



Medicare Advocacy Toolkit

# Prescription Drug Appeals

An Advocate’s Toolkit for Helping Individuals Appeal Prescription Drug Denials

Winter 2021

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## About the 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:

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

## About the Advocacy Toolkits

With over 30 years of counseling and advocacy experience, the Medicare Rights Center possesses specialized knowledge about the barriers people with Medicare face in accessing affordable health care, as well as strategies for overcoming these barriers. This series of Medicare Advocacy Toolkits has been developed for any New York advocate who is helping older adults and people with disabilities navigate health insurance benefits. The goal of this project is to empower New York advocates and those they serve to navigate Medicare coverage so that they can access needed care. While intended for a New York audience, the Medicare Advocacy Toolkits may offer lessons to other states and be useful resources as advocates and policymakers think about ways to improve the federal Medicare program, which today serves over 60 million Americans. **Advocates with additional questions can contact Medicare Rights' professional email inbox at [professional@medicarerights.org](mailto:professional@medicarerights.org). Consumers with questions can call Medicare Rights' national consumer helpline at 800-333-4114.**

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The Medicare Rights Center provides these Medicare Advocacy Toolkits as a public service. They are not intended as personalized legal advice, nor is Medicare Rights acting as a private attorney in providing guide content. For the latest information about toolkit topics and customized assistance, contact Medicare Rights, 1-800-MEDICARE, or a local [State Health Insurance Assistance Program](#) (SHIP).

## Introduction: Prescription Drugs

Every year, hundreds of callers reach out to the Medicare Rights Center's national helpline with issues related to accessing and affording medically necessary prescription medication, and over half a million people search for answers about Medicare prescription drug coverage on Medicare Interactive, Medicare Rights' online reference tool.

This is not surprising: U.S. spending on prescription drugs in 2020 is 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> Unfortunately, many individuals find it difficult to navigate Medicare's coverage for prescription drugs, particularly when they receive a denial of payment for their medication.

This Medicare Advocacy Toolkit serves as a step-by-step resource to help advocates and people with Medicare. The toolkit first describes the problem and target audience, then provides an overview of Medicare prescription drug issues and strategies to resolve them. Throughout the guide, content is organized in a way that parallels how its counselors evaluate and troubleshoot actual Medicare issues. In addition, the guide contains citations to the relevant rules that form the basis for helping people solve their Medicare problems.

## The Problem

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> Most of these denials are improper and, as a result, nearly three quarters of the denials are overturned or partially overturned on appeal.<sup>5</sup> This means that the ability to successfully

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<sup>1</sup> IQVIA, [The Global Use of Medicine in 2019 and Outlook to 2023](#) (Jan. 29, 2019).

<sup>2</sup> Kamal, R., Cox, C., & McDermott, D., [What are the recent and forecasted trends in prescription drug spending?](#) (Feb. 20, 2019).

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> Ibid.

navigate the appeals process is vital to ensuring affordable access to prescription medication for millions of beneficiaries.

Yet, Medicare Rights hears from hundreds of callers annually who face barriers to accessing their needed medical prescriptions because of denials from their Part D plan. Lack of affordable access to medication often has a cascading, negative effect on the lives of Medicare beneficiaries. Every year, Medicare Rights hears from people who are going without the medication they need, facing overwhelming anxiety due to out-of-control pharmacy costs, or rationing what is left of their medication. Accessing affordable and appropriate medication is a key component to ensuring the survival, health, and quality of life for individuals with Medicare.

## Target Audience

This Medicare Advocacy Toolkit is designed to help advocates address the needs of New Yorkers who are denied payment for prescription medication by their Medicare Part D plan. Medicare's benefits, coverage rules, and Part D policies do not change based on how you are entitled to Medicare (i.e., age, disability, or ESRD diagnosis), so this guide applies to all people with a Medicare Part D plan.

## The Part D Appeals Process<sup>6</sup>

### Background

Medicare Part D, the prescription drug benefit, is the part of Medicare that covers most outpatient prescription drugs. 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).<sup>7</sup> 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 leeway, however, there are certain drugs that Part D plans cannot cover.<sup>8</sup> These excluded drugs include:<sup>9</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

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<sup>6</sup> Medicare Rights, [Medicare prescription drug plan appeals](#).

<sup>7</sup> Medicare Rights, [The Medicare drug benefit \(Part D\)](#).

<sup>8</sup> 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").

<sup>9</sup> [42 CFR § 423.100](#); CMS, Medicare Prescription Drug Manual, Ch. 6, § 10; Medicare Rights, [Helping Clients with Part D Appeals – Frequently Asked Questions](#).

- 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.

## The Prescription

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 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.

### Advocacy 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>10</sup> Each plan will have its own specific reimbursement form, so individuals should review their plan's website or call the plan to have the form sent to them.

## Notice of Non-coverage<sup>11</sup>

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>12</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 has to file an exception request first before they get an appealable denial.<sup>13</sup>

<sup>10</sup> CMS, Medicare Prescription Drug Manual, [Ch. 5](#), § 90.2.2.

<sup>11</sup> Medicare Rights, [Troubleshooting Part D drug denials and appeals](#).

<sup>12</sup> 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.

<sup>13</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.12.3.

## Advocacy Tip: Keep Copies and Never Send Originals

In Medicare Rights' experience, 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<sup>14</sup>

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.

## Filing a Grievance

The Centers for Medicare & Medicaid Services (CMS), which oversees the Medicare program, requires Part D plans to provide adequate customer service to enrollees, including helping them with questions about the appeals process. If an individual is experiencing poor customer service or administrative issues with the plan (e.g., taking too long to process an appeal or to provide a refund) they can file a grievance (a formal complaint) with the plan.<sup>15</sup> A grievance is processed in the same part of the plan that handles appeals, but, instead of concerning a coverage issue, the grievance is about a customer service or administrative issue.<sup>16</sup> Consequently, it is important for individuals to understand that there is a difference between their appeal (which is their fight to get coverage for their drug) and their grievance (which is the formal complaint about how the plan is handling the appeal or interacting with them).<sup>17</sup> Another way to think about this is that a successful appeal means the plan covers the drug while a successful grievance means the plan addresses whatever issues the individuals was complaining about. It is important to understand this distinction

<sup>14</sup> Medicare Rights, [Troubleshooting Part D drug denials and appeals](#).

<sup>15</sup> [42 CFR § 423.564](#); Centers for Medicare and Medicaid Services (CMS), [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 30.

<sup>16</sup> [42 CFR § 423.564\(b\)](#).

<sup>17</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 30.1.



when submitting a grievance to avoid the plan incorrectly processing the complaint as an appeal or so that individuals does not use the wrong method to get the result that they want. When a plan incorrectly processes a complaint as an appeal or vice versa (as sometimes happens),<sup>18</sup> individuals should immediately file a complaint online, with 1-800-MEDICARE, or with their CMS Regional Office.<sup>19</sup>

To file a grievance, an individual can contact the plan via the plan's appeals and grievances number (found on the individual's insurance card or via the plan's website and print materials). Medicare Rights also encourages individuals filing a grievance to do so in writing and within 60 days of the incident that the individual is filing a complaint about.<sup>20</sup> The plan then has 30 days to respond (or 24 hours for an expedited grievance when the complaint involves a plan's refusal to grant a fast appeal and the individual has not yet received the drug that is in dispute).<sup>21</sup> When a plan responds inadequately or does not respond within the required 30-day deadline, individuals can escalate by filing a complaint online, with 1-800-MEDICARE, or with their CMS Regional Office.<sup>22</sup> For more assistance in filing a grievance, please see Medicare Rights' [Grievance Packet](#).

## Requesting a Fast Appeal

When an individual needs their drugs as soon as possible, they can request a fast appeal if they or their doctor feel that their health could be seriously harmed by waiting the standard timeline for a decision.<sup>23</sup> If their doctor supports the decision to file an expedited exception request, the plan must follow the expedited timeline.<sup>24</sup> A beneficiary can also request an expedited exception request without their doctor's support, but, in this case, the plan does not have to follow the expedited timeline. If the plan denies the request to expedite the process, then the plan should notify the individual that they will process the appeal using the standard timeline, and that the individual can file an expedited grievance disputing the decision and refile a new expedited request.<sup>25</sup> If the plan grants the request to expedite the process, the plan should send a decision to the individual within 24 hours of the initial exception request.<sup>26</sup> They can then proceed through the same steps of the formal appeal, but with an expedited timeline (see chart on page 10).<sup>27</sup>

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<sup>18</sup> Ibid. at § 40.13.

<sup>19</sup> Ibid. at § 30.1; CMS, [Filing complaints about your health or drug plan](#); CMS, [CMS Regional Offices](#).

<sup>20</sup> [42 CFR § 423.564\(d\)\(2\)](#); Medicare Rights, [Grievance Packet](#).

<sup>21</sup> [42 CFR § 423.564\(f\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 30.2.

<sup>22</sup> [42 CFR § 423.564\(e\)](#); CMS, [Filing complaints about your health or drug plan](#); CMS, [CMS Regional Offices](#).

<sup>23</sup> [42 CFR § 423.570](#).

<sup>24</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.8.

<sup>25</sup> Ibid. at § 40.12.2.

<sup>26</sup> Ibid. at § 40.10.

<sup>27</sup> [42 CFR § 423.572](#); Medicare Rights, [Helping Clients with Part D Appeals – Frequently Asked Questions](#).

## Additional Rights in Nursing Homes

If an individual's plan denies payment for a medication, the individual has the same right to appeal in a nursing home as they would if they lived elsewhere. While living in a nursing home, an individual has these additional rights:<sup>28</sup>

- If an individual lives in a nursing home or is entering a nursing home, their Part D plan must fill a 31-day emergency supply of their medication outside of the transition fill period.<sup>29</sup> This is to allow time for the individual to file an exception request and the plan to process it.
- Individuals in a nursing home have access to additional special enrollment periods to change their drug coverage. They have a chance to change their coverage when they first enter the nursing home, once a month while they live in the nursing home, and for the two months after they leave a nursing home.<sup>30</sup>
- Even if an individual's plan does not cover their drugs, the nursing home is still required to provide the medications (though they will likely charge for this service).

## Understanding the Plan's Deadlines

In some cases, it can be difficult to understand whether a plan has violated a deadline they were required to meet and, if they did, what to do about it. CMS has provided some guidance on this topic:

- Plans are required to receive appeals 24 hours a day and seven days a week (including holidays).<sup>31</sup>
- Appeal requests are counted from the day they are received, such that "day one" is the day after the plan receives the request.<sup>32</sup>
- Appeal requests are counted from the time they are received, such that a 24-hour deadline is 24 hours from when the voicemail requesting the appeal was left (or, e.g., the fax was sent, the mail was received, or the customer service representative was informed on the phone).<sup>33</sup>
- When calculating the plan's deadline, all calendar days, including holidays and weekends, are counted.<sup>34</sup>
- Written notification sent from the plan is considered delivered not when it is delivered, but when the plan puts it in its outgoing mailbox.<sup>35</sup>

<sup>28</sup> Medicare Rights, [Part D coverage in nursing homes](#).

<sup>29</sup> CMS, Medicare Prescription Drug Benefit Manual, [Ch. 6](#), § 30.4.6.

<sup>30</sup> [42 CFR 423.38](#)(c)(15); CMS, Medicare Prescription Drug Benefit Manual, [Ch. 3](#), § 30.3.8(5).

<sup>31</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 10.5.2.

<sup>32</sup> *Ibid.* at §10.5.1.

<sup>33</sup> *Ibid.*

<sup>34</sup> *Ibid.* To make it easier to calculate appeals deadlines, individuals and advocates may find it helpful to use one of the date calculators readily available for free on the internet.

<sup>35</sup> In some cases, a plan could also call and provide verbal notification of an appeal result and give themselves an extra three days from the call to mail out the written notification. [42 CFR § 423.568](#)(d)-(g); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), §10.5.3.



- While Medicare Rights often sees plans use the full amount of time they are allowed, CMS has instructed plans (and other appeals entities) that they “should not routinely take the maximum time permitted for adjudicating coverage requests...” and that they are required “to make decisions as ‘expeditiously as the enrollee’s health condition requires.’”<sup>36</sup>

When a plan has violated the deadline, individuals can file a grievance with the plan or a complaint with Medicare (see the previous advocacy tip for how to do this). In addition, the plan is required to forward the individual’s request to the Independent Review Entity within 24 hours of the deadline.<sup>37</sup>

### **Advocacy Tip: Language and Disability Accommodations**

Individuals with limited English proficiency or disabilities that affect their ability to communicate with their plan have a right to reasonable accommodations, such as materials in an alternative language or format.<sup>38</sup> In order to receive these accommodations, however, the individual or their representative must request them from the plan (usually by calling the customer service line, but some plans also have request forms on their website). If their request is ignored or denied, the individual can file a grievance with the plan or a complaint online, with 1-800-MEDICARE, or with their CMS Regional Office.<sup>39</sup> In addition, individuals may consider filing a civil rights complaint.<sup>40</sup>

<sup>36</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 10.4.1 (quoting [42 CFR § 422, Subpart M](#)).

<sup>37</sup> [42 CFR § 423.568\(h\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.11.

<sup>38</sup> [42 CFR §§ 422.110-.111](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 10.4.4.

<sup>39</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 30.1; CMS, [Filing complaints about your health or drug plan](#); CMS, [CMS Regional Offices](#).

<sup>40</sup> HHS, Office of Civil Rights, [How to File a Civil Rights Complaint](#).

## Part D Appeal Process Overview

This chart provides an overview of the appeal process, the entities involved, and the deadlines for filing appeals and receiving decisions. Following the chart, this guide goes into detail for each level of appeal.

<b>Before Filing Appeal</b>	<b>Pharmacist tells beneficiary that plan is not covering their drug</b>
<b>Initial Decision</b>	File exception request with plan <b>Deadline for standard decision: 72 hours</b> <b>Deadline for expedited decision: 24 hours</b>
<b>First Level of Appeal</b>	Appeal to plan <b>Deadline to file: 60 days</b>  Plan reviews appeal <b>Deadline for standard decision: 7 days</b> <b>Deadline for expedited decision: 72 hours</b>
<b>Second Level of Appeal</b>	Appeal to Independent Review Entity (IRE) <b>Deadline to file: 60 days</b>  IRE reviews appeal <b>Deadline for standard decision: 7 days</b> <b>Deadline for expedited decision: 72 hours</b>
<b>Third Level of Appeal</b>	Appeal to Office of Medicare Hearings and Appeals (OMHA) <b>Deadline to request hearing: 60 days</b>  OMHA makes decision <b>Deadline for standard decision: 90 days</b> <b>Deadline for expedited decision: 10 days</b>
<b>Fourth Level of Appeal</b>	Appeal to Medicare Appeals Council (Council) <b>Deadline to request review: 60 days</b>  Council makes decision <b>Deadline for standard decision: 90 days</b> <b>Deadline for expedited decision: 10 days</b>
<b>Final Level of Appeal</b>	Appeal to Federal District Court <b>Deadline to request review: 60 days</b>  Federal District Court makes decision <b>No deadline for decision</b>

## 1. 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, so this section contains many of the most common kinds and advice specific to them. 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>41</sup> 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>42</sup> It can be filled out by the individual if the doctor will not.<sup>43</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>44</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. Please see Medicare Rights' materials for sample letters from an individual/advocate and the prescribing doctor.<sup>45</sup> 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>46</sup>

### Advocacy Tip: Submit Appeals in Writing

Many plans accept appeals over the phone, but unless the prescribing doctor is calling the plan, Medicare Rights' advises clients to submit their appeal in writing. This allows the individual to keep a record of what they are submitting, ask for changes (if needed) with the doctors' documentation, and have a paper trail of submitting their requests and subsequent appeals on time. When possible, Medicare Rights encourages clients to submit by fax not only because it is fast, but also because it provides a free confirmation of receipt. When sending by mail, it is a best practice to get confirmation of receipt (which can be burdensome since it is usually more expensive and may require a trip to the post office).

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<sup>41</sup> CMS, [Coverage Determinations](#).

<sup>42</sup> CMS, Medicare Prescription Drug Benefit Manual, [Ch. 3](#), § 90.7.3; Model Form Instructions, [Request for a Medicare Prescription Drug Coverage Determination](#).

<sup>43</sup> Ibid.

<sup>44</sup> CMS, Model Form Instructions, [Request for a Medicare Prescription Drug Coverage Determination](#).

<sup>45</sup> Medicare Rights, [Medicare prescription drug plan appeals](#).

<sup>46</sup> "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.

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>47</sup> If the plan grants the request to expedite the process, they should send a decision within 24 hours of the initial request.<sup>48</sup> The decision is called a coverage determination and provides the individual with appeal rights.<sup>49</sup>

### **Advocacy Tip: Help is Available**

Especially at the early stages of the appeals process (i.e., through the OMHA level) there are several free resources that individuals can go to for help with their appeal. Most importantly, individuals should rely on their prescribing doctor for help as medical documentation is the key component of most successful appeals.<sup>50</sup> A provider may appeal on an individual's behalf or help with the appeal process but is not required to do so. In addition, Medicare Rights helps people nationwide navigate the appeals process through its helpline: 800-333-4114 (Medicare Rights' helpline number is also on the denial letters that individuals receive throughout the appeals process). Similarly, every state has a State Health Insurance Assistance Program (SHIP), which provides Medicare beneficiaries with Part D appeals assistance.<sup>51</sup> In New York, the SHIP program is called the Health Insurance Information Counseling and Assistance Program (HIICAP). Individuals can find their local HIICAP office by calling 800-701-0501.<sup>52</sup> In addition, individuals can request anyone to serve as their representative<sup>53</sup> for an appeal by submitting form CMS-1696 (or the plan's version of the same form) with their appeal documents.<sup>54</sup>

## **Common Types of Exception Requests**

Much of the strategy for successfully overcoming a Part D denial lies in identifying and addressing why the drug is being denied. This information determines the type of exception request the individual should make and what documentation they should provide. Thus, this section provides an overview of the most common Part D denials and the exception requests to address them. Following this section, the guide will move to the second level of the appeals process.

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<sup>47</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.10.

<sup>48</sup> Ibid.

<sup>49</sup> Ibid. at § 40.2.

<sup>50</sup> Ibid. at § 40.5.3.

<sup>51</sup> To find the SHIP helpline number for any state, visit <https://www.shiptacenter.org/>.

<sup>52</sup> New York State, Office for the Aging, [Health Insurance Information Counseling and Assistance Program \(HIICAP\)](#).

<sup>53</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.6.

<sup>54</sup> Ibid. at §§ 20.1 and 20.2; CMS, Appointment of Representative, [CMS-1696](#). While some plans have their own branded forms which can be used, every plan is required to accept the generic CMS-1696. Additionally, plans are required to include appointment of representation documentation when submitting case files to further appeal entities.

## Formulary Exception

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>55</sup> Other times, the plan puts certain restrictions on the medication, called utilization management.<sup>56</sup> The most common of these formulary exceptions situations are discussed in detail below. One note: Most of the time, exceptions last for the rest of the calendar year, but individuals who are appealing can ask for a more permanent exception that lasts for as long as they are enrolled in the plan.<sup>57</sup>

### 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>58</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.<sup>59</sup>

### Requesting a Formulary Exception

- **Get a letter of support** from the prescribing physician that explains why the individual needs the drug and, if possible, how other medications to treat the same condition would be ineffective or harmful to the individual.
- **Make sure the letter is complete.** The letter of support from the prescribing doctor is vital to successful formulary exceptions. Try to make sure it is accurate, clearly identifies the relevant medications, and is comprehensive. For example, rather than simply stating that an alternative medication would be ineffective, the doctor could explain in detail how the individual had already tried that drug for four months, but it did not relieve the individual's symptoms.

<sup>55</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.2.

<sup>56</sup> Ibid. at §§ 40.2 and 40.5.2.

<sup>57</sup> Ibid. at § 40.5.5.

<sup>58</sup> Ibid.

<sup>59</sup> Ibid. at § 40.5.3.

- **Submit the request** by having the doctor fill out a generic Coverage Determination Request form along with the supplemental information (or contact the plan for a plan-specific version of the form).<sup>60</sup> 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.
- **If needed, expedite.** If the prescribing doctor believes that the individual's health could be seriously harmed by waiting the standard timeline for appeal decisions (plan has 72 hours to make a decision), they can request a fast appeal (plan has 24 hours to make a decision).<sup>61</sup>
- **Document.** Take notes when anyone speaks to the plan (e.g., the plan employee's name, their phone number, the date/time of the call, and what was said). Keep track of when the doctor submits the request and copies of what they submitted.

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>62</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. Furthermore, once an individual has received a formulary exception, they cannot then request a tiering exception to make the drug more affordable (tiering exceptions are discussed below as a way to use the exception process to reduce cost-sharing for a specific drug).<sup>63</sup> Therefore, Medicare Rights often advises clients to only enroll in plans where their medications are on the formulary and to make sure, every fall, that their plan will continue to keep their drugs on the formulary for the following calendar year.

### Advocacy Tip: Misrepresentation by a Plan

Medicare Rights hears with some regularity from callers who join a plan because of specific information they are told (e.g., it will cover a particular medication they need), but that information later turns out to be incorrect. If an individual receives misinformation from a plan representative (including agents and brokers) or a SHIP representative, they can request a Special Enrollment Period (SEP) in order to disenroll from their current plan and into a different plan.<sup>64</sup> They can also request that this SEP allow a retroactive disenrollment from the plan they were erroneously enrolled in and a retroactive enrollment in the plan they were previously in or should have enrolled in.<sup>65</sup> Individuals can request an SEP by calling 1-800-MEDICARE. If they are requesting a retroactive change, their

<sup>60</sup> CMS, [Coverage Determinations](#).

<sup>61</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.5.4.

<sup>62</sup> See, e.g., *Ibid.* at § 40.5.2.

<sup>63</sup> [42 CFR §423.578\(c\)\(4\)\(iii\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.5.2.

<sup>64</sup> 42 CFR § 423.38(c)(34); CMS, Medicare Prescription Drug Manual. [Ch. 3](#), § 30.3.8(19).

<sup>65</sup> CMS, Medicare Prescription Drug Manual. [Ch. 3](#), §§ 60.3 and 60.4.



request should be transferred to the CMS Regional Office. For this reason, advocates assisting individuals needing a retroactive SEP for misleading information may consider contacting the Regional Office directly.<sup>66</sup>

### Quantity Limits

Plans can limit their coverage by a certain amount over a particular period of time.<sup>67</sup> For example, a plan may only provide coverage for up to 30 pills per month of a certain type of medication. 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.<sup>68</sup> 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>69</sup> In other words, that they approve a prescription before the individual is at the pharmacy. Information on whether a plan requires prior authorization for certain drugs is available in Medicare's Plan Finder, so individuals should consider this when shopping around for a Part D plan.<sup>70</sup> 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. While the plan will not pay for a prescription without the individual meeting the prior authorization requirement, approving a prior authorization requirement does not necessarily guarantee the plan will cover the prescription once it is actually requested at the pharmacy. In most cases, plans approve a prior authorization without also guaranteeing payment.

### 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>71</sup> Information on whether a plan requires step therapy for certain drugs is available in Medicare's Plan Finder, so individuals should consider this when shopping around for a Part D plan.<sup>72</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>73</sup>

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<sup>66</sup> CMS, New York, [RONYBENEFICIARY@cms.hhs.gov](mailto:RONYBENEFICIARY@cms.hhs.gov); CMS, [CMS Regional Offices](#).

<sup>67</sup> Medicare.gov, [Drug plan coverage rules](#).

<sup>68</sup> Medicare.gov, [Find a Medicare plan](#).

<sup>69</sup> Medicare.gov, [Drug plan coverage rules](#).

<sup>70</sup> Medicare.gov, [Find a Medicare plan](#).

<sup>71</sup> Medicare.gov, [Drug plan coverage rules](#).

<sup>72</sup> Medicare.gov, [Find a Medicare plan](#).

<sup>73</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.5.3.

## Advocacy Tip: Using the Right Pharmacy

Most, if not all, Part D plans have networks of pharmacies.<sup>74</sup> Within those networks, the plans normally designate preferred and non-preferred pharmacies.<sup>75</sup> The difference is important since, in almost all cases, an individual is going to get better cost-sharing at a preferred pharmacy. Unfortunately, not everyone is aware of this system and, as a result, Medicare Rights receives calls from individuals who think a drug has been denied when, actually, the cost-sharing is just higher because they are at a non-preferred pharmacy.

In a similar way, individuals can also be confused when their cost-sharing changes after switching between a mail-order pharmacy<sup>76</sup> and a retail (or brick-and-mortar) pharmacy.<sup>77</sup> Often, mail-order pharmacies fill prescriptions for 90 days while traditional pharmacies fill them for 30 days.<sup>78</sup> For that reason alone, there can be changes in how much an individual is expected to pay out-of-pocket.

For both issues, it is important for individuals to be aware of how the pharmacy they select will affect their pricing. And, if using a particular pharmacy is important to them, making sure they enroll in a drug plan that uses that pharmacy. Like the utilization management requirements and formulary information, individuals can find pharmacy network information in Medicare's Plan Finder.<sup>79</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>80</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>81</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

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<sup>74</sup> CMS, Medicare Prescription Drug Manual, [Ch. 5](#), § 50.

<sup>75</sup> *Ibid.* at § 50.9.

<sup>76</sup> *Ibid.* at § 50.2.

<sup>77</sup> *Ibid.* at § 50.1.

<sup>78</sup> *Ibid.* at § 50.10.

<sup>79</sup> Medicare.gov, [Find a Medicare plan](#).

<sup>80</sup> Medicare Rights, [Helping Clients with Part D Appeals – Frequently Asked Questions](#).

<sup>81</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.5.6.

for the individual.<sup>82</sup> If the plan approves the exception, it would normally grant it for the rest of the calendar year, although individuals can request a permanent exception. If the request is denied, the individual can challenge that decision using the normal Part D appeals process.<sup>83</sup>

Part D plans only have to approve a tiering exception if there is a drug on the lower tier approved for treating the same condition as the requested drug, and the prescribing doctor provides a supporting statement saying the lower tier drug would either not be as effective as the requested drug or would have adverse side effects.<sup>84</sup> There are also further limitations on when an individual can get a tiering exception. That is, plans do not have to grant tiering exceptions:

- From a brand-name tier to a generic tier.<sup>85</sup>
- From the specialty tier to a non-specialty tier.<sup>86</sup>
- For drugs that were placed on the formulary after a formulary exception.<sup>87</sup>

This means that tiering exceptions are normally from Tier 4 to Tier 3 or Tier 2 to Tier 1. As a result, people with Extra Help (a federal program that helps pay for Medicare prescription drug coverage) cannot get a tiering exception since there are only two tiers: brand name and generic.

Common Medicare Drug Plan Tiering Structure			
<b>Tier 5</b> <b>Extra Help Tier 2</b>	Specialty Drugs	Median coinsurance: 25% <sup>88</sup>	No tiering exceptions allowed.
<b>Tier 4</b> <b>Extra Help Tier 2</b>	Non- Preferred Drugs	Median coinsurance: 40%.	An individual may request a tiering exception to cover a Tier 4 drug at the Tier 3 cost-sharing level so long as there is a drug on Tier 3 approved for treating the same condition that the requested Tier 4 drug is being used to treat, and the Tier 3 drug is either not as effective as the Tier 4 drug or has adverse side effects.

<sup>82</sup> 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](#).

<sup>83</sup> Ibid.

<sup>84</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.5.3.

<sup>85</sup> Ibid. at § 40.5.1.

<sup>86</sup> Ibid.

<sup>87</sup> 42 CFR § 423.578(c)(4)(iii); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.5.2.

<sup>88</sup> Median cost-sharing information taken throughout the chart from Juliette Cubanski & Anthony Damico, Kaiser Family Foundation, [Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2021](#) (Oct. 29, 2020).

<b>Tier 3 Extra Help Tier 2</b>	Preferred Brand	Median copayment: \$40	No tiering exceptions allowed.
<b>Tier 2 Extra Help Tier 1</b>	Generics	Median copayment: \$5	A plan member may request a tiering exception to cover a Tier 2 drug at the Tier 1 cost-sharing level so long as there is a drug on Tier 1 approved for treating the same condition that the requested Tier 2 drug is being used to treat, and the Tier 1 drug is either not as effective as the Tier 2 drug or has adverse side effects.
<b>Tier 1 Extra Help Tier 1</b>	Preferred Generics	Median copayment: \$0	No tiering exceptions allowed.

### Requesting a Tiering Exception

- **Get a letter of support** from the prescribing physician that explains why similar drugs on the plan's formulary at lower tiers would be ineffective or harmful to the individual.
- **Make sure the letter is complete.** The letter of support from the prescribing doctor is vital to successful tiering exceptions. Try to make sure it is accurate, clearly identifies the relevant medications, and is comprehensive. For example, rather than simply stating that the lower tier drug would be ineffective, the doctor could explain in detail how the individual had already tried that drug for four months, but it did not relieve the individual's symptoms.
- **Submit the request** by having the doctor fill out a generic Coverage Determination Request form along with the supplemental information (or contact the plan for a plan-specific version of the form).<sup>89</sup> 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.
- **If needed, expedite.** If the prescribing doctor believes that the individual's health could be seriously harmed by waiting the standard timeline for appeal decisions (plan has 72 hours to make a decision), they can request a fast appeal (plan has 24 hours to make a decision).<sup>90</sup>
- **Document.** Take notes when anyone speaks to the plan (e.g., the plan employee's name, their phone number, the date/time of the call, and what was said). Keep track of when the doctor submits the request and copies of what they submitted.

<sup>89</sup> CMS, [Coverage Determinations](#).

<sup>90</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.10.

## Off-label

Under federal law, Part D plans must only cover FDA-approved Part D drugs that are prescribed for “medically-accepted indications.”<sup>91</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, American Hospital Formulary Service-Drug Information (AHFS-DI) and DRUGDEX.<sup>92</sup> (The compendia are listings of drugs that contain information on a drug’s effectiveness, clinical indications, and dosing.) 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>93</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, which are Clinical Pharmacology, National Comprehensive Cancer Network (NCCN) Drugs & Biologics, and Lexi-Drugs.<sup>94</sup> Part B drugs also have a different, more generous standard.<sup>95</sup>

### 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.<sup>96</sup>
- **Check the compendia.** Ask the prescribing doctor to look for support for the use of the drug in the approved compendia (AHFS-DI and DRUGDEX). 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

<sup>91</sup> [42 U.S.C. 1396r-8\(k\)\(6\)](#); CMS, Medicare Prescription Drug Benefit Manual, [Ch. 6](#) §10.6.

<sup>92</sup> [42 U.S.C. 1396r-8\(g\)\(1\)\(B\)\(i\)](#).

<sup>93</sup> HHS, Agency for Healthcare Research and Quality, [Off-Label Drugs: What You Need to Know](#).

<sup>94</sup> [42 C.F.R. §414.930](#); CMS, Medicare Benefit Policy Manual [Ch. 15](#), §50.4.5.

<sup>95</sup> [42 U.S.C. §1395x\(t\)](#); CMS, Medicare Benefit Policy Manual, [Ch. 15](#), § 50.4.2.

<sup>96</sup> FDA labels can be searched here: HHS, U.S. Food & Drug Administration, [Drugs@FDA: FDA-Approved Drugs](#).

commonly at the OMHA and Federal District Court levels). These legal arguments are beyond the scope of this guide, so individuals in this situation should consider reaching out to Medicare Rights at 800-333-4114.

- **Submit the request** by having the doctor fill out a generic Coverage Determination Request form along with the supplemental information (or contact the plan for a plan-specific version of the form).<sup>97</sup> 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.
- **If needed, expedite.** If the prescribing doctor believes that the individual's health could be seriously harmed by waiting the standard timeline for appeal decisions (plan has 72 hours to make a decision), they can request a fast appeal (plan has 24 hours to make a decision).<sup>98</sup>
- **Document.** Take notes when anyone speaks to the plan (e.g., the plan employee's name, their phone number, the date/time of the call, and what was said). Keep track of when the doctor submits the request and copies of what they submitted.

## Part B vs. Part D

Medicare drug coverage is confusing because different parts of Medicare can cover different drugs (and sometimes the same drug) depending on the situation.<sup>99</sup> So, for instance, a hospital inpatient during a Medicare-covered stay will have medications covered under Part A that would have been covered under Part D if the patient was outside the hospital.<sup>100</sup>

The greatest confusion Medicare Rights sees is in determining when drugs are covered by Part B and when they are covered by Part D. This is an important distinction to understand, since the difference can have a large impact on an individual's cost-sharing, the appeals process they use, and even who covers the drug.

Speaking very generally, Part D covers medications that individuals can pick up in a pharmacy and administer themselves, while Part B covers medications that are administered by a doctor. That is a good rule of thumb, but it over-generalizes the situation. While a comprehensive listing of all Medicare drug coverage rules is beyond the scope of this guide, here are a few common examples:<sup>101</sup>

- **Insulin**, when administered through an implantable pump, is paid for under Part B. This is because the pump through which it is administered is considered to be durable medical equipment and the insulin is a supply for that durable medical

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<sup>97</sup> CMS, [Coverage Determinations](#).

<sup>98</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.10.

<sup>99</sup> CMS, [Medicare Drug Coverage under Medicare Part A, Part B, Part C, & Part D](#); CMS National Training Program, [Medicare Drug Coverage Under Part A, Part B, and Part D](#); Medicare Rights, [Prescription drug coverage \(Parts A, B, and D\)](#).

<sup>100</sup> *Ibid.*

<sup>101</sup> CMS, Medicare Prescription Drug Manual, [Ch. 6](#), § 20.2 and Appendix C; Medicare Rights, [Medicare Drug Coverage: Part D vs. Part B](#).



equipment. However, insulin administered through a syringe or a disposable pump is covered under the Part D benefit. So, most Medicare beneficiaries have their insulin covered under Part D, but, if they had an insulin pump, the very same insulin would be covered under Part B.

- **Medications taken through a nebulizer** are covered under Part B. A nebulizer is a device that allows individuals to inhale certain types of medication. Once again, even if a medication would normally be covered by Part D, it is covered by Part B if it will be taken through a nebulizer.
- **Immunosuppressant** medication, used to prevent the body from rejecting transplanted organs, is covered by Part B if Medicare helped pay for the transplant and Part D if Medicare did not help pay for the transplant.

Since determining whether a drug is covered by Part B or Part D is sometimes dependent on specific facts, Medicare Rights often hears from callers who have Part D plans incorrectly denying a drug saying that it should be covered by Part B when, really, the drug should be covered by the plan. This even happens at MA Plans that cover both Part B and Part D drugs but whose Part B and Part D sections seem to operate independently of each other without adequate communication that would prevent someone receiving a denial from a plan that is required to cover the drug one way or the other.

### Resolving a Part B vs. Part D Denial

- **Ensure that the provider is correctly submitting the claim.** Medicare Rights has often been successful by sharing CMS' educational material on Part B vs. Part D billing with the provider.<sup>102</sup>
- **Contact the plan** or, ideally, have the pharmacist or prescribing doctor contact the plan, to determine what documentation the plan needs to prove that this is a Part D and not a Part B drug use (e.g., date of the transplant, attestation that insulin is taken by syringe, or letter stating the individual no longer has a nebulizer).
- **Address the plan's reason for considering it a Part B drug.** The plan is not required to assume the drug is for a Part D use, so individuals should proactively prove to the plan why their specific use of the drug is covered by Part D. This is true even when the plan has covered the drug under Part D for several years. If it is unclear what part of Medicare should cover a drug, please reach out to Medicare Rights at 800-333-4114.
- **Submit the request** by having the doctor fill out a Coverage Determination Request form along with the supplemental information (or contact the plan for a plan-specific version of the form).<sup>103</sup> 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>102</sup> CMS, MLN Matters, [Medicare Part B versus Part D Drug Coverage Determinations](#) (SE0652) and [Pharmacy Billing for Drugs Provided "Incident To" a Physician Service](#) (MM7397).

<sup>103</sup> CMS, [Coverage Determinations](#).

- **If needed, expedite.** If the prescribing doctor believes that the individual's health could be seriously harmed by waiting the standard timeline for appeal decisions (plan has 72 hours to make a decision), they can request a fast appeal (plan has 24 hours to make a decision).<sup>104</sup>
- **Document.** Take notes when anyone speaks to the plan (e.g., the plan employee's name, their phone number, the date/time of the call, and what was said). Keep track of when the doctor submits the request and copies of what they submitted.

## Safety Edits

Safety edits are stops put on coverage requests where the patient's safety may be threatened if the prescription is filled. Most commonly, safety edits are found on opioids and serve as a catch to stop Medicare beneficiaries from being provided with dangerous amounts of opioids.<sup>105</sup> They can also, however, serve as a barrier to people who have medical needs for higher levels of opioids. For example, at the pharmacy, an alert should go up if an individual was prescribed an amount over a certain recommended dosage and quantity of opioids.<sup>106</sup> It can also be triggered if an individual is getting opioids from several different prescribers or pharmacies.<sup>107</sup> Some people are excluded from these edits, such as those who are residents of long-term care facilities, being treated for cancer, in hospice or receiving end-of-life palliative care, or have sickle cell disease (if the plan implements this recommendation from CMS).<sup>108</sup>

Safety edits come in two forms. A soft edit means the pharmacist can use a code to override the catch.<sup>109</sup> A hard edit means the plan will have to provide prior authorization or make a coverage determination before the claim goes through.<sup>110</sup> For hard edits, the pharmacist can attest to medical necessity and request an expedited determination.<sup>111</sup> In most cases, this should work. If a hard edit is approved, this approval should be valid for the remainder of the calendar year. Medicare Rights has not heard of any hard edit approvals which were valid beyond the end of the calendar year. Safety edits apply even during a transition refill (transition refills, which are discussed later in this guide, allow individuals to get a temporary supply of a drug that they currently take but is not covered by their plan).<sup>112</sup>

<sup>104</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.10.

<sup>105</sup> Medicare Rights, [Safety edits for opioid prescriptions](#).

<sup>106</sup> CMS, MLN Matters, [A Prescriber's Guide to the New Medicare Part D Opioid Overutilization Policies for 2019](#) (SE18016); [Frequently Asked Questions \(FAQs\) about Formulary-Level Opioid Point-of-Sale \(POS\) Safety Edits](#).

<sup>107</sup> Ibid.

<sup>108</sup> Ibid.

<sup>109</sup> Ibid.

<sup>110</sup> Ibid.

<sup>111</sup> Ibid.

<sup>112</sup> CMS, Medicare Prescription Drug Manual, [Ch. 6](#), § 30.4.8.

## Resolving a Safety Edit

- **Confer with the pharmacist about the cause of the edit and what is needed to override the edit.** Pharmacists are provided with information on the edit when they attempt to send the claim to the Part D plan. If they need more information, the pharmacist can also contact the plan through the plan's pharmacy help desk.
- **If the individual should be excluded from safety edits, have the pharmacist provide documentation to the plan.** When a safety edit is applied to someone who should be excluded from them (e.g., a person on hospice), the pharmacist should be able to use a process at the plan to provide the documentation to confirm this. How exactly to do this depends on the plan, so if the pharmacist does not know, they should contact the plan's pharmacy help desk.
- **Determine whether the pharmacist can override (soft edit) or needs to submit a coverage determination (hard edit).** The full array of edits and how to resolve them is beyond the scope of this article,<sup>113</sup> so if the pharmacist is not aware of how to address the edit, please consider contacting Medicare Rights at 800-333-4114.
- **If it is a hard edit, submit the request** by having the doctor fill out a [Coverage Determination Request](#) form along with the supplemental information (or contact the plan for a plan-specific version of the form).<sup>114</sup> 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.
- **If needed, expedite.** If the prescribing doctor believes that the individual's health could be seriously harmed by waiting the standard timeline for appeal decisions (plan has 72 hours to make a decision), they can request a fast appeal (plan has 24 hours to make a decision).<sup>115</sup>
- **Document.** Take notes when anyone speaks to the plan (e.g., the plan employee's name, their phone number, the date/time of the call, and what was said). Keep track of when the doctor submits the request and copies of what they submitted.

## Compounded Drugs

A compounded drug is a combination medication created by mixing or altering drug ingredients to create a custom medication for a particular patient.<sup>116</sup> Doctors might prescribe compounded drugs when a patient is allergic to a dye or filler in one of their medications or for patients with illnesses that require small amounts of many different medications, such as in a drug cocktail. Part D plans can choose to cover the costs associated with the Part D-drug component of a compounded drug, but will not cover

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<sup>113</sup> Medicare Rights, [Safety edits for opioid prescriptions](#).

<sup>114</sup> CMS, [Coverage Determinations](#).

<sup>115</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.10.

<sup>116</sup> FDA, [Compounding and the FDA: Questions and Answers](#).

compounds made from bulk powders, as these are not considered Part D drugs.<sup>117</sup> Compounded drugs can contain all, some, or no Part D-drug components. Only costs associated with those components that satisfy the definition of a Part D drug are allowable costs under Part D.<sup>118</sup> The “costs associated” includes the labor costs from mixing the drug, which must be included in the dispensing fee; however, they do not include bulk powders or fillers, since these are typically not FDA-approved. While most compounded drug issues can be resolved through the appeals process, there are many complex aspects to Medicare coverage of compounded drugs which are beyond the scope of this guide. So, please consider reaching out to Medicare Rights at 800-333-4114, particularly if there is a compounded drug access or cost issue.

### Resolving a Compound Drug Denial

- **Determine whether the plan chooses to cover compounded drugs.** Not all plans cover compounded drugs, so an individual may want to check their plan materials or contact the plan to determine whether an appeal is viable or whether they should switch plans or medications.
- **Determine which parts of the drug should be covered.** Even if the plan covers portions of the compounded drug, it is likely it will not have to cover all portions. In particular, even drugs that are normally covered are not covered if they are used in their bulk powder form (which is very common in compounding). Medicare Rights has helped some individuals get coverage for their compounded drug by having the pharmacy switch from using bulk powder for its ingredients to using FDA-approved individual dosages (like pills) when compounding the drug. These determinations are difficult, so please consider reaching out to Medicare Rights at 800-333-4114 for help.
- **Submit the request** by having the doctor fill out a Coverage Determination Request form along with the supplemental information (or contact the plan for a plan-specific version of the form).<sup>119</sup> 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.
- **If needed, expedite.** If the prescribing doctor believes that the individual’s health could be seriously harmed by waiting the standard timeline for appeal decisions (plan has 72 hours to make a decision), they can request a fast appeal (plan has 24 hours to make a decision).<sup>120</sup>
- **Document.** Take notes when anyone speaks to the plan (e.g., the plan employee’s name, their phone number, the date/time of the call, and what was said). Keep track of when the doctor submits the request and copies of what they submitted.

<sup>117</sup> [42 CFR § 423.120](#)(d); CMS, Medicare Prescription Drug Manual, [Ch. 6](#), §§ 10.3-10.4.

<sup>118</sup> *Ibid.*

<sup>119</sup> CMS, [Coverage Determinations](#).

<sup>120</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.10.

## 2. Request a Redetermination (Appeal the Initial Decision)

If an individual's exception request is denied, they can begin the appeals process by requesting a redetermination.<sup>121</sup> The plan should send them a Notice of Denial of Medicare Prescription Drug Coverage which indicates that their exception request was denied. Individuals have 60 days from the date listed on this notice to begin the formal appeal process by filing an appeal with their plan.<sup>122</sup> Individuals should follow the directions on the notice to appeal. If a doctor is not appealing on an individual's behalf, they should ask their doctor to write a letter of support addressing the plan's reasons for not covering the needed drug. The plan is required to provide information on why they are denying the result, so it is very important for individuals to address those issues in their appeal request.<sup>123</sup>

The plan should issue a decision within seven days (or 72 hours for a fast appeal). If the appeal is denied, the individual can continue the appeals process by requesting an independent review.

### Submitting a Late Appeal

Medicare Rights encourages individuals to make every effort to submit their appeals on time, even if they are submitting an appeal without all the evidence they would want to provide. However, we do hear from callers who have already missed the deadline. Such individuals can request an exception to a deadline at any level of appeal by explaining that they had good cause for not filing on time.<sup>124</sup> Extension requests are considered on a case-by-case basis, so there is no complete list of acceptable reasons for filing a late appeal. Some examples include:<sup>125</sup>

- An appeal notice was mailed to the wrong address. (In most cases, though, this request will be rejected if the individual did not update their address in a timely fashion.)
- A Medicare or plan representative gave the individual incorrect information about the claim they are appealing.
- Illness—either the individual's or a close family member's—prevented the individual from handling business matters.
- The individual filing the appeal is illiterate, does not speak English, or has a disability that prevented them from reading or understanding the coverage notice.

<sup>121</sup> Ibid. at § 50 *et seq.*

<sup>122</sup> CMS, [Plan Sponsor Notices and Other Documents](#), Notice of Denial of Medicare Part D Prescription Drug Coverage (CMS-10146); [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 40.12.3.

<sup>123</sup> E.g., "If the plan issues an adverse decision due to the inability to obtain clinical information needed to approve coverage, the plan should clearly identify that basis and the necessary information in the written denial notice." [42 CFR § 423.568\(f\)-\(g\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 10.6.

<sup>124</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 50.3.

<sup>125</sup> Ibid.; Medicare Rights, [Helping Clients with Part D Appeals – Frequently Asked Questions](#).

If an individual thinks they have a good reason for not appealing on time, they should send in their appeal as they normally would and include a clear explanation of why their appeal is late. If the reason has to do with illness or other medical conditions, a letter or supporting documentation from the beneficiary's health care provider can be helpful. For example, Medicare Rights has occasionally gotten appeal deadline extensions for individuals recently diagnosed with dementia by providing a doctor's letter about the illness and a letter from a family member explaining the practical issues created by the illness.

In addition, plans are also required to grant late appeals when the individual has requested appeal-related information in an alternative format and the plan has delayed in providing it.<sup>126</sup> Lastly, if an individual has missed their appeal deadline, they may consider starting over with a new prescription and, if needed, an exception request.

### 3. Request an Independent Review

If the appeal is unfavorable, an individual can ask an Independent Review Entity (IRE) to make a decision on their request.<sup>127</sup> The deadline to request this appeal is 60 days from the date of the redetermination notice. The IRE should issue a decision within seven days (or 72 hours for a fast appeal). You can call the IRE to check on your appeal or to ask for an address or fax number to which to send more information. For several years, the IRE has been MAXIMUS Federal Services, which provides their contact information and an appeal status lookup tool on their website.<sup>128</sup> On February 1, 2021, C2C Solutions became the IRE.<sup>129</sup>

#### **Advocacy Tip: Address the Reasons for the Denial**

When requesting review by the IRE, an individual already has a written explanation from the plan about why they will not pay for the prescription.<sup>130</sup> Since this is what the IRE will be looking at (along with both Medicare's and the plan's coverage rules) it is important to address the reasons for the denial when appealing. That is, when making an appeal at the IRE stage (and all the levels thereafter) individuals should explain why the plan's reason for denying the drug is wrong and, if possible, provide documentation in support.

<sup>126</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 10.4.4.

<sup>127</sup> *Ibid.* at § 60 *et seq.*

<sup>128</sup> [MedicarePartDAppeals.com](https://www.medicarepartdappeals.com).

<sup>129</sup> C2C Solutions, [QIC Part D](#).

<sup>130</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 50.10.2.



## 4. Request Review by the Office of Medicare Hearings and Appeals

If an individual's IRE appeal is unfavorable and their drug is worth a certain amount, they can choose to appeal to the Office of Medicare Hearings and Appeals (OMHA) level.<sup>131</sup> The OMHA appeal request must be filed within 60 days of the date on the IRE decision letter.<sup>132</sup> Individuals should send a [Request for Administrative Law Judge \(ALJ\) Hearing or Review of Dismissal](#) form to the IRE following the instructions on their denial, but they can also send the request directly to OMHA.<sup>133</sup> With the form, the individual should also send any additional evidence they have that supports their case, including any written testimony they would like to provide (keeping in mind that individuals can provide testimony from themselves and witnesses at the phone hearing set up by OMHA).<sup>134</sup> If an individual wants to submit additional evidence but does not have it ready when they want to file for their hearing, Medicare Rights suggests requesting the hearing and then, when a specific OMHA office is assigned to their case, submitting the evidence directly there.<sup>135</sup> One thing to keep in mind is that any evidence being submitted should also be forwarded to the plan and the IRE.

Not every IRE denial can be appealed to the OMHA level: the denial must meet an amount in controversy (\$180 in 2021).<sup>136</sup> The amount in controversy for a particular case is calculated by projecting the value of the drug coverage to the individual based on the number of prescribed refills for the calendar year.<sup>137</sup> While the full details of the OMHA level hearing is beyond the scope of this guide, Medicare Rights encourages individuals to reach out to its helpline at 800-333-4114.<sup>138</sup> Individuals can also use the OMHA Beneficiary Help Line 844-419-3358 to get their OMHA-level appeal questions answered.<sup>139</sup> The appeal should be decided within 90 days of the request (or 10 days for fast appeals).<sup>140</sup> Individuals can check the status of their appeal online.<sup>141</sup>

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<sup>131</sup> Ibid. at 70 *et seq.*

<sup>132</sup> CMS, [Decision by the Office of Medicare Hearings and Appeals \(OMHA\)](#).

<sup>133</sup> HHS, [Request for Administrative Law Judge \(ALJ\) Hearing or Review of Dismissal](#) (OMHA-100).

<sup>134</sup> A small number of OMHA-level hearing decisions are publicly posted and can be helpful to review in order to understand what the hearing and decision process looks like. HHS, [DAB Administrative Law Judge \(ALJ\) Decisions](#).

<sup>135</sup> The rules around submitting evidence are stricter for individuals who have representation, although they are not always enforced. See, e.g., [42 CFR § 405.1018](#).

<sup>136</sup> CMS, [Decision by the Office of Medicare Hearings and Appeals \(OMHA\)](#).

<sup>137</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 70.2.

<sup>138</sup> See also, [42 CFR §§ 405.1000-1058](#); HHS, [OMHA Case Processing Manual \(OCPM\)](#); Medicare Rights, [Appealing to the Office of Medicare Hearings and Appeals \(OMHA\)](#).

<sup>139</sup> HHS, [Medicare Beneficiary and Medicare Advantage Part C Plan Enrollee or Part D Plan Enrollee Appeals and Assistance](#).

<sup>140</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 70.4.1.

<sup>141</sup> HHS, [Appeals Status Lookup](#).

## Requesting the Case File

During the appeals process, individuals can request a copy of their case file. Due to the quick decision timelines for the first two levels of appeal, many individuals do not request their case file until the OMHA level; however, they do have the right to request the case file during the redetermination and IRE levels of appeal.<sup>142</sup> The case file should include any information the plan used to make a decision (e.g., plan policies and medical records).<sup>143</sup> While plans are allowed to charge “a reasonable amount for copying and mailing the case file,” Medicare Rights does not normally see plans charging for the case file.<sup>144</sup>

## Advocacy Tip: Do Not be Intimidated

Medicare Rights hears from many callers who really need coverage for their medication but are afraid to file an OMHA appeal or think it is not worth their time. Yet, most individuals win their OMHA appeals and the process is specifically set up to help Medicare beneficiaries without legal counsel navigate the hearings themselves. Therefore, Medicare Rights often encourages individuals to pursue their appeal to this level. Unless their appeal is totally without merit, it is often worth filing an appeal with OMHA even if the beneficiary does not have a legal advocate assisting them.

## 5. Request Review by the Medicare Appeals Council

If the individual’s OMHA appeal is unfavorable, they have the right to continue appealing to the Medicare Appeals Council (Council).<sup>145</sup> The appeal to the Council<sup>146</sup> must be sent within 60 days of the date on the beneficiary’s OMHA-level decision letter and can be submitted online.<sup>147</sup> The individual’s appeal must reference the parts of the OMHA decision with which the beneficiary disagrees and explain why they disagree. Many of the advantages that beneficiaries have at the OMHA level (e.g., being able to provide testimony and share their story, an OMHA who may actively ask them questions to bolster their case, or a clear right to introduce new evidence) are no longer available.<sup>148</sup> This is because Council review is not a hearing; instead, the Council is

<sup>142</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 50.5.2.

<sup>143</sup> *Ibid.* at §§ 50.5.2, 50.12.3, and 50.12.4.

<sup>144</sup> *Ibid.* at § 50.5.2.

<sup>145</sup> [42 CFR §§ 405.1100-1140](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 70 *et seq.*

<sup>146</sup> Department of Health and Human Services (HHS), [Request for Review of Administrative Law Judge \(ALJ\) Medicare Decision/Dismissal \(DAB-101\)](#).

<sup>147</sup> CMS, [Review by the Medicare Appeals Council](#).

<sup>148</sup> A small number of Council-level hearing decisions are publicly posted and can be helpful to review in order to understand what the hearing and decision process looks like. HHS, [Medicare Appeals Council \(Council\) Decisions](#).

reviewing what is already on the record. Individuals or, more likely, their legal advocates can submit briefs to supplement the record. The Council should issue a decision within 90 days of the request (10 days for fast appeals).<sup>149</sup>

## 6. Seeking Relief in Federal District Court

If an individual's Council appeal is unfavorable and their drug is worth at least \$1,760 in 2021, they can appeal to a Federal District Court within 60 days of the date on their Council decision letter.<sup>150</sup> There is no timeframe for the Federal District Court to issue a decision about the appeal.

At this point, the appeals process is no longer something designed for Medicare beneficiaries to navigate on their own; instead, it is designed for individuals with legal representation. In most cases, paying for legal representation would cost more than would be saved by successfully getting the medication covered. In addition, Medicare Rights is not aware of many providers of free legal services who regularly bring Part D appeals cases to federal court. When such attorneys do, they are often trying to bring about a larger systemic change rather than only assisting an individual beneficiary in accessing their medication. Therefore, for most people, it is not realistic to bring their appeal to court.

## After the Appeal

### Reopening and Revising a Decision

While it is very rare, a decision at any level of the appeals process can be reopened and revised by the appeal entity who made the decision once the appeals process has been exhausted.<sup>151</sup> A reopening is different from an appeal: it is a distinct process used to catch clerical mistakes and obvious errors.<sup>152</sup> The reopening can either occur based on the appeals entity deciding to do it or based on a request from one of the parties to the appeal, such as the individual who initiated it.<sup>153</sup> For Part D plan decisions, an individual normally has to request a reopening within one year of the original decision,<sup>154</sup> though this deadline can be extended to four years if the individual can show good cause.<sup>155</sup> The deadline for individuals to request a reopening from other appeals entities (i.e., IRE, OMHA, Council) is 180 days from the decision and only if they have good cause.<sup>156</sup> It is a high bar to successfully request a reopening and revision by showing good cause. The individual requesting it must show a clerical error,<sup>157</sup> that "there is new and material

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<sup>149</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 70.4.1.

<sup>150</sup> *Ibid.* at § 70 *et seq*; CMS, [Review by a Federal District Court](#).

<sup>151</sup> [42 CFR § 423.1978\(a\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 80.1.

<sup>152</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 80.2.

<sup>153</sup> [42 CFR § 423.1980\(b\)-\(c\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 80.1.

<sup>154</sup> [42 CFR § 423.1980\(c\)](#).

<sup>155</sup> [42 CFR 423.1986\(a\)](#).

<sup>156</sup> [42 CFR § 423.1980\(e\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 80.3.1.

<sup>157</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 80.4.

evidence that was not available or known at the time of the determination or decision and may result in a different conclusion,”<sup>158</sup> or that “the decision was clearly incorrect based on all evidence presented in the case file.”<sup>159</sup> If a revision is made, this revision is not appealable,<sup>160</sup> and if the decision is not reopened, then this refusal to reopen is not appealable.<sup>161</sup>

In Medicare Rights’ experience, it is rare to find an example where an individual would meet the criteria for a reopening and revision and would benefit from one. The most common scenario Medicare Rights does see is where a plan (or other appeal entity) erroneously dismissed an appeal for being filed late. Assuming the individual has proof that they submitted an appeal on time, they should be able to have the decision reopened and revised. And, since they cannot continue with their appeal as it was dismissed (rather than denied), a reopening may be their only way to continue their fight for coverage.<sup>162</sup>

## Effectuating the Decision

Once an appeal is won, the plan has to effectuate the decision (i.e., cover the medication) as expeditiously as the individual’s health requires.<sup>163</sup> CMS has provided a generic deadline of within 72 hours of the decision (or 24 hours for fast appeals).<sup>164</sup> In the unlikely event a plan does not comply with a decision, individuals can file a grievance with the plan or a complaint online, with 1-800-MEDICARE, or with their CMS Regional Office.<sup>165</sup> Reimbursements usually take several weeks or even a few months to be sent to individuals.

## 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. Most commonly, this happens when an individual moves to a new Part D plan, but it could also happen when an individual’s Part D plan changes its formulary by taking the individual’s medication off of the formulary or imposing new restrictions on the medication’s coverage. Often, Medicare Rights hears from callers in this situation at the beginning of each year (this is because during Fall Open Enrollment, from October 15 to December 7 every year, Medicare beneficiaries can switch their Part D plan and have

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<sup>158</sup> Ibid. at § 80.5.1.

<sup>159</sup> Ibid. at § 80.5.

<sup>160</sup> [42 CFR § 423.1978\(c\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 80.1.

<sup>161</sup> [42 CFR § 423.1978\(d\)](#); CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 80.1.

<sup>162</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 10.1.

<sup>163</sup> CMS, [Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance](#), § 90.

<sup>164</sup> Ibid. at § 90.1.

<sup>165</sup> Ibid. at § 30.1; CMS, [Filing complaints about your health or drug plan](#); CMS, [CMS Regional Offices](#).

the new one become effective on January 1).<sup>166</sup> Unfortunately, many people may enroll in a new plan based solely on premium cost or other factors and overlook that the new plans' formulary does not cover the medication they need or only covers it with restrictions. There is a short-term fix for this problem: transition refills (also called transition fills).<sup>167</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>168</sup> Beneficiaries who are in a long-term care facility, such as a nursing home, will be provided with all available refills during their first 90 days in the plan (receiving refills for a 91- to 98-day supply), instead of a one-time fill.<sup>169</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>170</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>171</sup> Thus, transition refills can only be requested within the first 90 days of coverage under a new plan.<sup>172</sup> Keep in mind, though, that the cost sharing for transition refills (for off-formulary drugs) will often be higher,<sup>173</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>174</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>175</sup> Plans should also make a reasonable effort to contact the individual's prescribing doctor.<sup>176</sup>

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<sup>166</sup> Medicare Rights, [Six things to know about Fall Open Enrollment](#).

<sup>167</sup> [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](#).

<sup>168</sup> 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."

<sup>169</sup> CMS, Medicare Prescription Drug Manual, [Ch. 6](#), §30.4.4.2. For more information on access to medication rights in nursing homes, see also Medicare Rights, [Part D coverage in nursing homes](#).

<sup>170</sup> 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.

<sup>171</sup> CMS, Medicare Prescription Drug Manual, [Ch. 6](#), § 30.4.

<sup>172</sup> *Ibid.* at § 30.4.4.

<sup>173</sup> *Ibid.* at § 30.4.9.

<sup>174</sup> *Ibid.* 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.

<sup>175</sup> CMS, Medicare Prescription Drug Manual, [Ch. 6](#), §§ 30.4.2 and 30.4.10.

<sup>176</sup> *Ibid.* at §30.4.10.1.

## 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>177</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>178</sup>

Individuals enrolled in a MA 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>179</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>180</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>181</sup>

At Medicare Rights, many of its callers are able to switch into a plan that better covers their medications using two programs that provide both an SEP and financial assistance with drug costs: EPIC and Extra Help.

**EPIC** (Elderly Pharmaceutical Insurance Coverage) is the New York State Pharmaceutical Assistance Program (SPAP) that helps older adults with Medicare pay for prescription drug costs.<sup>182</sup> EPIC is available to New York residents who:<sup>183</sup>

- Are 65 years or older;
- Have annual incomes below \$75,000 if single or \$100,000 if married;
- Do not receive full Medicaid benefits; and
- Are enrolled, or eligible to be enrolled, in a Part D plan.

For those who are eligible and enrolled, EPIC can help lower Part D-related costs but generally only for drugs that are on the individual's Part D formulary. However, EPIC

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<sup>177</sup> Medicare Rights, [Six things to know about Fall Open Enrollment](#).

<sup>178</sup> Medicare.gov, [Find a Medicare plan](#).

<sup>179</sup> Medicare Rights, [How to switch Medicare Advantage Plans or switch from Medicare Advantage to Original Medicare](#).

<sup>180</sup> Medicare Rights, [Special Enrollment Periods for Medicare Advantage Plans and Medicare Part D Drug Plans](#).

<sup>181</sup> CMS, Medicare Managed Care Manual, [Ch. 2](#); Medicare Prescription Drug Manual, [Ch. 3](#).

<sup>182</sup> New York State Department of Health, [Elderly Pharmaceutical Insurance Coverage \(EPIC\) Program](#); Medicare Rights, [EPIC program overview](#).

<sup>183</sup> Ibid.



does provide coverage for a small list of drugs that Part D does not cover (namely prescription vitamins and minerals).<sup>184</sup> Unfortunately, other than this small list of Part D-excluded drugs, EPIC will not usually cover drugs that are off the formulary of an individual's Part D plan.<sup>185</sup> In addition, EPIC will also provide an SEP (that can be used once a year) for anyone enrolled in the program. Many other states also have programs that are similar to EPIC.<sup>186</sup>

**Extra Help** (also called the Low-Income Subsidy or LIS) is a federal program that helps pay for some of the out-of-pocket costs of Medicare prescription drug coverage.<sup>187</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 an SEP for anyone who has Extra Help.<sup>188</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>189</sup> The coverage change is effective the first of the month after an individual applies for the new drug plan.<sup>190</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>191</sup> Medicine Assistance Tool,<sup>192</sup> and Rx Assist<sup>193</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.

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<sup>184</sup> And also including certain benzodiazepines, barbiturates, drugs for anorexia, weight loss or gain, drugs for cosmetic purposes, and drugs to relieve cough and cold symptoms. See New York State Department of Health, [EPIC Drug Coverage](#); [Provider Bulletin 08-02](#); [Provider Bulletin 10-02](#); Medicare Rights, [EPIC program overview](#).

<sup>185</sup> New York State Department of Health, [EPIC Drug Coverage](#).

<sup>186</sup> Medicare Rights, [State Pharmaceutical Assistance Programs](#).

<sup>187</sup> 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.*

<sup>188</sup> [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.

<sup>189</sup> *Ibid.*

<sup>190</sup> *Ibid.*

<sup>191</sup> [NeedyMeds.org](#).

<sup>192</sup> [MedicineAssistanceTool.org](#).

<sup>193</sup> [RxAssist.org](#).

- 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>194</sup>
- Some manufacturers of drugs offer patient assistance programs for the uninsured.<sup>195</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.

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<sup>194</sup> [GoodRx.com](https://www.goodrx.com).

<sup>195</sup> 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."