The Medicare Appeals Process:

Reforms Needed to Ensure Beneficiary Access

November 17, 2020

EXECUTIVE SUMMARY

Medicare provides health coverage for more than 61 million Americans.[1] Given that the incidence of cancer increases with age, the Medicare program is vitally important to millions of Americans who are undergoing active cancer treatment, are cancer survivors or who have not yet developed cancer. Yet, without Congressional action in the next few years, the Medicare Trust Fund, will become insolvent.[2] Considering the forthcoming pressure to shore up this essential health program, Congress is apt to consider policies that would shift costs more to enrollees and/or tighten program benefits. To the extent that Congressional action results in the use of more utilization management tools the result would likely mean beneficiaries would more often have to use the appeals process in order to access medically necessary products and services.

Public and private payers increasingly employ a variety of measures to minimize their liability for paying for high-cost services, such as cancer therapies.[3] As a result, cancer patients increasingly have to go through appeals or exceptions processes in order to access medically necessary drugs or services – either because their prescribed product or service is subject to utilization management tools or because their insurer may choose not to cover a particular therapy or service as part of its benefit design. Without coverage for a needed service or treatment, cancer patients face having to pay the full cost out of pocket or making the difficult decision to forego care that could save their lives.

To better understand how the Medicare program's appeals process works for beneficiaries who have a history of cancer, this paper analyzes the existing appeals processes used by the Medicare program by walking through the Medicare Part A and B appeals process (including a discussion of an expedited process) using hypothetical patient profiles as illustrations. The paper then details the process used by Medicare private plans – Part C and D plans – to control costs and the process a beneficiary would undergo to obtain access to a Part C or Part D covered benefit. The paper concludes with

[1] According to the 2020 Medicare Trustees' Report, in 2019 Medicare covered 61.2 million people: 52.6 million aged 65 and older and 8.7 million persons with disabilities. 2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds. Apr. 22, 2020. Available at https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.

[2] According to the Congressional Budget Office (CBO), absent intervening Congressional action the Medicare Hospital Insurance Trust Fund (which funds Medicare Part A) will become insolvent in fiscal year 2024, two years earlier than CBO predicted in March 2020 (prior to the pandemic). Congressional Budget Office. The Outlook for Major Federal Trust Funds: 2020 to 2030. Sept. 2020. Available at https://www.cbo.gov/system/files/2020-09/56523-Trust-Funds.pdf.

[3] American Society of Clinical Oncology Statement on the Impact of Utilization Management Policies for Cancer Drug Therapies. DOI: 10.1200/JOP.2017.024273 *Journal of Oncology Practice* 13, no. 11 (Nov. 1, 2017) 758-762.

recommendations for specific policies that would improve Medicare appeals and exceptions processes for both patients and the providers who treat them.

KEY FINDINGS

The Medicare Appeals Process is Overly Complex: The Medicare appeals processes are confusing and can be cumbersome and time-consuming. There are many rules and requirements regarding what can be appealed, what is needed to file an appeal, the timeframes by which an enrollee has the opportunity to file an appeal, and timeframes under which a decision is made. Beneficiaries can be at a disadvantage if they are unfamiliar with the system.

Cumulative timeframes may create barriers to care: From a beneficiary's perspective, the number of levels of review can be daunting and can deter a beneficiary from filing an appeal. In addition, multiple levels of appeal delay a beneficiary's access to medically appropriate products or services. Even though the appeals process allows for expedited consideration, each level of review has various timeframes by which the reviewing entity must act. Adding up all of those timeframes can result in a beneficiary – even one experiencing, by definition, exigent circumstances for which expedited review is warranted – who is unable to access the product or service that is on appeal for several days or weeks (depending on how many levels of review are undergone). On the provider side, providers report delays in being able to provide cancer care because of having to wait for approval from Medicare plans (Medicare Advantage (MA) or Part D plans) to override utilization management tools.

Evidence suggests that plans' initial denials are often overturned: In 2019, the Health and Human Services (HHS) Office of the Inspector General released a report on the Part D appeals process and found that enrollees and providers appealed very few preauthorization and payment denials, but among those that were appealed, Medicare Advantage (MA) plans overturned 75 percent of their own denials.[4] This data suggests that MA plans' default is to deny claims, regardless of the medical necessity involved.

Lack of information on the utilization of the appeals process hinders progress: Medicare does not routinely publish information about the utilization of the appeals process – including information sorted by program and level of appeal. Without that information, it can be challenging to ascertain what specific improvements are needed.

Many beneficiaries do not exercise their appeals rights: Unfortunately, it is not known how many beneficiaries do not exercise their appeals rights, either because they were not informed of their right to appeal or because they were daunted by the process. Beneficiaries might choose to pay out of pocket for services that should be covered by Medicare or choose to forgo care altogether instead of appealing, which could have negative implications for their overall health and wellbeing.

[4] U.S. Department of Health and Human Services-Office of Inspector General. Some Medicare. Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs. Revised September 2019. Accessed April 2020. https://oig.hhs.gov/oei/reports/oei-09-16-00411.pdf.

POLICY RECOMMENDATIONS SUMMARY

The Medicare appeals process is confusing and can be cumbersome and time-consuming, particularly for someone who is also battling a serious illness. Over the years Medicare has made improvements to the appeals process. However, there is more that can be done to improve the process for beneficiaries. Below are some recommendations for ways to improve the process from the beneficiary's perspective:

- Streamline the appeals process
- Simplify appeals terminology
- Implement more direct oversight of the appeals process
- Improve funding for the appeals process
- Provide more data on the appeals process
- Recommendations specific to Part D:
    - Improve appeals information provided at the point of sale
    - Improve the tiering exceptions process
    - Implement 2019 HHS Office of Inspector General recommendations
- Review the flexibilities provided to plans in light of the COVID-19 pandemic

BACKGROUND

The Medicare program consists of several parts – each with its own rules and regulations concerning the appeals and exceptions process.

Table 1: Summary of the Parts of Medicare

Part	What's Covered
Part A	Medicare Part A pays for inpatient hospital services, some skilled nursing facility stays, home health visits, and hospice care.
Part B	Medicare Part B covers physician services (like doctors' visits) and outpatient services (such as care provided in hospital emergency room departments, ambulatory surgical centers, durable medical equipment, clinical laboratory services, physical therapy, and some home-health visits).
Part C	Medicare Part C is administered through private plans (Medicare Advantage plans) that contract with Medicare to provide the same benefits that are administered under Medicare Part A and Part B. Approximately 37 percent of Medicare beneficiaries choose to enroll in these private plans.[5]
Part D	Medicare Part D covers outpatient prescription drugs. It is administered entirely through private plans that contract with Medicare. Approximately 47.2 million beneficiaries are enrolled in Part D plans,[6] other beneficiaries may have another source of coverage such as a retiree benefit.

Each part of the Medicare program maintains separate rules and regulations regarding how beneficiaries can file appeals in order to access medically necessary care. While there are some similarities between the various rules and regulations, there are also significant differences.

[5] 2020 Trustees Report.
[6] Id. at 16.

Beneficiaries are often unfamiliar with the rules regarding whether and how to file an appeal, and the process can seem daunting. Furthermore, beneficiaries utilizing the appeals process likely do so during times of extreme stress. Beneficiaries seeking a pre-service coverage decision may feel anxiety regarding the service and/or diagnosis they have received, and the outcome of the appeal could impact whether or not they receive medically necessary care, which is also stressful. Similarly, beneficiaries appealing a post-service claim denial may be under financial strain due to additional cost-sharing.

It is also worth noting that the appeals process favors beneficiaries who have a support structure to enable them to utilize the appeals process. Most beneficiaries do not file appeals solely on their own, and often rely on their providers or friends and family members to facilitate the process. Beneficiaries are often confused by the process,[7] particularly those who have language access issues, limited means, or additional stresses (such as family issues, significant changes in income, etc.) face additional challenges in accessing the appeals process and unfortunately many choose to forego care as a result.

MEDICARE PART A and B (TRADITIONAL MEDICARE) RULES AND REGULATIONS

Medicare Administrative Contractors (MACs) administer Part A and B claims.[8] Currently there are twelve MACs[9] across the country who process claims for nearly 68 percent of the total Medicare population.[10] The following provides an overview of the process a beneficiary[11] must go through in order to file an appeal for a service[12] provided under Part A or Part B.[13]

When a claim is filed with Medicare, contractors make the initial determination regarding whether the service is covered under Part A or Part B; whether the beneficiary's deductible is met;[14] the amount of

[7] Department of Health and Human Service Office of Inspector General. Medicare Advantage appeal outcomes and audit findings raise concerns about service and payment denials. Sept. 2018 OEI-09-16-00410. Available at https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf.

[8] Separate DME MACs also administer claims related to durable medical equipment (DME), which is not discussed in this white paper.

[9] A list of MACs is available at https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-Jurisdiction-Map-Jun-2019.pdf.

[10] Centers for Medicare & Medicaid Services. What is a MAC. Available at https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC.

[11] This paper will use the term "beneficiary" to describe individuals enrolled in traditional Medicare (Parts A and B).

[12] In most cases in traditional Medicare beneficiaries are unable to obtain a pre-service coverage decision. In these cases, a beneficiary's best source for whether a particular service is covered under traditional Medicare is via their physician or Medicare educational materials such as the Medicare & You handbook that is published by CMS on an annual basis. The Medicare & You handbook provides beneficiaries with a summary of their benefits, rights, and protections. The Medicare & You 2021 edition is available at https://www.medicare.gov/Pubs/pdf/10050-Medicare-and-You.pdf.

[13] Note that Medicare rules regarding appeal rights for Part B covered drugs are addressed in the section related to Part D drugs.

[14] In 2021 the standard Part A deductible is $1,484 for each benefit period.

the beneficiary's co-insurance;[15] and whether the service is medically necessary.[16] For most services provided under Part A or B, a beneficiary is not able to obtain a pre-service coverage determination. Typically, a claim is filed after a service is performed.

In the event the contractor denies the claim, the beneficiary may file an appeal. In some cases, the beneficiary may have assigned their appeal rights to a provider or supplier in which case the provider files the appeal.[17] However, providers can only represent a beneficiary in an appeal if the provider waives any rights for payment from the beneficiary involving the services at issue. This policy is designed to protect the beneficiary, as the beneficiary could otherwise be exposed to significant cost-sharing as a result of the appeal.[18]

Timeframes for Filing Appeals

Beneficiaries have a limited time in which to file a Medicare appeal (see Table 2). Under the Center for Medicare and Medicaid Services (CMS) rules, a request is considered to have been filed as of the date it is received by the MAC. MACs will also allow an extra 5 days beyond the time limit for requesting a redetermination (appeal) in order to account for mail delivery.[19]

Extensions: CMS regulations allow for these timeframes to be extended if there is good cause shown for late filing. Generally, this bar is high for providers and suppliers, but more lenient for beneficiaries. Beneficiaries can demonstrate good cause in a number of ways, including: circumstances beyond the beneficiary's control (such as physical or mental impairments); damage to or destruction of the beneficiary's medical records; or a beneficiary's serious illness or the serious illness or death in the beneficiary's immediate family.[20]

Levels of Review

There are five levels of review for Part A and Part B services, and beneficiaries must file appeals within certain statutory timeframes.

[15] For information on co-insurance related to Part A services, see https://www.medicare.gov/your-medicare-costs/medicare-costs-at-a-glance.

[16] Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 29 – Appeals of Claims Decisions. Section 200(B). Revised Aug. 30, 2019. Available at https://w ww.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c29.pdf. [hereinafter "Medicare Claims Processing Manual Ch. 29."]

[17] The Medicare program has extensive rules and regulations regarding who can act as a beneficiary's representative for purposes of filing an appeal. This paper is intended to provide an overview of the appeals process and a discussion of such is outside the scope of this paper.

[18] Medicare Claims Processing Manual Ch. 29, section 210.

[19] Medicare Claims Processing Manual Ch. 29, section 220.

[20] Medicare Claims Processing Manual Ch. 29, section 240.

Table 2: Levels of Review for Items and Services Covered by Medicare Part A and B (standard review)

Appeal Level	Time to File	Decision Made	Add'l requirements
Redetermination	Must be made within 120 days[21] after the date of receipt of the Medicare Summary Notice.	MACs must complete and mail a redetermination notice within 60 days of receipt of the request. MACs get an additional 14-day extension if parties provide additional evidence after filing a redetermination request.	There are no monetary threshold requirements.
Reconsideration	Must be made within 180 days after the date of receipt of the redetermination notice.[22]	Qualified Independent Contractors (QICs) must process reconsiderations within 60 days.	There are no monetary threshold requirements.
Office of Medicare Hearings and Appeals (OMHA)	Must be made within 60 days of receipt of the reconsideration.	A decision is supposed to be made within 90 days.[23]	$170*[24]
Departmental Appeals Board (DAB) Review/Appeals Council	Must be made within 60 days from the date of the OMHA hearing decision.	A decision must be made within 90 days if appealing an OMHA decision or dismissal. A decision will be rendered within 180 days if the OMHA review expired without a decision.	There are no monetary threshold requirements.
Federal Court Review	Must be made within 60 days of the date of the Appeals Council decision.	There is no timeline by which a decision must be made	$1,670*

* Amount in controversy threshold amounts (monetary threshold amounts) are updated each year. The amount shown in this table reflect the threshold amount for 2020.

[21] Unless otherwise noted, references to "day" or "days" means calendar days.
[22] However, if the issue is the contractor's dismissal of the request for redetermination, the time limit is 60 days from the date of receipt of the contractor's dismissal notice.
[23] However, CMS acknowledges this timeframe often slips given the volume of cases. Centers for Medicare & Medicaid Services. MLN Booklet. Medicare Parts A & B Appeals Process. ICN MLN006568. Jan. 2020. Available at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/medicareappealsprocess.pdf.
[24] Centers for Medicare & Medicaid Services. Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2020. 84 Fed. Reg. 53445.

Redetermination

If a beneficiary or provider is dissatisfied with the MAC's initial determination regarding whether an item or service is covered under Part A or Part B, they can file a redetermination, which is the first level of review.[25] Essentially, it is a second look at the claim and is conducted by a person within the MAC who was not party to the initial determination.[26] Redetermination requests must be filed in writing.[27]

MACs are required to limit their determinations reviews to the reason(s) the claim was initially denied and are not permitted to render a decision beyond those stated reasons.[28] Beneficiaries or providers seeking a redetermination may submit written evidence and arguments relating to the claim that is the issue of the redetermination. Medicare requires that MACs must accept and consider any relevant documentation submitted.[29] In cases where the beneficiary initiates the redetermination, but does not supply the necessary documentation, the MAC advises the provider to supply the information within 14 calendar days. If documentation is not provided within that timeframe, the redetermination will be made based on the information provided in the file.[30]

MACs are required to transmit a redetermination decision within 60 days of receipt of the beneficiary's request.[31] MACs must effectuate – adjust the claim and issue payment or change liability for payment – within 30 days after the date of the redetermination decision.

Reconsideration

If a beneficiary or provider is not satisfied with the redetermination, they may file a reconsideration, which is conducted by the Quality Independent Contractor (QIC) that has the appropriate jurisdiction.[32] Once a request for reconsideration has been made, the QIC requests the case file from the MAC and the MAC must provide the case file within 7 calendar days of the QIC's request.[33] The QIC has 60 days to make a determination. If the QIC agrees with the provider or beneficiary filing the appeal, the MAC has 30 days in which to effectuate (e.g., adjust the claim or issue payment or change

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[25] Medicare Claims Processing Manual Ch. 29, section 310.

[26] However, if an initial determination was never made by the MAC then there are no appeal rights and the issue cannot be subject to a redetermination (or any other appeal). For example, a determination of whether the beneficiary's appeal meets the qualifications for expedited review is not something that can be appealed. Medicare Claims Processing Manual Ch. 29, section 200.C. However, a beneficiary may request their claim be re-opened. For example, if a beneficiary's claim was dismissed because the MAC determined the claim was filed late, the beneficiary can't appeal the MAC's determination, but the beneficiary can ask the MAC to re-open the claim and show proof that the claim was submitted in a timely manner.

[27] Beneficiaries may request a redetermination by submitting a copy of their Medicare Summary Notice (MSN), by filing a completed form CMS-20027, or by filing a letter. Medicare Claims Processing Manual Ch. 29, section 310.1.

[28] Medicare Claims Processing Manual Ch. 29, section 310.4.C.

[29] Medicare Claims Processing Manual Ch. 29, section 310.4.C.6.

[30] Medicare Claims Processing Manual Ch. 29, section 310.4.D.3.

[31] Medicare Claims Processing Manual Ch. 29, section 310.4.

[32] Medicare Claims Processing Manual Ch. 29, section 310.6.B. Medicare maintains different QIC jurisdictions for Part A (see Medicare Claims Processing Manual Ch. 29, section 320.7.A) and Part B (see Medicare Claims Processing Manual Ch. 29, section 320.7.B).

[33] Medicare Claims Processing Manual Ch. 29, section 320.6.

liability) the claim.[34] This is the last level of review available if the amount in controversy does not meet a given monetary threshold.

Office of Medicare Hearings and Appeals (OMHA) Level of Appeal

A party to the reconsideration (beneficiary or provider) may request a hearing before an Administrative Law Judge (ALJ) if the party files a written request within 60 days of notice of the QIC's reconsideration and the amount in controversy exceeds a certain threshold (which is updated every year to account for inflation – and is $170 in 2020).[35] However, if the appeal is still pending before the QIC at the end of the QIC's decision-making timeframe, a party may decide not to wait for a decision by the QIC and may instead proceed to the next level of review – the OMHA – if the party first files a written request to the QIC and no final decision is made within 5 days of receiving the request for escalation.[36] QIC's final reconsideration notices will identify the appropriate OMHA in which to file a request.[37] The OMHA is supposed to make a determination within 90 days, but CMS recognizes this timeframe is often not met due to caseload issues.[38]

Departmental Appeals Board – Appeals Council

The fourth level of review, and the last level of review before judicial review, is the Appeals Council review. A party may request an Appeals Council review provided that they file the request within 60 days after receipt of the OMHA's determination.[39] The Appeals Council has 90 days to make a determination. CMS may refer a case to the Appeals Council review (so-called "agency referral").[40]

Federal judicial court review

The fifth level of review is referral to a federal district court. A party may request judicial review of the Appeals Council's determination provided that a complaint is filed with the appropriate court within 60 days of the Appeals Council's determination and the amount in controversy is met ($1,670 in 2020).[41] The entity filing the appeal is responsible for determining the appropriate court to file the complaint. As with other judicial proceedings, there is no timeframe by which the court must render its decision.

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[34] Medicare Claims Processing Manual Ch. 29, section 320.9.
[35] Medicare Claims Processing Manual Ch. 29, section 330.
[36] Id.
[37] Medicare Claims Processing Manual Ch. 29, section 330.1.A.
[38] Medicare publishes the average processing time for OMHA processing by fiscal year which shows a steady increase in processing times. Department of Health and Human Services. Average Processing Time by Fiscal Year. Available at https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html.
[39] Medicare Claims Processing Manual Ch. 29, section 340.
[40] Medicare Claims Processing Manual Ch. 29, section 340.1.
[41] Medicare Claims Processing Manual Ch. 29, section 345.

Expedited Considerations

In some instances, it may be necessary for a beneficiary or a provider to obtain an expedited review – for example if a beneficiary's inpatient care is being terminated.[42] Hospitals must notify beneficiaries who are inpatients of their hospital discharge rights by providing them with an Important Message from Medicare (IM) statement, which includes among other things, notification to the beneficiary about their right to appeal discharge from the hospital.[43] The IM is a standard notice provided to all beneficiaries and does not include information specific to the beneficiary's medical condition or reason for hospital stay.

Meet Norman

Norman has recently been diagnosed with gallbladder cancer. Norman's case is complex and requires him to stay in the hospital following surgery. Follow along as Norman files an expedited appeal to try to remain in the hospital.

First level of review – QIO

Hospitals must issue an IM within two calendar days of the beneficiary having been admitted to the hospital. Beneficiaries (or their representatives) must sign the notice and be provided a copy of the IM.[44] Beneficiaries who dispute the medical necessity of their discharge must file a request to the Quality Improvement Organization (QIO) that contracts with Medicare for a particular region where the beneficiary is an inpatient. The request (which may be made either orally or in writing) must be made no later than midnight of the day of discharge and must be made before the beneficiary leaves the hospital.[45] If the beneficiary fails to file an make a timely request for an expedited review and decides to remain at the hospital, they do not lose their rights to an expedited review; however, they run the risk of being held responsible for charges incurred after the date of discharge set out in the IM.[46]

Filing appeals can be challenging when the patient is hospitalized.

The hospital has determined that Norman is well enough to go home and wants to discharge him back to his home with home health benefits. However, Norman is still apprehensive because he thinks he needs full-time care and is afraid that even with home health benefits he won't be able to manage his care. He was given a notice explaining his right to appeal discharge shortly after his surgery, but it takes him some time to find it because it's buried with other paperwork the hospital provided and Norman still is not feeling well. Once he finds it, Norman files an appeal.

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[42] There are similar, but slightly different rules related to when a beneficiary is discharged from another facility (e.g., from a Skilled Nursing Facility, Home Health Agency, Hospice, or Comprehensive Outpatient Rehabilitation Services). A discussion of these rules and regulations are outside the scope of this paper.

[43] A sample IM form is available at https://www.cms.gov/Medicare/Medicare-General-Information/BNI/HospitalDischargeAppealNotices.

[44] Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 30 – Financial Liability Protections. Section 200. Revised Mar. 8, 2019. Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c30.pdf. [hereinafter "Medicare Claims Processing Manual Ch. 30."]

[45] Medicare Claims Processing Manual Ch. 30, section 200.4.1.

[46] Id. This is another example of the complexity of the program. In this context, the term "discharge" can mean both physically leaving the hospital and/or physically remaining in the hospital but losing Medicare coverage for

Once the QIO informs the hospital that a beneficiary has requested an expedited review, the hospital must provide the beneficiary with a Detailed Notice of Discharge (Detailed Notice) no later than 24 hours after the QIO's notification.[47] The hospital must provide the QIO any and all information the QIO needs to make an expedited determination. If the hospital fails to provide this information, the QIO may make a decision based on the existing evidence or could defer its decision until the information is provided (however, if the delay results in extended coverage of a beneficiary's inpatient stay, then the hospital may be held financially liable for those services). The burden of proof is on the hospital to demonstrate that discharge is the appropriate decision – either because of medical necessity or because it complies with Medicare coverage policies.[48]

A QIO must issue a decision within one calendar day after it receives the pertinent information. Before making its determination, the QIO must solicit the views of the beneficiary who requested the expedited review and provide the hospital with an opportunity to respond.[49] When the QIO makes an expedited determination, it must notify the beneficiary, hospital, and the physician of its decision by phone, followed by a written notice. QIO's determinations are binding, except if the beneficiary remains an inpatient and decides to appeal further.[50]

Second level of review – Qualified Independent Contractor (QIC)

If the beneficiary remains an inpatient and is dissatisfied with the QIO's determination, they may request a reconsideration by a Qualified Independent Contractor, which is an independent entity. The request (which may be made either orally or in writing) must be made no later than noon of the calendar day following the initial notification of the QIO's determination.[51] When a beneficiary makes a timely request for expedited determinations, the provider may not bill the beneficiary for any disputed claims until the independent review entity (IRE) makes its determination.[52]

Higher levels of appeal may not offer immediate relief.

Norman's first appeal to stay in the hospital was denied. Norman cannot afford to pay for hospital care on his own and is forced to leave the hospital. He still has the right to appeal a second time, but those appeals take a long time and there isn't a process that would allow him to remain in the hospital while he waits for a decision.

Unless the beneficiary requests an extension (which may only be requested by the beneficiary and cannot exceed 14 days), the QIC must make a determination within 72 hours after the request for expedited reconsideration. If the QIC fails to make a determination within that timeframe, it must notify the beneficiary of their rights to file an appeal with the OMHA.[53]

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their stay. Also, to be clear, beneficiaries who are no longer an inpatient at the hospital still may file an appeal but must do so within 30 calendar days of the date of discharge. Id.

[47] Medicare Claims Processing Manual Ch. 30, section 200.4.2.

[48] Id.

[49] Medicare Claims Processing Manual Ch. 30, section 200.4.3.

[50] Medicare Claims Processing Manual Ch. 30, section 200.4.4.

[51] Medicare Claims Processing Manual Ch. 30, section 300.1.

[52] Medicare Claims Processing Manual Ch. 30, section 300.5.

[53] Medicare Claims Processing Manual Ch. 30, section 300.2.

Third level of review: OMHA hearings

If a beneficiary is still not satisfied with the resolution of the case, they may appeal to an ALJ, provided that the amount in controversy has been met ($170 in 2020, adjusted for inflation each year). As with the standard appeals time, beneficiaries have 60 days in which to file with the OMHA

Delays in care can be harmful.

Two weeks after having been discharged, Norman goes to a routine follow up appointment with his surgeon where they discover Norman's surgical incision is not healing properly and he needs additional treatment. Norman would have come in sooner to get it checked out, but he doesn't have reliable transportation. Had Norman been able to remain in the hospital, he may have had a better outcome.

Table 3: Levels of Review for Items and Services Covered by Medicare Part A and B (standard and expedited review)

Standard Appeals		Appeal Level	Expedited Appeals[54]	
Deadline to File	Decision		Deadline to File	Decision
120 days after receipt of Medicare Summary Notice	Deadline: 60 days after request receipt[55] Arbiter: MACs	**Redetermination**	Midnight of day of hospital discharge	Deadline: 24 hours Arbiter: Quality Improvement Organization
180 days after receipt of redetermination notice[56]	Deadline: 60 days Arbiter: Qualified Independent Contractors (QICs)	**Reconsideration**	Noon of day following the denial	Deadline: 72 hours Arbiter: Qualified Independent Contractors (QICs)
60 days after receipt of reconsideration notice	Deadline: 90 days[57]	**Office of Medicare Hearings and Appeals (OMHA)[58]**	Same as the standard appeals process	
60 days after OMHA hearing decision	Deadline: 90 days	**Departmental Appeals Board (DAB) Review/Appeals Council**	Same as the standard appeals process	

[54] The expedited process outlined here reflects the process for hospital discharge appeals.
[55] MACs get an additional 14-day extension if parties provide additional evidence after filing a redetermination request.
[56] However, if the issue is the contractor's dismissal of the request for redetermination, the time limit is 60 days from the date of receipt of the contractor's dismissal notice.
[57] However, CMS acknowledges this timeframe often slips due to the volume of cases.
[58] In order to reach this level of review, the amount in controversy must be at least $170, which is the 2020 minimum amount. The figure is updated each year.

Standard Appeals		Appeal Level	Expedited Appeals[54]	
Deadline to File	Decision		Deadline to File	Decision
60 days after Appeals Council decision	There is no timeline by which a decision must be made	**Federal Court Review[59]**	Same as the standard appeals process	

MEDICARE PART C (MEDICARE ADVANTAGE) RULES AND REGULATIONS

Medicare Part C is operated by private plans. Medicare Part C plans – otherwise known as Medicare Advantage (MA) Plans[60] – are generally required to cover the same basic benefits as are covered under traditional Medicare (Parts A and B).[61] Enrollment in MA plans has been steadily increasing and CMS is predicting that 42 percent of beneficiaries will choose to enroll in an MA plan in 2021.[62] MA plans often use various methods to steer beneficiaries towards lower cost alternatives – for example, plans may choose what items to cover or may impose utilization management tools (like prior authorization or step therapy) on drugs or services. In fact, 99 percent of MA enrollees are enrolled in plans that require prior authorization for some services, such as inpatient hospital stays, Part B drugs, and home health services.[63]

When an MA plan processes a request for prior authorization (PA) or other utilization management (UM) requirements – like step therapy, quantity limits – it is considered an initial determination and is subject to appeal. MA plans may place a Part B covered drug on a PA list or subject it to another UM requirement.[64] The following provides an overview of the appeals processes for the Part C program.

Calculation of Timeframes and Standard of Review[65]

Medicare rules and regulations require MA plans to make decisions as "expeditiously as the enrollee's health condition requires."[66] The amount of time it takes for a plan to act upon a claim will vary

[59] In order to reach this level of review, the amount in controversy must be at least $1,670, which is the 2020 minimum amount. The figure is updated each year.

[60] Medicare Advantage plans can be offered either as health maintenance organizations (HMOs), preferred provider organizations (PPOs), private fee-for-service (PFFS) plans, or special needs plans (SNPs). Most MA plans also offer prescription drug coverage. Unlike Part A and Part B, premiums and cost-sharing for MA plans will vary.

[61] This paper will use the term "enrollee" to describe individuals who are enrolled in MA Plans and Medicare Part D plans.

[62] Centers for Medicare & Medicaid Services. Press Release; Trump Administration Announces Historically Law Medicare Advantage Premiums and New Payment Model to Make Insulin Affordable Again for Seniors. Sept. 24, 2020. Available at https://www.cms.gov/newsroom/press-releases/trump-administration-announces-historically-low-medicare-advantage-premiums-and-new-payment-model.

[63] Anthony Damico and Tricia Neuman. A dozen facts about Medicare Advantage in 2020. Apr. 22, 2020. Available at https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020/.

[64] The plan's determination of whether to subject a particular drug to a PA requirement is not subject to appeal, though the enrollee may appeal the imposition of the UM tool in order to gain access to the drug or service.

[65] The Medicare rules regarding the calculation of timeframes and standard of review is the same for Medicare Part D plans.

[66] Centers for Medicare & Medicaid Services. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Section 10.4.1. Effective Jan 1, 2020. Available at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-

depending on the nature of the claim. "Day one" is considered to be the day after the plan receives the request.[67] MA Plans must have in place a process to accept requests (including grievances, appeals, coverage requests) 24 hours a day, 7 days a week (including holidays).

When Medicare rules consider an MA plan to have officially received the request varies and generally favors the plan over the enrollee. For example, for standard requests the MA plan's timeframe begins when any unit in the plan, or a delegated entity (including a delegated entity that is not responsible for processing requests) receives the request. Plans can also provide verbal notification, which is considered to be delivered on the date and time the plan speaks to the enrollee. In expedited cases, the timeframe begins when the appropriate department receives the request.[68] On the other hand, notice to the enrollee is considered delivered on the date the plan "deposited the notice in the courier drop box or external outgoing mail receptacle."[69]

MA plans make decisions based on the information provided to them, which includes clinical documentation. If plans have insufficient information in which to make a pre-service or pre-benefit decision, they should "make reasonable and diligent efforts to obtain all necessary information."[70] MA plans may request additional information from providers. However, Medicare only requires them to make one attempt to obtain additional information, and plans may not adopt the best practices for reaching out to providers (which may include contacting them via fax, which many consider to be antiquated given current technological advancements).[71] If the plan does not receive any additional information, Medicare rules require the plans to make the best decision they can with the information they have.

Levels of Review

There are five levels of review for MA plans, which are similar to those described above with respect to Part A and B services.

Organizational determinations

Unlike under Part A and B, MA plans don't use Medicare contractors (MACs) to process claims or to determine appeals. The MA plan makes its own "organizational determinations." MA plans can also choose to use a network of providers and/or require beneficiaries to undergo utilization management services before seeking treatment. Enrollees or their providers often must request a pre-service organization determination for a service to be covered.

Meet Carla

Carla is enrolled in a Medicare Advantage plan with a restrictive network of providers that does not cover out-of-network care. Carla has been recently diagnosed with pancreatic cancer. Follow along as Carla tries to get coverage for an out-of-network specialist.

Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf. [herein after "Part C&D Appeals Guidance"]

[67] Part C&D Appeals Guidance, section 10.5.1.

[68] Part C&D Appeals Guidance, section 10.5.2.

[69] Part C&D Appeals Guidance, section 10.5.3.

[70] Part C&D Appeals Guidance, section 10.6.

[71] In cases of organization determinations and reconsideration requests, if information is needed from a non-contract provider, the MA plan must request the information within 24 hours of receipt of the request. Part C&D Appeals Guidance, section 10.6.

Table 4 outlines the timelines under which MA plans are required to respond to enrollee requests for organizational determinations. If an MA plan fails to provide a determination within the appropriate timeframe that constitutes an adverse determination and the enrollee may appeal the claim.

Table 4: Timelines for MA Plans to respond to Organizational Determinations

Service	Standard Review	Expedited Review
Pre-service	14 days[72] with a possible 28-day extension	72 hours with a possible 17-day extension
Part B drug	72 hours	24 hours (no extensions permitted)

Medicare Advantage enrollees may need to file appeals to access specialists that are not in their plan's network.

Carla files a request to see an out-of-network doctor who specializes in her type of pancreatic cancer. Her plan doesn't have an in-network provider who has the same level of expertise as the out-of-network doctor. Unfortunately, her plan denies her request.

If a beneficiary requests it, the MA plan must expedite the request if the plan determines that applying the standard timeframe "could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function."[73] MA plans may extend the determination timeline for standard or expedited request if the enrollee requests it (for example, if the enrollee needs additional time to compile information necessary to file); if the extension is in the enrollee's interest; or due to exigent circumstances.[74]

Reconsideration (Level 1 Appeal)

Filing appeals can be challenging when patients are dealing with serious illnesses, like cancer.

Even though she's feeling overwhelmed with her cancer diagnosis, Carla decides her best hope is to file an appeal in order to get coverage to see the specialist.

Enrollees who are dissatisfied with the outcome of the organizational determination may file an appeal. Appeals can be filed in writing, though standard appeals may be submitted verbally (depending on the plan). MA plans must accept verbal expedited appeals. MA plans have the option to accept appeals via web/internet.[75]

Both standard and expedited requests must be filed within 60 days from the date of the initial determination. For standard requests, the processing timeframe begins when the MA plan – or any unit of the plan – receives a request. For expedited requests, the processing timeframe begins when the appropriate department receives the request.

All parties in a level 1 appeal have a "reasonable opportunity" to present evidence related to the appeal (either in-person or in writing), though parties may also choose to submit additional evidence.[76] The MA plan must take into account all evidence when making its decision.

[72] Unless otherwise noted, references to "day" or "days" means calendar days.
[73] Part C&D Appeals Guidance, section 40.8.
[74] Id.
[75] Part C&D Appeals Guidance, section 50.2.1.
[76] Part C&D Appeals Guidance, section 50.5.1.

The level 1 appeal is administered by the MA plan but must be conducted by someone other than the person making the initial determination. If the initial determination was based on a lack of medical necessity, then the level 1 appeal must be administered by a physician with expertise related to the issue on appeal.[77] The physician performing the reconsideration must apply a prudent layperson standard in cases involving urgently needed or emergency services.[78] MA plans must make a decision on the Level 1 appeal as outlined in the table below:

Table 5: Timeframe for Level 1 Appeal Adjudications

Service	Part C Plan	Extension
Standard Pre-service or Benefit	30 days[79]	+ 14 days
Expedited Pre-service or Benefit	72 hours	+ 14 days
Standard Part B drugs	7 days	No extensions granted
Expedited Part B drugs	24 hours	No extensions granted

Waiting for a final decision can add to patient stress.

Carla is experiencing stress as she waits for her plan to rule on her appeal. Her pancreatic cancer makes her more prone to weight loss, and the stress of waiting for the appeal is causing her to lose more weight. So far, she's waited 30 days to hear whether her plan will approve her request to see the out-of-network specialist.

MA plans may extend the adjudication timeframe for standard pre-service and expedited reconsiderations for items and services, in certain limited instances.[80] (However, Part B drug timeframes may not be extended.) MA plans that choose to extend the timeframe must notify the enrollee.

If an MA plan fails to provide a decision within the timeframes provided, the lack of a decision constitutes a determination that is adverse to the enrollee. In such cases the MA plan forwards the entire case file to the Independent Review Entity (IRE).[81] The plan is not required to provide the enrollee with notice that the decision has been forwarded to the IRE.

[77] Part C&D Appeals Guidance, section 50.6. However, this does not mean that the physician reviewing the case must have the same specialty training as the prescribing physician. Medicare only requires that the reviewing physician have "the appropriate level of training and expertise to evaluate the necessity of the requested drug, item, or service." Id.

[78] Part C&D Appeals Guidance, section 50.6.

[79] Unless otherwise noted, references to "day" or "days" means calendar days.

[80] Medicare allows an extension if: (1) it is requested by the enrollee; (2) the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a non-contract provider; or (3) it is in the enrollee's best interest due to extraordinary circumstances. Part C&D Appeals Guidance, section 50.7.1.

[81] Part C&D Appeals Guidance, section 50.7.2.

Reconsiderations by the Independent Review Entity (Level 2 Appeal)

For MA plan appeals, if an enrollee receives an adverse or partially adverse determination (for example, if the plan agrees with the enrollee in part, but disagrees with other parts of the enrollee's request) on the first level of review, the MA plan will automatically forward the decision to the IRE.[82] MA plans are not required to notify the enrollee that the case has been forwarded to the IRE.[83]

Higher levels of review can mean more waiting.

Carla's plan denies her appeal request, too. Carla appeals again. This time her case will be reviewed independently, but it could take another 30 days.

Table 6: Timeframes for Level 2 Appeal Adjudications

Service	Part C Plan
Standard Pre-service or Benefit	30 days
Expedited Pre-service or Benefit	72 hours
Standard Part B drugs[84]	7 days

IRE decisions are final and binding on the enrollee and the MA plan, unless a party files an appeal before an ALJ or attorney adjudicator (Level 3 Appeal).

Delays in care can be harmful.

The independent reviewer also denies her out-of-network coverage request. Carla still has more options to appeal the decision, but all of them require a court appearance and aren't bound to a specific timeframe. Carla is unsure how long she will have to wait to be treated, meanwhile her cancer could get worse or spread, making it harder to successfully treat.

Subsequent Levels of Review

Similar to the appeals process with respect to Part A and B claims, enrollees have the right to file additional levels of appeal for Part C claims, provided certain thresholds are met. In each of these levels of review, the request for appeal must be filed within 60 calendar days of receipt of the decision from the entity reviewing the claim.

Table 7: Higher Levels of Review for Part C Claims

Appeal Level	Who May File	Amount on Controversy
Third Level: ALJ/Attorney Adjudicator	Any party (e.g., enrollee, provider) MA Plan may NOT file appeal	Amount in controversy must meet or exceed $170[85]*
Fourth Level: Council	Any party – including the MA Plan	No amount in controversy is required
Fifth Level: Federal Court	Any party – including the MA Plan	Amount in controversy must meet or exceed $1,670[86]*

* Amount in controversy threshold amounts are updated each year. The amount shown in this table reflect the threshold amount for 2020.

[82] Part C&D Appeals Guidance, section 60.1.
[83] Part C&D Appeals Guidance, section 50.10.1.
[84] Part B drug requests cannot be expedited. Part C&D Appeals Guidance, section 60.3.
[85] Centers for Medicare & Medicaid Services. Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2020. 84 Fed. Reg. 53445.
[86] Id.

Table 8: Levels of Review for Items and Services Covered by Medicare Part C (standard and expedited review)

Standard Appeals		Appeal Level	Expedited Appeals	
Deadline to File	Decision		Deadline to File	Decision
Within 60 days of receiving the coverage determination	Deadline: • *Pre-service*:[87] 14 days (with a possible 28-day extension) • *Part B drugs*: within 72 hours Arbiter: Medicare Advantage Plan	**Organizational Determination**	Within 60 days of receiving the coverage determination	Deadline: • *Pre-service*: 72 hours • *Part B drugs*: within 24 hours Arbiter: Medicare Advantage Plan
Within 60 days of receiving the organizational determination	Deadline: • *Pre-service*: 30 days • *Part B drugs*: within 7 days Arbiter: Medicare Advantage Plan	**Reconsideration**	With 60 days of receiving the organizational determination	Deadline: • *Pre-service*: within 72 hours • *Part B drugs*: within 24 hours Arbiter: Medicare Advantage Plan
Automatic forwarding to IRE if plan reconsideration upholds the denial of services	Deadline: • *Pre-service*: within 30 days • *Part B drugs*: within 7 days Arbiter: IRE	**Independent Review Entity (IRE)**	Automatic forwarding to IRE if plan reconsideration upholds the denial of services	Deadline: • *Pre-service*: within 72 hours • *Part B drugs*: within 72 hours Arbiter: IRE
Within 60 days of receipt of the IRE's decision.	Deadline: 90 days[88]	**Office of Medicare Hearings and Appeals (OMHA)[89]**	Same as the standard appeals process	
Within 60 days from the date of the OMHA hearing decision.	Deadline: 90 days[90]	**Medicare Appeals Council**	Same as the standard appeals process	

[87] The term "pre-service" refers to items or services for which coverage is requested prior to the item or service being provided to the enrollee.
[88] However, CMS acknowledges this timeframe often slips due to the volume of cases.
[89] In order to reach this level of review, the amount in controversy must be at least $170, which is the 2020 minimum amount. The figure is updated each year.
[90] A decision will be rendered within 180 days if the ALJ review expired without an ALJ decision.

Standard Appeals		Appeal Level	Expedited Appeals	
Deadline to File	Decision		Deadline to File	Decision
Within 60 days of the date of the Appeals Council decision.	There is no timeline by which a decision must be made	**Federal Court Review**[91]	Same as the standard appeals process	

MEDICARE PART D RULES AND REGULATIONS

Medicare Part D covers outpatient prescription drugs. Like Medicare Part C, Medicare Part D is operated by private plans that often use various methods to steer beneficiaries towards lower cost alternatives. For example, plans may choose what items to cover or impose utilization management tools (like prior authorization or step therapy) on drugs or services. The Medicare Part D appeals system works similarly to the Part C system, with a few notable exceptions, discussed below.

Meet Cliff

Cliff is a long-time smoker who has been treated for heart disease in the past. Cliff is excited to be eligible for Medicare after a few years with no coverage and eager to get back on his heart medication. When Cliff sees a doctor, he learns that he also has lung cancer. Follow along as Cliff tries to access his medications.

Levels of Review

The Medicare Part D appeals process has five levels of review.

Enrollees can request an expedited determination if medically warranted.[92] Part D plans are permitted to deny a request for expedited timeframe. However, upon doing so they must transfer the request to the standard initial determination process; give the enrollee prompt verbal response; and deliver written notice within three calendar days of the verbal notice.[93]

Initial Determination

Part D plans often use prior authorization or other utilization management tools in order to shift enrollee behavior. When a plan processes a request for prior authorization (PA) or other utilization management (UM) requirements, it is considered an initial determination and is subject to appeal. Part D plans may place a drug on a PA list or subject it to another UM requirement. The Part D plan's determination on whether to subject a drug to an UM requirement is not subject to appeal.

[91] In order to reach this level of review, the amount in controversy must be at least $1,670, which is the 2020 minimum amount. The figure is updated each year.

[92] Medicare Part D requires that a request must be expedited if the Part D plan determines that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. Part C&D Appeals Guidance, section 40.8.

[93] Part C&D Appeals Guidance, section 40.8.

Table 9: Types of Utilization Management tools

UM tool	Description	Subject to Appeal
Prior authorization (PA)	Requires the beneficiary or provider to seek approval from the plan before the service is covered	Yes
Step therapy	Requires the beneficiary to try a lower-cost drug and fail on that drug before the plan will cover a higher-cost drug. (Also known as "fail first")	Yes
Quantity limits	Limits the number of drugs a beneficiary can receive	Yes
Use of UM tools	The process by which a Part D Plan decides whether to subject a specific drug to any UM tool	No

A Part D plan's initial determination may involve either coverage determinations or exceptions requests:

Coverage determinations

Medicare Part D plans are not required to cover all drugs, but rather can limit drug coverage by placing drugs on a formulary.[94] Part D plans also make "coverage determinations" which include a decision on whether to provide coverage of a drug;[95] a decision on the enrollee's cost-sharing for the drug; whether the enrollee has satisfied a prior authorization or other utilization management requirement; a tiering exception request (e.g., requesting the plan cover the drug at a lower-cost formulary tier); or a decision about a formulary request. Coverage determinations include instances where the prescriber is attempting to satisfy a PA or other UM requirement – for example, the prescriber is aware that a PA requirement exists on a given drug and is attempting to provide the requested information in order to satisfy the PA requirement.

Part D plans do not cover all medications. It can be challenging for physicians to know what is covered and contend with utilization management tools.

Cliff's physician has prescribed the same medication to multiple Medicare patients with lung cancer, but he didn't know that Cliff's Medicare Plan requires prior authorization for this particular drug. His doctor was also unaware that Cliff's Part D plan didn't cover the heart medication that Cliff's doctor will think will work best.

An enrollee may request an exception from a Part D plan's requirement related to a specific drug. Once an exception has been granted, the plan sponsor is prohibited from requiring the enrollee to request approval for a refill or new prescription using the drug for the remainder of the year so long as the enrollee remains in the plan, the provider continues to prescribe the drug, and the drug continues to be safe.[96] Plan sponsors have flexibility to determine whether to require the enrollee to re-submit an exception at the start of the plan year, but they have to provide notice within 60-days of the end of the plan year regardless.[97]

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[94] For more information on the Medicare Part D benefit see https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/.

[95] This includes whether a Part D drug is not on the plan's formulary; not determined to be medically necessary; furnished by an out-of-network provider; or otherwise excluded under the Act. Part C&D Appeals Guidance, section 40.2.

[96] Part C&D Appeals Guidance, section 40.5.5.

[97] Id.

Formulary exceptions: A "formulary exception" occurs when an enrollee requests a Part D plan provide coverage for a non-formulary drug or for Part D plans to waive PA and other UM requirements for a specific drug. In seeking a formulary exception a provider must file a supporting statement which must indicate that the requested drug is medically necessary for one of the following reasons: (1) all covered Part D drugs would not be as effective or would have adverse effects; (2) the number of doses has been ineffective to treat the enrollee's condition/based on sound medical and scientific knowledge and characteristics of the enrollee/drug is likely to be ineffective or adversely affect the patient; or (3) the alternatives in the formulary has been ineffective to treat the enrollee or has resulted in adverse effects to the enrollee. Unlike the tiering exceptions process, there are no requirements for the appropriate cost-sharing an enrollee would incur for a formulary exception. Plan sponsors have flexibility for determining the appropriate cost-sharing – however, they have to choose a single cost-sharing level that applies to one of its existing tiers.[98] Medicare rules prohibit a beneficiary from request a tiering exception for a non-formulary drug approved under the formulary exceptions process.

Tiering exceptions: All Part D plans use tiering structures – covered drugs grouped into various categories – with the lower tiers having lower cost-sharing. Enrollees are able to request a tiering exception that would allow them to obtain a non-preferred drug that resides in a higher tier at a lower cost-sharing applicable to drugs in a lower cost-sharing tier.[99] However, Part D plans can limit the availability of these tiering exceptions. For example, Part D plans can restrict an enrollee's eligibility only to the lowest-cost tier associated with brand name alternatives. Enrollees requesting a tiering exception for biologics can only request a tiering exception for another tier with biologics. Part D plans are not required to offer tiering exceptions for branded products to a tier with only generics or authorized drugs. Drugs placed on the specialty tier (the highest tier and one for which there is the most cost-sharing) are not eligible for a tiering exception. Enrollees seeking an exception to the tiering placement of a drug must provide a supporting statement from their provider which must indicate that the drug in the lower cost-sharing tier would not be as effective as the requested drug or would have adverse effects to the enrollee.[100]

Adjudication Timeframes

Part D plans must provide enrollees notices of the plan's initial determination "using the most efficient manner of delivery to ensure the enrollee receives the notice in time to act."[101]

[98] Part C&D Appeals Guidance, section 40.5.2.
[99] Part C&D Appeals Guidance, section 40.5.1.
[100] Part C&D Appeals Guidance, section 40.5.3.
[101] Part C&D Appeals Guidance, section 40.12.

Pharmacy Point of Sale: Most Part D plans maintain pharmacy networks as a way to control costs. Enrollees presenting a prescription at a pharmacy counter may encounter problems obtaining the prescription – for example, if the drug is not covered under the Part D plan's formulary or if it is subject to a PA or other UM requirement. Despite the fact that the enrollee encounters problems filling the prescription, this transaction does not constitute a coverage determination. As a result, enrollees are not provided a written denial notice at the pharmacy and must file a separate request for a coverage determination. However, Part D plan sponsors must arrange with network or preferred pharmacies to provide enrollees with a written copy of a standardized – not individualized to the beneficiary – pharmacy notice if the prescription is unable to be filled at the point of sale.[102] Notices must also be provided for mail order prescriptions no later than 72 hours from the pharmacy's receipt of the prescription.

Pharmacy counter notices can be confusing.

Cliff's physician has prescribed medications for both his lung cancer and his heart disease and urges him to pick it up at the pharmacy right away. When Cliff arrives at the pharmacy his medications aren't available to be picked up. The pharmacist gives him a standard notice saying his plan denied coverage, but Cliff doesn't understand it. So, Cliff has to get back in touch with his doctor to figure out what's going on.

The adjudication timeframes are the same for coverage determinations and exceptions requests.[103] The following table provides an outline of the timeframe for Part D requests for initial determinations of coverage determinations.

Table 10: Timeframes for Part D plans to Respond to Initial Determinations

Benefits Not Yet Received		Benefits Already Received
Standard Review	Expedited Review	
72 hours	24 hours	Must provide payment within 14 days[104] of favorable determination

[102] Part C&D Appeals Guidance, section 40.12.3.

[103] However, if the exceptions request involves benefits that have not yet been received, the start of the timeframe may be tolled until the Part D Plan receives the prescriber's supporting statement. Tolling of the start of the adjudication timeframe is only permissible if all of the following conditions are met: (1) the request is at the coverage determination level; (2) the request involves an exception; (3) the prescriber is not provided a supporting statement; and (4) it involves a request for benefits (not reimbursement). Part C&D Appeals Guidance, section 40.5.4.

[104] Unless otherwise noted, references to "day" or "days" means calendar days.

Plans may request additional information from providers in order to process the coverage determination or exceptions request. However, this timeframe may not be tolled if the plan sponsor asks for additional information after it received the written supporting statement.[105] If the provider's supporting statement isn't received by the Part D plan within 14 calendar days, then the Part D plan must notify the enrollee of its decision within 72 hours for a standard request (24 hours in expedited cases).[106]

If the Part D plan fails to provide the enrollee notice of its coverage determination within the appropriate timeframe, such action constitutes an adverse determination and the Part D plan must forward the request to the IRE within 24 hours after the expiration of the adjudication timeframe.[107] Within 24 hours of having forwarded the case to the IRE, the Part D plan must provide enrollees notice that the case has been forward to the IRE.

Appeal timeframes can differ.

Both of Cliff's prescriptions were denied at the pharmacy counter. His doctor wants to appeal both. Cliff's lung cancer medication is eligible for expedited review, but his heart medication must go through standard review. The process for appeal is the same, but he'll have to wait longer to hear about his heart medication.

Part D plans must abide by transition process for new enrollees who, prior to enrolling in the plan, have been stabilized on a medication that is not on the plan's formulary or is subject to utilization management requirement. If the enrollee in this transition period files an exceptions request regarding the drug and the Part D plan fails to respond in a timely manner and/or fails to forward the request to the IRE, the Part D plan must provide the enrollee with a temporary supply of the drug until the issue is resolved.[108]

Redeterminations (Level 1 Appeals)

Like Part C requirements, enrollees who are dissatisfied with the outcome of their Part D plan's organizational determination may file an appeal. Appeals can be filed in writing. Standard appeals may be submitted verbally (depending on the plan), but the plan must accept verbal expedited appeals.[109] Unlike Part C plans, which have the option to accept appeals via web/internet, Medicare rules require that Part D plans must accept web/internet requests.[110]

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[105] Part C&D Appeals Guidance, section 40.5.3.
[106] Part C&D Appeals Guidance, section 40.5.4.
[107] Part C&D Appeals Guidance, section 40.11. Adjudication timeframes for an exception request involving a request for benefits does not begin until the Part D Plan receives the prescriber's supporting statement. Thus, Part D Plans must not automatically forward case files to the IRE if a supporting statement has not been received. Id.
[108] Part C&D Appeals Guidance, section 40.11.
[109] If the enrollee's verbal request to expedite a Level 1 appeal is denied by the Part D Plan, the plan must automatically transfer the request to the standard process. In such instances, the Part D Plan is prohibited from requiring the enrollee to re-file the request in writing. Part C&D Appeals Guidance, section 50.2.1.
[110] Part C&D Appeals Guidance, section 50.2.1.

Both standard and expedited requests must be filed within 60 days from the date of the initial determination. For standard requests, the processing timeframe begins when the Part D plan – or any unit of the plan – receives a request. For expedited requests, the processing timeframe begins when the appropriate department receives the request.

All parties in a level 1 appeal have a "reasonable opportunity" to present evidence related to the appeal (either in-person or in writing). Parties may also choose to submit additional evidence.[111] The Part D Plan must take into account all evidence when making its decision. Enrollees may request copies of the content of the case file on appeal, but the plan may charge the enrollee "a reasonable amount" for copying and mailing the file.

Sometimes beneficiaries have to file multiple appeals to get coverage of their drugs.

Cliff's initial appeals for both of his medications were denied. Now his doctor has to make a hard choice. He could prescribe one of the medications that Cliff's plan does cover, but he's afraid Cliff will stop taking them because of the side effects. Cliff's doctor decides to file yet another appeal, knowing that it will continue to delay Cliff's care and still might not get approved.

The level 1 appeal is administered by the Part D plan but must be conducted by a person other than the person making the initial determination. If the initial determination was based on a lack of medical necessity, then the level 1 appeal must be administered by a physician with expertise related to the issue on appeal.[112] Plans must make a decision on the Level 1 appeal as outlined in the table below:

Table 11: Timelines for Level 1 Appeal Adjudications

Service	Part D
Standard Pre-service	7 days
Expedited Pre-service	72 hours

[111] Part C&D Appeals Guidance, section 50.5.1. However, in expedited appeals, the opportunity to present additional evidence may be limited by the short timeframe the Part D Plan has in making a decision. In such cases, the Part D Plan must inform all parties (enrollee/prescriber) of the conditions for submitting evidence.
[112] Part C&D Appeals Guidance, section 50.6. However, this does not mean that the physician reviewing the case must have the same specialty training as the prescribing physician. Medicare only requires that the reviewing physician have "the appropriate level of training and expertise to evaluate the necessity of the requested drug." Id.

Unlike the requirements in Part C, extensions of adjudication timeframes are not permitted in Part D.[113] If a Part D plan fails to provide a decision within the timeframes provided, it constitutes an adverse determination in which case the plan forwards the case to the IRE.[114] The Part D plan is not required to provide the enrollee with notice that the decision has been forwarded to the IRE.

If a Part D plan fails to make a timely decision, it must inform the IRE within 24 hours after the expiration of the adjudication timeframe.[115] The case files must be forwarded to the IRE in a timely manner. Expedited cases must be forwarded within 24 hours of receipt of the IRE's request for the case. Standard cases must be forwarded not later than 48 hours of receipt of the IRE's request for case files.

Appeals can compound beneficiaries' problems accessing care.

Cliff's appeal for his lung cancer medication was approved! However, his plan didn't approve coverage for his heart medication yet. Cliff's doctor decides to file an appeal for coverage of the heart medication. Cliff lives in a rural area and it can sometimes take him 3 hours just to get to the pharmacy and back. So, he decides to wait until he hears about the heart medication so that he can just make the trip once.

Reconsiderations by the Independent Review Entity (Level 2 Appeal)

Under Part D, if an enrollee is not satisfied with the outcome of the redetermination, they would have to file an appeal with the IRE.[116] Enrollees must submit a written (not oral) request within 60 days from the date of the notice of reconsideration (Level 1 review).[117] The 60-day timeframe is applicable regardless if the appeal is for standard or expedited consideration. IREs must review the case as expeditiously as possible, but in no case longer than the following timelines:[118]

Table 12: Timelines for Level 2 Appeal Adjudications

Service	Timeline
Standard Pre-service or Benefit	7 days
Expedited Pre-service or Benefit	72 hours
Payment[119]	14 days

[113] Part D Plans are also not permitted to extend the timeframes by dispensing a temporary supply of the requested medication. Part C&D Appeals Guidance, section 50.7.1.
[114] Part C&D Appeals Guidance, section 50.7.2.
[115] Part C&D Appeals Guidance, section 50.12.2.
[116] This policy is different than that under Part C, in which a party does not have to make a request for a Level 2 appeal (all partially favorable or adverse reconsideration decisions are forwarded to the IRE).
[117] If an enrollee misses the 60-day timeframe for requesting an IRE reconsideration, she may request a good-cause extension, which must be filed in writing and explain the reason the request was not made in a timely manner. Part C&D Appeals Guidance, section 60.4.
[118] Part C&D Appeals Guidance, section 60.3.
[119] Payment considerations can't be expedited.

IRE decisions are final and binding on the enrollee and the plan, unless a party files an appeal before an ALJ or attorney adjudicator (Level 3 Appeal).

Subsequent Levels of Review

Similar to the appeals process under Part C, Part D enrollees have the right to file additional levels of appeal for Part D claims, provided certain thresholds are met. In each of these levels of review, the request for appeal must be filed within 60 calendar days of receipt of the decision from the entity reviewing the claim.

However, unlike the Part C appeals process, there are set decision-making timeframes. Timeframes begin on the date the request is received, unless the timeframe has otherwise been extended.[120]

Drug treatments work in combination

Cliff's appeal for his heart mediation is denied again. He still has options to ask for further review, but the wait times for additional appeals just get longer and longer. His next review could take months. In the meantime, he hasn't been taking his lung cancer medication either. His doctor convinces him to make the trip to the pharmacy and start taking his lung cancer medication while they wait for a decision on the heart medication.

Table 13: Higher Levels of Review for Part D Claims

Appeal Level	Who May File	Financial Threshold	Timeframe for decision	
			Standard	Expedited
Third Level: ALJ/Attorney Adjudicator	Enrollee	$170*[121]	Generally within 90 calendar days	Generally within 10 calendar days
Fourth Level: Council[122]	Enrollee	None	Generally within 90 calendar days	Generally within 10 calendar days
Fifth Level: Federal Court	Enrollee	$1,670*[123]	None	None

* Amount in controversy threshold amounts are updated each year. The amount shown in this table reflect the threshold amount for 2020.

Delays in care can be harmful.

In the end, Cliff is lucky. After one more round of appeals, his heart medication is approved. But thanks to the complicated process, he ended up waiting 2 weeks to start taking his lung cancer medication and over 3 months to start taking the heart medication. While he was waiting, his health continued to deteriorate, and he had to make an expensive trip to the ER, which might have been avoided if he had quicker access to his medications.

[120] Part C&D Appeals Guidance, section 70.4.1.
[121] Centers for Medicare & Medicaid Services. Medicare Program; Medicare Appeals; Adjustment to the Amount in Controversy Threshold Amounts for Calendar Year 2020. 84 Fed. Reg. 53445.
[122] The OMHA prioritizes enrollee-requested appeals and maintains a dedicated help line and an enrollee mailing address that enables fast identification and processing. Part C&D Appeals Guidance, section 70.4.1.
[123] Centers for Medicare & Medicaid Services, 84 Fed. Reg. at 53446.

Table 14: Levels of Review for Items and Services Covered by Medicare Part D (standard and expedited review)

Standard Appeals		Appeal Level	Expedited Appeals[124]	
Deadline to File	Decision		Deadline to File	Decision
There is no statutory deadline	Deadline: 72 hours Arbiter: Part D Plan	**Coverage Determination**	There is no statutory deadline	Deadline 24 hours Arbiter: Part D Plan
60 days after the date of receipt of the coverage determination notice.	Deadline: 7 days Arbiter: Part D Plan	**Redetermination**	60 days after the date of receipt of the coverage determination notice.	Deadline: 72 hours Arbiter: Part D Plan
60 days after the date of receipt of the redetermination notice.	Deadline: 7 days Arbiter: IRE	**Independent Review Entity**	60 days after the date of receipt of the redetermination notice.	Deadline: 72 hours Arbiter: IRE
60 days of receipt of IRE decision.	Deadline: 90 days[125]	**Office of Medicare Hearings and Appeals (OMHA)[126]**	60 days of receipt of IRE decision.	Deadline 10 days
60 days from the date of the OMHA hearing decision.	Deadline: 90 days[127]	**Departmental Appeals Board (DAB) Review/Appeals Council**	60 days from the date of the OMHA hearing decision.	Deadline: 10 days
60 days of the date of the Appeals Council decision	There is no timeline by which a decision must be made	**Federal Court Review[128]**	Same as the standard appeals process	

[124] The expedited process outlined here reflects the process for hospital discharge appeals.
[125] However, CMS acknowledges this timeframe often slips due to the volume of cases.
[126] In order to reach this level of review, the amount in controversy must be at least $170, which is the 2020 minimum amount. The figure is updated each year.
[127] A decision will be rendered within 180 days if the ALJ review expired without an ALJ decision.
[128] In order to reach this level of review, the amount in controversy must be at least $1,670, which is the 2020 minimum amount. The figure is updated each year.

POLICY RECOMMENDATIONS

As this paper illustrates, the Medicare appeals process is confusing and can be cumbersome and time-consuming particularly for someone who is also battling a serious illness. There are many rules and requirements regarding what can be appealed, what is needed to file an appeal, the timeframes by which an enrollee may file an appeal, and timeframes for a decision to be made.

Beneficiaries are at a disadvantage because of their lack of familiarity with the system. The private plans and contractors that operate Part C and D, on the other hand, have an advantage given their familiarity with the program and expertise regarding appeals. While Medicare tracks the number of appeals filed each year, this number excludes those individuals who did not engage in the appeals process, either because they are not made aware of its existence or because they feel overwhelmed or daunted by the process.

Beneficiaries are also at a disadvantage because in many cases, they are undergoing a health event – in some cases a health event significant enough to warrant an expedited appeal – and physically may not be up to the task of contending with an unknown and at times cumbersome process. Many beneficiaries do not have immediate family members, friends, or caregivers who can assist them with the appeals process, and even those that do will also need the help of individuals who are knowledgeable about the appeals process.

Over the years Medicare has made improvements to the appeals process. However, there is more that can be done. Following are some recommendations on ways to improve the process for Medicare beneficiaries:

Streamline the appeals process

For many beneficiaries, the number of levels of review can be daunting, potentially deterring them from filing an appeal and/or delaying access to medically appropriate products or services. Even with expedited consideration, each level of review has various timeframes by which the reviewing entity must act. Adding up all those timeframes can result in a beneficiary not having access to a needed product or service for several days, if not weeks (depending on how many levels of review are undergone). In addition, providers report delays in cancer care because of having to wait for approval from Medicare Advantage or Part D plans to overturn utilization management tools.[129]

Recommendation: Under the Medicare rules, the initial levels of review are conducted in-house (whether it be the MACs for Part A and B claims or private plans for Part C and D claims), while subsequent levels are external to the plan organization. While the rules require reviewers to examine the claim based on the evidence presented, if the reviewer is employed by the plan, impartiality can be hard to achieve. The appeals process should be streamlined so that the plan or contractor is responsible for only one level of review before the appeal is handled by a neutral third

> If this recommendation had been implemented, Carla would not have had to go through two levels of review conducted by the plan (organizational determination and reconsideration) before an independent entity reviewed her request to see an out-of-network specialist.

[129] American Cancer Society Cancer Action Network, *New Survey: Utilization Management Delays Cancer Care; Leads To More Stress And Contributes To Worse Outcomes* (Mar. 2019).

party. This will not only improve impartiality but could also allow Medicare to gain better access to data.

Simplify appeals terminology

Medicare beneficiaries have the right to file a series of "appeals" with respect to coverage decisions about products or services provided under the Medicare program. However, the language in the process is anything but simple. Medicare has different rules and regulations depending on whether the beneficiary is filing an inquiry, grievance,[130] or request for coverage. While to a certain extent it makes sense from a plan/program perspective to compartmentalize the various issues, such things are not intuitive from a beneficiary perspective. Because the beneficiary is not familiar with the program vernacular, it may be challenging for them to communicate their concerns.

For example, the rules vary depending on the perceived intent of the beneficiary. For example, in some circumstances the beneficiary may be simply making an "inquiry" as to coverage, in which case the request could be classified as a grievance (which is not appealable). However, it is possible that the beneficiary's "inquiry" was more akin to a request for coverage of an item/service, which would be considered a coverage determination (and thus something the beneficiary could appeal).

In addition, language used in the appeals process is slightly different depending on the rules specific to the program. While this may make sense from a program perspective, it can be incredibly confusing from a beneficiary perspective.

Recommendation: The Medicare program should examine the appeals process from the beneficiary perspective. As part of this process, Medicare should review its standard denial notices, including those provided by MA and Part D plans, to ensure that the notices are provided to beneficiaries in languages other than English and are accessible to people with diverse health literacy levels. As part of this process, Medicare should consult with beneficiary- and patient-advocacy organizations on ways to improve clarity in the program for beneficiaries and consider consumer testing of the notices.

If this recommendation had been implemented, Cliff could have gotten information at the pharmacy explaining the appeal process for each of his two drugs. If he had understood from the beginning that his heart medication could take much longer to get approved than his cancer medication, he likely would have gone to the pharmacy earlier and start taking his approved cancer medication right away.

[130] A "grievance" is an enrollee's dissatisfaction with any aspect of the operation of the plan. Grievances do not include requests for coverage of specific items or services. In some cases, the enrollee's communication to the plan will contain both a grievance and a coverage request. If the enrollee raises two or more issues at the same time, each issue should be separately processed (simultaneously, if possible) under the appropriate procedure. Part C&D Appeals Guidance, section 30.1.

Clarify what constitutes an "expedited" appeals request

There is also inconsistency across the various parts of Medicare regarding what constitutes an "expedited appeal." In traditional Medicare, while a beneficiary can request an expedited appeal, the MAC determines whether a repeal request meets the requirements to be considered on an expedited basis. In Part C, if a beneficiary requests it, the MA plan must expedite the request if the plan determines that applying the standard timeframe "could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function." However, in Part D if the physician determines an expedited appeal is needed, the appeal is expedited without the Part D plan (or Medicare) making an independent assessment as to the sense of urgency.

Recommendation: The Medicare program should ensure that a consistent standard is applied across the program to determine what constitutes an expedited determination. In so doing, Medicare should err on the side of caution and ensure that beneficiaries do not experience delays in accessing medically appropriate care.

> Carla's appeal for her Medicare Advantage plan to cover her out-of-network provider wasn't treated as an expedited appeal (most likely because Carla didn't know to ask for it). However, Cliff's lung cancer medication was considered on an expedited basis (largely because his physician knew to request it).

Implement more direct oversight of the appeals process

There are several instances in the Medicare rules that require plans to perform self-audits to ensure that certain processes are being followed. For example, Part C and D plans are required to audit their own appeals and grievance process for the presence of errors and institute the appropriate quality improvement projects as needed.[131] Medicare does require plans to comply with the rules and requirements concerning the appeals process – including the timelines – as a condition of their contract with the Medicare program. Plans that do not comply may face sanctions or contract termination. However, in order for these requirements to be meaningful, the Medicare program needs to devote significant resources to oversee that plans are complying with these requirements.

Each year, Medicare audits a certain number of Part C and D plans to determine the extent to which these plans are in compliance with Medicare rules and regulations, including the rules related to appeals.[132] CMS has the authority to impose sanctions, civil monetary penalties, and can terminate plans that are not in compliance. However, CMS only audits a few plans each year.

[131] Part C&D Appeals Guidance, section 50.11.

[132] See Centers for Medicare & Medicaid Services. 2018 Part C and Part D Program Audit and Enforcement Report. Medicare Parts C and D Oversight and Enforcement Group. Sept. 13, 2019. Available at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2018ProgramAuditEnforcementReport.pdf.

Recommendation: The Medicare program – not a contractor – should conduct robust audits and spot checks (such as secret shopper programs) to evaluate whether plans are complying with appeals process requirements. In addition, CMS should increase its capability to audit Part C and D plans' compliance with Medicare rules and regulations and impose meaningful sanctions on entities that fail to comply.

If this recommendation had been implemented, Cliff may not have had to go through so many levels of appeals before his plan approved coverage. Cliff's doctor should not have had to go through two levels of review to get his lung cancer drug approved.

Improve funding for the appeals process

While there are rules within the Medicare program by which certain decisions must be made, these timeframes are not always followed. The Medicare brochure to beneficiaries even recognizes that due to high volume, the Office of Medicare Hearings and Appeals (OMHA) often fails to act within a timely manner.[133] A 2016 Government Accountability Office (GAO) study found that statutory guidelines were often not met at all levels of review, with the most frequent delays occurring in the higher levels of review.[134]

In addition, beneficiaries need more information of their rights to appeal. The Medicare program produces a Medicare & You handbook each year that it provides to beneficiaries, but not all beneficiaries keep a copy of this handbook and may not recall that it contains information regarding one's appeals rights.

Beneficiaries also need more one-on-one assistance from impartial, highly trained individuals who can help walk them through the appeals process. The Medicare program provides funding for State Health Insurance Program (SHIP) counselors that provide one-on-one assistance to Medicare beneficiaries on a wide variety of issues, including appeals. This program is vitally important to beneficiaries, but funding for the program – which relies on a highly trained volunteer workforce – is not sufficient.

[133] Centers for Medicare & Medicaid Services. MLN Booklet. Medicare Parts A & B Appeals Process. ICN MLN006568. Jan. 2020. Available at https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/medicareappealsprocess.pdf.

[134] United States Government Accountability Office. MEDICARE FEE- FOR-SERVICE Opportunities Remain to Improve Appeals Process. Revised May 2016. Accessed 2020. https://www.gao.gov/assets/680/677034.pdf.

Recommendation: Medicare should improve its funding for education and outreach materials to beneficiaries to notify them of their appeals rights and the appeals process. Medicare should also better educate hospital discharge planners, pharmacy staff, and others who may have direct contact with beneficiaries that may need assistance in filing an appeal. In addition, the Medicare program should be provided increased funding for SHIP counselors and devote additional resources to informing beneficiaries of the availability of these services. Finally, beneficiaries often experience significant delays in the adjudication of their claims, particularly at the advanced levels of review. Policymakers should examine the source of the delay and determine whether additional funding may be necessary to ensure appeals are adjudicated on a timely basis.

If this recommendation had been implemented, Norman could have been provided with the information necessary to understand how to appeal his discharge from the hospital. Norman lives alone without anyone to care for him (which is why he was apprehensive about being discharged) and relied on staff in the hospital to help him file his appeal. He was lucky that staff were able to help, but not everyone is as fortunate.

Provide more data on the appeals process

It is challenging to find information regarding the effectiveness of the Medicare appeals program. While Medicare routinely publishes very limited information related to appeals before the Office of Medicare Hearings and Appeals,[135] this information fails to provide a complete picture of all of the appeals filed and processed through the various parts of the Medicare program. CMS does not routinely make publicly accessible appeals information by level of appeal and disposition. CMS fails to provide information on whether certain plans have higher appeal rates, or with respect to Part D appeals whether beneficiaries file more appeals seeking formulary exceptions versus exceptions to utilization management tools.

Medicare has a tremendous amount of data that could be used to improve the process. For example, Medicare could conduct specific research to determine whether there are geographic variations on appeals filed, whether beneficiaries with certain diseases or conditions are subject to more appeals, or whether specific plans have higher appeals rates.

Recommendation: Improving the public availability of data on the Medicare appeals process – at all levels – could help identify areas of needed improvement and areas that are functioning well in the Medicare appeals process. CMS should annually publish data regarding the number and disposition of appeals by provider type, by disease/condition/drug/service and detailed information on level of review. Such information should be released on an annual basis so as to better identify specific trends.

If this recommendation had been implemented, Medicare – and patient advocacy organizations – would be better able to spot trends where beneficiaries encounter problems access their care. For example, it would be helpful to know how often beneficiaries, like Carla, appeal for coverage of an out-of-network specialist. This information could be used to improve network adequacy standards.

[135] U.S. Department of Health & Human Services. Beneficiary Appeals Data. Updated July 24, 2019. Accessed April 2020. https://www.hhs.gov/about/agencies/omha/about/current-workload/beneficiary-appeals-data/index.html.

Recommendations specific to Part D

Having access to medically necessary drugs is often an important part of a cancer patient's treatment. This is true not only for oral chemotherapy, but also given that cancer care often requires a number of supportive drug regimens. The following recommendations could improve the Part D appeals process for beneficiaries:

Appeals information provided at the point of sale

The Medicare Part D program covers outpatient prescription drugs and is administered by private plans. Some beneficiaries may go to the pharmacy and encounter a problem with respect to their prescription drugs – for example, when the prescription cannot be filled because the drug is not on the plan's formulary or it requires an exception to the utilization management process. In such instances, the beneficiary may not understand why they are unable to access their prescription drugs.

Recommendation: Medicare should require Part D plans to provide to the beneficiary at the point of sale (the pharmacy counter) individually tailored information regarding the issue related to the beneficiary's prescription drug. This notice should count as a coverage determination, thus obviating the need for the beneficiary (or her provider) to have to file a separate request for a coverage determination.

> Cliff was confused by the notice he received at the pharmacy counter when he tried to pick up his prescription drugs. Had this recommendation been implemented, it would have saved him from having to go through one level of appeal with his Part D plan before his appeal for his heart medication was heard by an independent entity.

Improve tiering exceptions process

Currently, beneficiaries are able to file a tiering exceptions request, which would allow the beneficiary to obtain a non-preferred drug that resides in a higher tier at a lower cost-sharing applicable to drugs in a lower cost-sharing tier. Unfortunately, most beneficiaries are not aware of their opportunity to request a tiering exception. Also, drugs that reside on the specialty tier are not subject to tiering exceptions. These drugs have the highest cost-sharing and are the most expensive.

Recommendation: Beneficiaries should be provided additional information regarding their opportunity to obtain a tiering exception. Beneficiaries should also be permitted to file a tiering exception in order to gain better access to these medications.

> Cliff wasn't aware that he could even ask for a tiering exception for his lung cancer drug. Even if he were aware, he may not have decided to go through the process since his doctor already had to undergo prior authorization to get the drug.

Implement HHS OIG recommendations

In September 2019, the HHS Office of Inspector General (OIG)[136] examined the current Part D appeals program and determined that the existing process can result in beneficiaries' delayed access to Part D drugs. The report found that enrollees and providers appealed roughly one percent of preauthorization and payment denials, but among those that were appealed, Medicare Advantage plans overturned 75 percent of their own denials. This data is concerning in that it suggests that MA plans' default is to deny claims, regardless of medical necessity. In addition, the report does not take

[136] U.S. Department of Health and Human Services-Office of Inspector General. Some Medicare. Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs. Revised September 2019. Accessed April 2020. https://oig.hhs.gov/oei/reports/oei-09-16-00411.pdf.

into account the number of beneficiaries who failed to appeal their plan's decision (which many do), suggesting that the data could be even higher.

Recommendation: CMS should adopt the HHS OIG recommendations, which include: (1) taking additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials; (2) taking action to reduce inappropriate pharmacy rejections; (3) taking action to reduce inappropriate coverage denials; and (4) providing beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials.

> Had these recommendations been adopted, Cliff's doctor would have known what drugs were covered under Cliff's plan and could have started the prior authorization process before Cliff had gone to the pharmacy.

Recommendations relevant to the COVID-10 pandemic

As part of its response to the COVID-19 pandemic, CMS has implemented several temporary changes in an effort to streamline the Medicare appeals process. For example, CMS is allowing extensions to file appeal requests and the opportunity for plans to extend timeframes to adjudicate appeals.[137] CMS is also allowing Part D plans to waive or relax prior authorization requirements for drugs to treat COVID-19 or other formulary drugs in order to facilitate beneficiary access.[138] Such flexibility may be necessary in the immediate response to a pandemic. However, the long-term ramifications of such flexibility remain unclear.

In addition, the Medicare program relies on the United States Postal Service (USPS) to serve as a means of notification to beneficiaries of information regarding their appeals – both in terms of timeframes by which plan responses are due and a means by which beneficiaries can communicate with their plans. Unfortunately, the USPS has experienced significant delays, and mail service is not as reliable in all areas of the country.

Recommendation: Following the pandemic, CMS should evaluate the flexibilities it instituted with respect to the Medicare appeals process to determine which, if any, flexibilities should be retained as a way to improve beneficiary access to products and services. In particular, CMS should examine whether the effect of Part D plans' waiving of prior authorization requirements improved beneficiary access and whether such waivers should continue beyond the COVID-19 pandemic. Given the mail service delays, CMS should give great thought to whether alternative means of communication may be preferable for beneficiaries, keeping in mind that not all beneficiaries have access to or can afford broadband internet and that many struggle with technology issues.

> Cliff lives in a rural area. Mail order could have been a viable option for him. However, he doesn't use the internet because he doesn't have broadband access (which makes electronic communication with the plan hard) and given the mail delays in his area he runs the risk of his

[137] Centers for Medicare & Medicaid Services. Hospitals: CMS flexibilities to fight COVID-19. July 30, 2020. Available at https://www.cms.gov/files/document/covid-hospitals.pdf.
[138] Medicare Advantage and part D Plans: CMS Flexibilities to Fight COVID-19. Nov. 4, 2020. Available at https://www.cms.gov/files/document/covid-ma-and-part-d.pdf.

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