timely notice regarding their transition refill, i.e., letting them know this is just a temporary refill and does not mean the medication will be covered the rest of the year.<sup>40</sup> Plans should also make a reasonable effort to contact the individual's prescribing doctor.<sup>41</sup>

## Switching Plans

A helpful solution for many individuals facing issues accessing prescription medications is to simply switch plans. How quickly an individual can switch plans depends on their situation.

Every Medicare beneficiary can switch plans during **Fall Open Enrollment** (which occurs each year from October 15 to December 7).<sup>42</sup> Using Medicare's Plan Finder, individuals can see if there is a plan in their area that would provide better coverage for their prescriptions and then enroll in that plan effective January 1 following the end of the open enrollment period.<sup>43</sup>

Individuals enrolled in a Medicare Advantage Plan can also switch their drug coverage during the **Medicare Advantage Open Enrollment Period** (which occurs each year from January 1 through March 31).<sup>44</sup> A beneficiary can make one change during this period, and it will take effect the first of the month following the month they enroll.

Throughout the year, individuals may also be eligible for various **Special Enrollment Periods** (SEP). For example, individuals can qualify for SEPs when they move, if they become eligible for Medicaid, or if their Part C or Part D plan is ending.<sup>45</sup> Each type of SEP provides its own eligibility criteria and effective date for the change, though many allow people to enroll in a new plan as soon as the first of the month after they make their new plan selection.<sup>46</sup>

## Enrolling in Extra Help

Extra Help is a federal program that helps pay for some of the out-of-pocket costs of Medicare prescription drug coverage.<sup>47</sup> It only provides cost-sharing assistance for drugs that are on an individual's formulary, so it is not generally helpful when an appeal is lost, except that it does provide a SEP for anyone who has Extra Help.<sup>48</sup> This SEP can be used once per calendar quarter during the first three quarters of the year (January through March, April through June, and July through September).<sup>49</sup> The coverage change is effective the first of the month after an individual applies for the new drug plan.<sup>50</sup>

## Switching Drugs

When appeals fail, an individual can consider speaking to the prescribing doctor about any alternative medications. Medicare Rights counsels people in this situation to ask their provider about any generic forms or a similar drug on the plan's formulary and for any samples they might be able to provide to help the person at least have a few doses while they search for a longer-term solution.

## Pay Out-of-Pocket

When everything else fails, a Medicare beneficiary can pay out-of-pocket for their medication. There are a few ways to help reduce the price of medication that is not covered (most of them require that the pharmacist bill the individual without submitting the claim to the Part D plan):

- There are various prescription assistance programs that can be found through databases (e.g., NeedyMeds,<sup>51</sup> Medicine Assistance Tool,<sup>52</sup> and Rx Assist<sup>53</sup>) as well as by contacting organizations and foundations designed to assist people with specific medical conditions. Many of these programs focus on

the uninsured, so they may not be available for someone with Part D.

- Pharmacies may offer special promotions for certain drugs that will lower the cost. Some pharmacies also have discount programs for generics. Individuals can also shop around for better prices on their medications by contacting their local pharmacies or using a database, such as GoodRx.<sup>54</sup>
- Some manufacturers of drugs offer patient assistance programs for the uninsured.<sup>55</sup> Often, people with Part D coverage cannot take advantage of these, but, on occasion, manufacturers will sometimes provide assistance through the patient assistance program or as one-off charity assistance.
- Many localities have charity programs that provide assistance affording medication.

## Conclusion

Though at first the appeals process can seem daunting, identifying the reason why an individual's drug was denied will help you structure your appeal and navigate the process effectively. Be sure to keep copies of all appeal documents and adhere to appeal deadlines. In the event that a beneficiary's appeal is not successful, there are other strategies you can employ to try and help them get access to the prescriptions they need.

## Additional Resources

- Casey Schwarz, Senior Counsel for Education & Federal Policy, [CSchwarz@medicareright.org](mailto:CSchwarz@medicareright.org), 212-204-6271.



## Endnotes

- 1 IQVIA, [The Global Use of Medicine in 2019 and Outlook to 2023](#). (Jan. 29, 2019).
- 2 Kamal, R., Cox, C., & McDermott, D., [What are the recent and forecasted trends in prescription drug spending?](#) (Feb. 20, 2019).
- 3 The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, [2020 Medicare Trustees Report](#) (Apr. 22, 2020), Table II.B1.—Medicare Data for Calendar Year 2019
- 4 U.S. Department of Health and Human Services (HHS), Office of Inspector General, [Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs](#) (OEI-09-16-00411) (Sept. 2019), Report in Brief.
- 5 *Id.*
- 6 Some excluded drugs can be covered by enhanced Part D plans that offer additional benefits (e.g., coverage during the coverage gap, better cost sharing, or coverage for some excluded drugs). See Centers for Medicare & Medicaid Services (CMS), Medicare Prescription Drug Manual, Ch. 5, § 10.2 (“Supplemental drugs”).
- 7 42 CFR § 423.100; CMS, Medicare Prescription Drug Manual, Ch. 6, § 10; Medicare Rights, [Helping Clients with Part D Appeals – Frequently Asked Questions](#).
- 8 CMS, Medicare Prescription Drug Manual, Ch. 5, § 90.2.2.
- 9 CMS, Plan Sponsor Notices and Other Documents, Medicare Prescription Drug Coverage and Your Rights (CMS-10147); Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, § 40.12.3.
- 10 CMS, Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, § 40.12.3.
- 11 CMS, [Coverage Determinations](#)
- 12 CMS, Medicare Prescription Drug Benefit Manual, Ch. 3, § 90.7.3; Model Form Instructions, [Request for a Medicare Prescription Drug Coverage Determination](#).
- 13 CMS, Model Form Instructions, [Request for a Medicare Prescription Drug Coverage Determination](#)
- 14 “Plans are not required to conduct outreach prior to denying claims payments if they believe they have all the necessary information needed to make a coverage decision.” CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 10.6.
- 15 CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.10.
- 16 *Id.*
- 17 *Id.* at § 40.2
- 18 CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.2
- 19 *Id.* at § 40.5.5.
- 20 *Id.* at § 40.5.2.
- 21 Medicare.gov, [Drug plan coverage rules](#).
- 22 *Id.*
- 23 *Id.*
- 24 CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.5.3
- 25 Medicare Rights, [Helping Clients with Part D Appeals –Frequently Asked Questions](#).
- 26 CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.5.6.
- 27 42 CFR § 423.578; CMS, Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, § 40.5.1; Medicare Rights, [Requesting a tiering exception](#).
- 28 42 U.S.C. 1396r–8(k)(6); CMS, Medicare Prescription Drug Benefit Manual, Ch. 6§10.6
- 29 42 U.S.C. 1396r–8(g)(1)(B)(i).
- 30 HHS, Agency for Healthcare Research and Quality, [Off-Label Drugs: What You Need to Know](#).
- 31 42 C.F.R. §414.930; CMS, Medicare Benefit Policy Manual Ch.15, §50.4.5.
- 32 42 U.S.C. §1395x(t); CMS, Medicare Benefit Policy Manual, Ch. 15, § 50.4.2
- 33 [42 CFR § 423.120\(b\)\(3\)](#); Medicare Rights, [Transition drug refills](#); NCOA, [Getting to Know: Part D Transition Policy](#); Justice In Aging, [Medicare Part D – 2017 Transition Rights](#).
- 34 CMS, Medicare Prescription Drug Manual, [Ch. 6](#), §30.4.4.1: “In the retail setting, the transition fill of non-formulary Part D drugs must be for at least 30 days, unless the prescription is written by a prescriber for less than 30 days. Part D sponsors must allow multiple fills to provide at least 30 days of medication in accordance with 42 CFR §423.120(b)(3)(iii)(A). If the smallest available marketed package size exceeds a 30 day supply, the sponsor must still provide a transition supply when required.”
- 35 However, if the plan cannot determine whether the individual was previously taking the drug, they are to assume the individual was doing so. See CMS, Medicare Prescription Drug Manual, [Ch. 6](#), §30.4.3. See also Appendix E for the different scenarios that qualify someone for a transition refill.
- 36 CMS, Medicare Prescription Drug Manual, [Ch. 6](#), § 30.4.
- 37 *Id.* at § 30.4.4.
- 38 *Id.* at § 30.4.9.
- 39 *Id.* at § 30.4.8. See also §30.4.1. If the plan sets a quantity limit that is the same as the FDA’s maximum does limit, then the plan does not have to allow a transition fill above its quantity limit.
- 40 CMS, Medicare Prescription Drug Manual, [Ch. 6](#), §§ 30.4.2 and 30.4.10.

- 41 Id. at §30.4.10.1.
- 42 Medicare Rights, [Six things to know about Fall Open Enrollment](#).
- 43 Medicare.gov, [Find a Medicare Plan](#).
- 44 Medicare Rights, [How to switch Medicare Advantage Plans or switch from Medicare Advantage to Original Medicare](#).
- 45 Medicare Rights, [Special Enrollment Periods for Medicare Advantage Plans and Medicare Part D Drug Plans](#).
- 46 CMS, Medicare Managed Care Manual, [Ch. 2](#); Medicare Prescription Drug Manual, [Ch. 3](#).
- 47 Social Security Administration (“SSA”), Program Operations Manual System (“POMS”) HI 03001.000 *et seq.*; CMS, Medicare Prescription Drug Benefit Manual, [Ch. 13](#); Medicare Rights, [Extra Help basics et seq.](#)
- 48 [42 CFR § 423.38\(c\)\(4\)](#); CMS, Medicare Managed Care Manual, [Ch. 2](#), § 30.4.4(5); Medicare Prescription Drug Manual, [Ch. 3](#), 30.3.2.
- 49 Id.
- 50 Id.
- 51 [NeedyMeds.org](#).
- 52 [MedicineAssistanceTool.org](#).
- 53 [RxAssist.org](#).
- 54 [GoodRx.com](#).
- 55 Often these programs are found on the manufacturer’s website, though Medicare also has a database. *See* Medicare.gov, [Find a Pharmaceutical Assistance Program for the drugs you take](#). Medicare Rights often simply searches the web with the name of the drug and “assistance program.”