Medicare Part D Appeals Process

Introduction

This discussion of the Part D appeals process is intended to provide you with the information you need to ensure an appeal will proceed as the Medicare regulations intend it to. [A graphic representation of how the appeals process proceeds is attached]. All appeals will begin with a denial of a prescribed drug (a coverage determination) by the Part D prescription drug plan (PDP) the patient is enrolled with. It is vital that you have an understanding of how the regulations define the appeals process when you interact with a PDP on a patient's behalf.

What follows is information about:

- who may access the appeals process;
- the various steps that define the process;
- the timeframes the PDPs and other entities involved in the appeals process are supposed to adhere to; and,
- documentation requirements for different types of exceptions requests.

There's a lot of detail, and the specificity of the rules governing appeals may make it seem more difficult than it is. We wish we could simplify it, but since we want to provide you with the correct information you need to conduct a successful appeal, all the*ifs* and *howevers* that make things seem so confusing need to be there. If, after reading this, you have questions, you can e-mail the APA's Office of Healthcare Systems and Financing with your specific questions at partd@psych.org or call us at 866-882-6227.

Preliminaries

A PDP's formulary coverage policy comprises which drugs are included in the formulary, cost-sharing tiers, prior authorization, step therapy, and dose and quantity limits, among other things. Before the official appeals process begins, an enrollee may request an exception to the coverage policy:

- If a medically necessary drug is not on the PDP formulary, or is on the formulary as other than a preferred drug (i.e., it requires a higher co-pay).
- If a utilization management (UM) edit, such as prior authorization or step therapy must be complied with before the enrollee can obtain the necessary drug; or
- If there are dosage or quantity limits that prohibit appropriate treatment.

So, for example, if a plan denies an exception request based on cost-utilization tools such as step therapy or because the enrollee's prescription exceeds quantity limits, this denial constitutes a coverage determination and can be appealed.

A coverage determination is usually a formal written decision by a PDP that it will or will not provide or pay for a Part D drug. However, if a PDP fails to respond to a prior authorization request in a timely manner, this would also be considered a coverage determination and the appeals process could go forward. (The terms *coverage determination* and *exception* are often used interchangeably and inappropriately, which is one of the many things that often creates confusion in discussions of Part D procedures. But it should be understood that a coverage determination in response to an exceptions request is one type of coverage determination. A denial of a prior authorization request is also a coverage determination.)

Essentially, if a physician prescribes a drug, but the pharmacist cannot dispense that drug because the patient's PDP has a policy that will not permit it, a request to override that policy, even if it is only a request from the prescriber for prior authorization, constitutes a coverage determination. It is important to let patients know that if the PDP denies a prescription, the pharmacist is required to inform the patient of their rights to appeal the denial and who they need to contact to make the appeal. There is a form available for pharmacists to communicate denial information to prescribers [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartDPharmacyFaxForm.pdf], and you might want to consider giving these to your patients with a prescription.

The request for a coverage determination that will override the PDP's denial may be made by:

- the enrollee;
- the enrollee's appointed representative;
- or by the prescribing physician.

If the coverage determination received from the PDP is positive, allowing the enrollee to receive the prescribed medication as requested, the process is complete. If, however, the enrollee receives an adverse coverage determination in writing, denying the request for drug access, the official appeals process then may begin. The coverage determination from the PDP should provide information about the right to appeal the determination and how the appeals process is to be accessed. The appeals process cannot officially begin until the coverage determination has been received in writing.

Requests for exceptions to formulary policies are defined by regulation as being based on the three different issues:

1. The drug is not on formulary or is not a preferred drug;
2. A UM edit prohibits access to the drug; or
3. A dosage or quantity limit prohibits proper treatment.

Each of these three has specific and different documentation requirements that stipulated by the Part D regulations (42 CFR §423.578 (b)(5)). **Following these requirements is vital for having an appeal accepted as legitimate by reviewers (e.g., the PDP; the Independent Review Entity, or Quality Improvement Contractor; or the Administrative Law Judge (ALJ)). The chart below provides the stipulated requirements.**

Documentation Requirements for the 3 kinds of Exceptions Requests

1. **For Exceptions Requests for Drugs Not on the Formulary or on a Higher Financial Tier** : The physician must show that all of the covered drugs on any tier of the plan's formulary for the same condition:
    a. would not be as effective for the enrollee as the non-formulary drug; or
    b. would have adverse effects for the enrollee; or
    c. both (would not be as effective and would have adverse effects).

2. **For Exceptions Requests Based on Utilization Management Edit Restrictions**: The physician must show that the drug alternatives listed on the formulary or required to be used in accordance to step therapy requirements:
    a. has been (1) ineffective in the treatment of the enrollee's condition or (2) based on both sound clinical evidence & medical & scientific evidence, the known relevant physical & mental characteristics of the enrollee, and the known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drugs' effectiveness or patient compliance; or
    b. has caused or, based on sound clinical & medical & scientific evidence, is likely to cause an adverse reaction or other harm.

3. **For Exceptions Requests Based on Dosage or Quantity Limits**: The physician must show that:
    a. the number of doses that is available under the restrictions has been ineffective in the treatment of the enrollee's condition; or
    b. based on (1) both sound clinical evidence & medical & scientific evidence, (2) the known relevant physical& mental characteristics of the enrollee, and (3) the known characteristics of the drug regimen, it is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

Each PDP is required to have coverage determination procedures that it disseminates to its enrollees at the time of enrollment, and these procedures must also be posted on the PDP's website. Issues such as what method the individual requesting the determination must use to communicate with the PDP (i.e., fax or phone call) and what form the PDP's response will take are supposed to be delineated in these two places. While the regulations say a physician may request a coverage determination orally, they add that a written statement may also be required. We recommend that requests be made in writing since the PDP has the option of demanding it in writing anyway, and will probably do so. Also, it should be noted here that the time periods delineated for how long a PDP or the Independent Review Entity (IRE/QIC, see below) has to respond to a coverage determination request do not officially begin until the reviewing body has received a written request.

The information provided in this document is the general information about how the appeals process, beginning with the initial coverage determination request, should work based on the Part D regulations, CMS guidances, and the published QIC/IRE manual. Since each PDP can devise its own forms and communications requirements, it is important to check the PDP's website before attempting to file a coverage determination request.

The Coverage Determination

Coverage determinations may be either 1.) expedited, or 2.) standard.

Expedited Coverage Determination (24 hours)

If an expedited coverage determination is requested and granted, the PDP must respond "as expeditiously as the enrollee's health condition requires," but no later than 24 hours after the request is received in writing. We advise that requests be faxed and that you call for confirmation that the fax has been received. When the prescribing physician requests an expedited coverage determination, stipulating that the standard timeframe "may seriously jeopardize the life of health of the enrollee or the enrollee's ability to regain maximum function, "the PDP must grant it, whereas if an expedited coverage determination is requested by the enrollee or the enrollee's representative, the PDP has the option of deciding a standard coverage determination will suffice. As noted above, however, the 24 hours doesn't officially begin until the PDP has received a written request for the coverage determination.

If there is an unfavorable response, i.e., a negative coverage determination, the enrollee, the enrollee's representative, or the prescribing physician may request a redetermination from the PDP, or Level I of the official appeals process. If a denial is received within the proscribed time period, the physician or patient must actively file for the redetermination (downloadable contact information for filing exceptions and appeals can be found in an Excel file on the CMS website at the following URL http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp#TopOfPage). If the PDP fails to respond to the coverage determination request within 24 hours, the appeal is supposed to automatically move on to the redetermination level. It has yet to be determined how the status of an appeal can be tracked to make certain that the PDP is complying with the Part D regulations.

Standard Coverage Determination (72 hours)

A standard coverage determination works just like the expedited one except the timeframe the PDP has in which to respond is longer. If a standard coverage determination is requested, either orally or in writing, the PDP must respond to the request within 72 hours after receipt of the request. If there is an unfavorable response within that time, the enrollee, the enrollee's representative, or the prescribing physician may request a redetermination, moving on to Level I of the official appeals process. If the PDP fails to respond to the request within 72 hours, the appeal is supposed to automatically move on to the first level of the official appeals process.

Level I: Coverage Redetermination

A coverage redetermination may be requested from a PDP within 60 days after a PDP gives an unfavorable response to a request for an exception, or coverage determination. According to the regulations, a redetermination must be requested in writing, although a PDP may elect to accept oral requests. (We are unaware of any that have chosen to do this.) We advise that requests be faxed and that you call for confirmation that the fax has been received. The 60-day timeframe may be extended if the enrollee submits a written request stating why the deadline was not met. If the PDP failed to respond to the request for the exception, or coverage determination, within the required timeframe (24 hours for expedited; 72 hours for standard) the appeal is supposed to automatically move on to the coverage redetermination level. As stated above, however, it is unclear what mechanism is in place to ensure that this is done.

The PDP remains the reviewing entity for the coverage redetermination. However, if the issue disputed is a denial of coverage based on medical necessity, the redetermination must be made by a physician "with expertise in the field of medicine that is appropriate for the services at issue, although the reviewing physician need not be of the same specialty as the prescribing physician." The redetermination is a review of an adverse coverage determination, "the evidence and findings upon which it is based, and any other evidence the enrollee submits or the Part D plan sponsor [PDP] obtains." The PDP must provide the enrollee or prescribing physician with a "reasonable opportunity to present evidence and allegations of fact or law, related to the issue in dispute, in person as well as in writing."

As with the coverage determination, an enrollee, an enrollee's representative, or the prescribing physician may request an expedited coverage redetermination, or the physician may provide oral or written support for the enrollee's request. However, when the request comes from the physician, indicating that the standard timeframe "may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function," an expedited redetermination must be provided.

Although the prescribing physician may request an expedited redetermination, if a standard redetermination is requested, the request can only be made by the enrollee or the enrollee's representative unless an Appointment of Representative (AOR) Form (CMS Form 1696) is submitted with the request making the prescribing physician the representative.

Expedited Coverage Redetermination (72 hours)

If an expedited coverage redetermination is requested (or, presumably, if the PDP failed to meet the timeline for the expedited coverage determination), the PDP must return a decision in writing within 72 hours after the request was received (or after the end of the coverage determination period). The PDP is required to request, within 24 hours after the request for an expedited redetermination is received, any necessary medical information needed for making its redetermination. It is vital that this request be fulfilled as quickly as possible or the PDP may use the delay as cause for denying the appeal. If a decision is not provided within the 72-hour timeframe, the appeal is supposed to automatically move on to the next appeal level, or the review by an independent review entity (IRE, now also referred to as the QIC, or qualified independent contractor).

Standard Coverage Redetermination (7 days)

If a standard coverage redetermination is requested, the PDP must respond in writing with its decision within 7 days after the receipt of the request. (This would also be the case if the PDP failed to respond within 72 hours to the request for a standard exception. It is unclear whether the 7 days begins 24 hours after the deadline was missed, or exactly when.) If the PDP fails to provide a decision within that timeframe, the appeal is supposed to automatically move to the next level of appeal, the IRE reconsideration.

Level II: Reconsideration by the Independent Review Entity (IRE)

CMS has contracted with a firm called Maximus to serve as the independent review entity (IRE). Although the term *IRE* is used in the regulations, the term *QIC*, or qualified independent contractor, is sometimes used for this entity as well. (PDPs may use either term, or even their own term.) It is the IRE's job to conduct all Part D reconsiderations, not matter which PDP or MA-PD made the redetermination. (If you'd like to access the procedures manual Maximus is using for the reconsideration process, you can download a copy at http://www.medicarepartdappeals.com/PartDReconsiderationManual.pdf.)

A reconsideration by the IRE may be requested if the enrollee is not satisfied with the redetermination decision made by the PDP. The enrollee or a representative appointed by the enrollee must file a written request for the reconsideration within 60 days of the redetermination decision. **An Appointment of Representative (AOR) Form (CMS Form 1696) must be submitted with the reconsideration request making the prescribing physician the representative if physician wishes to continue the appeal for the enrollee.** If the PDP failed to respond with any redetermination decision within the appropriate timeframe, the appeal is supposed to automatically move on to the IRE reconsideration (although, as stated above, it is currently unclear as to how one can be sure this has occurred).

The IRE is "required to solicit the views of the prescribing physician." If the redetermination decision was to not provide a drug that is not on the PDP's formulary, the prescribing physician "must determine that all covered Part D drugs on any tier of the formulary for treatment of the same condition would not be as effective for the individual as the nonformulary drug, would have adverse effects for the individual, or both" (see above chart with documentation requirements for exceptions requests). The IRE is required to conduct the reconsideration as "expeditiously as the enrollee's health condition requires," but may not exceed 72 hours for an expedited request or 7 days for a standard request.

When the IRE makes its determination, it is responsible for sending notice of its decision in writing to the enrollee, the PDP, and to the Centers for Medicare and Medicaid Services (CMS). The notice must be written in understandable language and must state the specific reasons for the decision reached.

If the decision reached fails to reverse the PDP's coverage redetermination, the IRE notice must inform the enrollee of the right to an administrative law judge (ALJ) hearing if the amount of money in question meets the "threshold requirement," which is an amount established

annually by the Secretary of HHS, and must describe the procedures that need to be followed to obtain an ALJ hearing; as well as "any other requirements specified by CMS," also undefined.

The IRE decision is considered final unless the enrollee files a request for an ALJ hearing.

Level III: Hearing by an Administrative Law Judge (ALJ)

Administrative Law Judge (ALJ) hearings are notorious for taking months to be scheduled, due to the number of ALJs available to hear cases. When CMS was queried about this aspect of the Part D appeals process, the representative stated that CMS did not really expect any appeals to go beyond the IRE level; that if appropriate documentation was presented at the IRE level (see documentation requirements in the chart above) the IRE would certainly grant the physician's request for a specific medication. This does not seem to be the way it's working.

Level IV: The Medicare Appeals Council (MAC) Hearing

An enrollee who is dissatisfied with the decision of the ALJ may request a Medicare Appeals Council (MAC) hearing to review the ALJ's decision or dismissal of the appeal. The MAC review is the final decision from CMS on the enrollee's appeal. If the MAC denies the request for the review or decides against the enrollee, the enrollee can move on to the fifth and final level of appeal, the judicial review.

Level V: The Judicial Review

To obtain a judicial review, the enrollee must file a civil action in a U.S. District Court. This action must be filed within 60 days after the decision of the MAC has been handed down.

Attachment: **Exceptions and Appeals Flowchart**

Exceptions & Appeals

Exceptions (Coverage Determinations) Can be Sought From PDPs for the Following Issues:

Cost-sharing or tier status of a drug
UM requirement for a drug
Drug not included on PDP formulary
Dosage or Quantity limits apply that effectively deny access

Who May File for an Exception?

The **Enrollee**
An **Appointed Representative** of the enrollee (varies by state)
The **Physician** who prescribed the medication (no authorization needed until Level II)

You Must Determine the Specific PDP Requirements for Filing for an Exception

PDP contact information is available at
http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp#TopOfPage

For an Exception for a Drug Not on Formulary or Not a Preferred Drug At Least One of These Must Be Established

1. The other drugs on the formulary will not be as effective or
2. Will have an adverse effect, or
3. Both 1 & 2

1

For an Exception Based on UM Management Requirements
At Least One of These Things Must Be Established

The other drugs on the formulary that are required to be used in accordance with step therapy requirements:

- a. Have been ineffective in treating the enrollee's condition, or
  b. Based on both sound clinical evidence and medical and scientific evidence, the known characteristics of the enrollee (physical & mental), and the known characteristics of the drug regimen are likely to be ineffective or adversely affect the drugs' effectiveness or patient compliance, or
- Have caused, or, based on sound clinical evidence and medical and scientific evidence, are likely to cause an adverse reaction or other harm to the enrollee

For an Exception Based on Dosage or Quantity Limitations
At Least One of These Things Must Be Established

- The number of doses that is available under a dose restriction for the drug has been ineffective in the treatment of the enrollee's disease or condition; or
- Based on 1.)both sound clinical evidence and medical and scientific evidence, 2.) the known relevant physical or mental characteristics of the enrollee, and, 3.) the known characteristics of the drug regimen, it is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance

2

Appeals Process Overview

There Are 5 levels to the Appeals Process
(which begins after a negative coverage determination, or response to an exception request, from the PDP**)**

Redetermination by the PDP
Reconsideration by an Independent Review Entity (IRE)
Hearing by an Administrative Law Judge (ALJ)
Review by a Medicare Appeals Council (MAC)
Judicial Review in a District Court

An Appeal May Be Either
Expedited or Standard

When a physician requests an expedited appeal, the PDP is required to honor that request. If the enrollee or the enrollee's representative requests an expedited appeal, the PDP may determine a standard appeal is adequate.

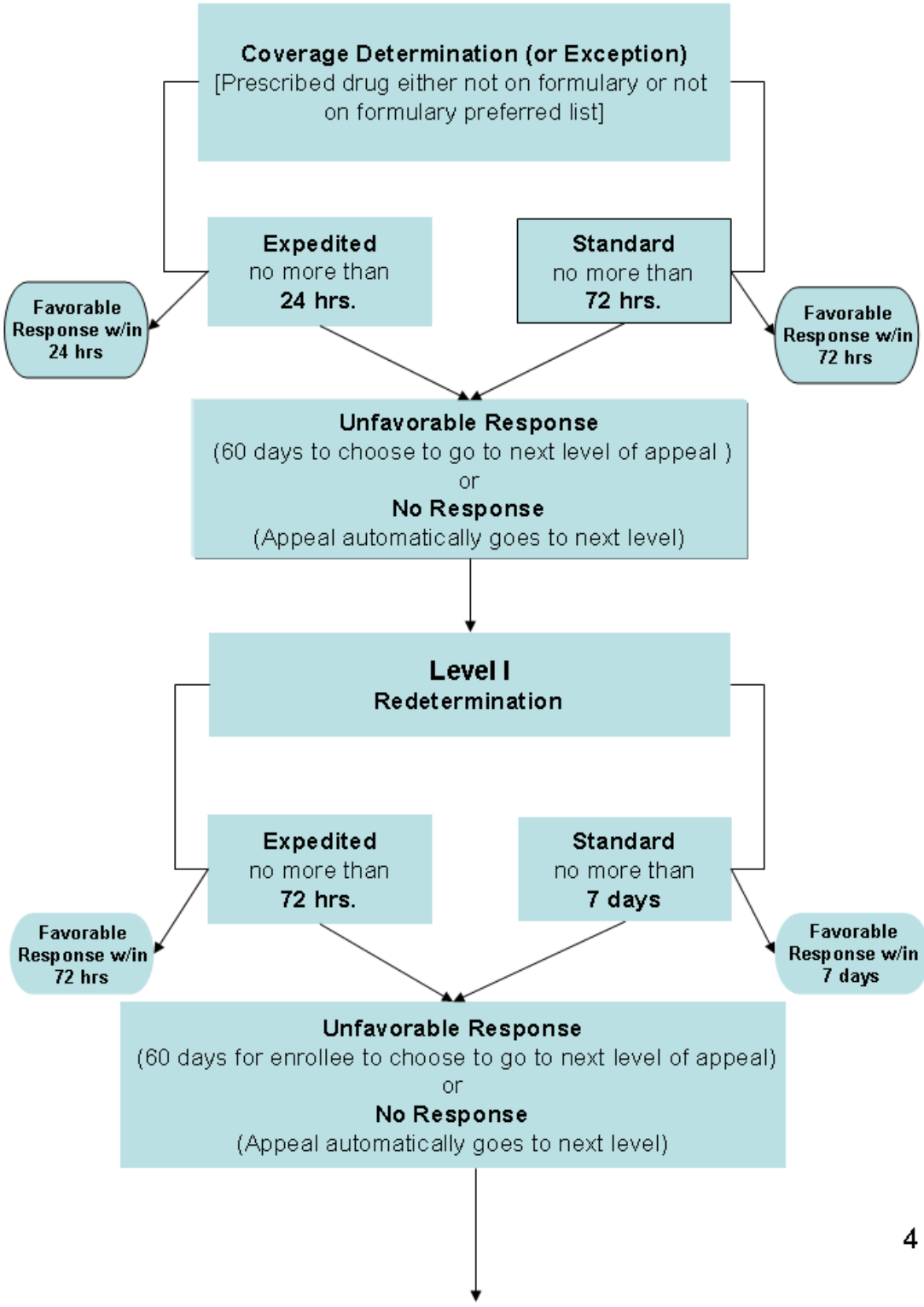
A PDP may take no more than 24 hours to issue an expedited coverage determination (response to an exception request), or no more than 72 hours to issue a standard coverage determination.

At the first two levels of the official appeals process, a decision on an expedited appeal must be reached within 72 hours, while a standard appeal may take up to 7 days. The ALJ Hearing, MAC Review, and Judicial Review levels make no distinction between expedited and standard appeals.

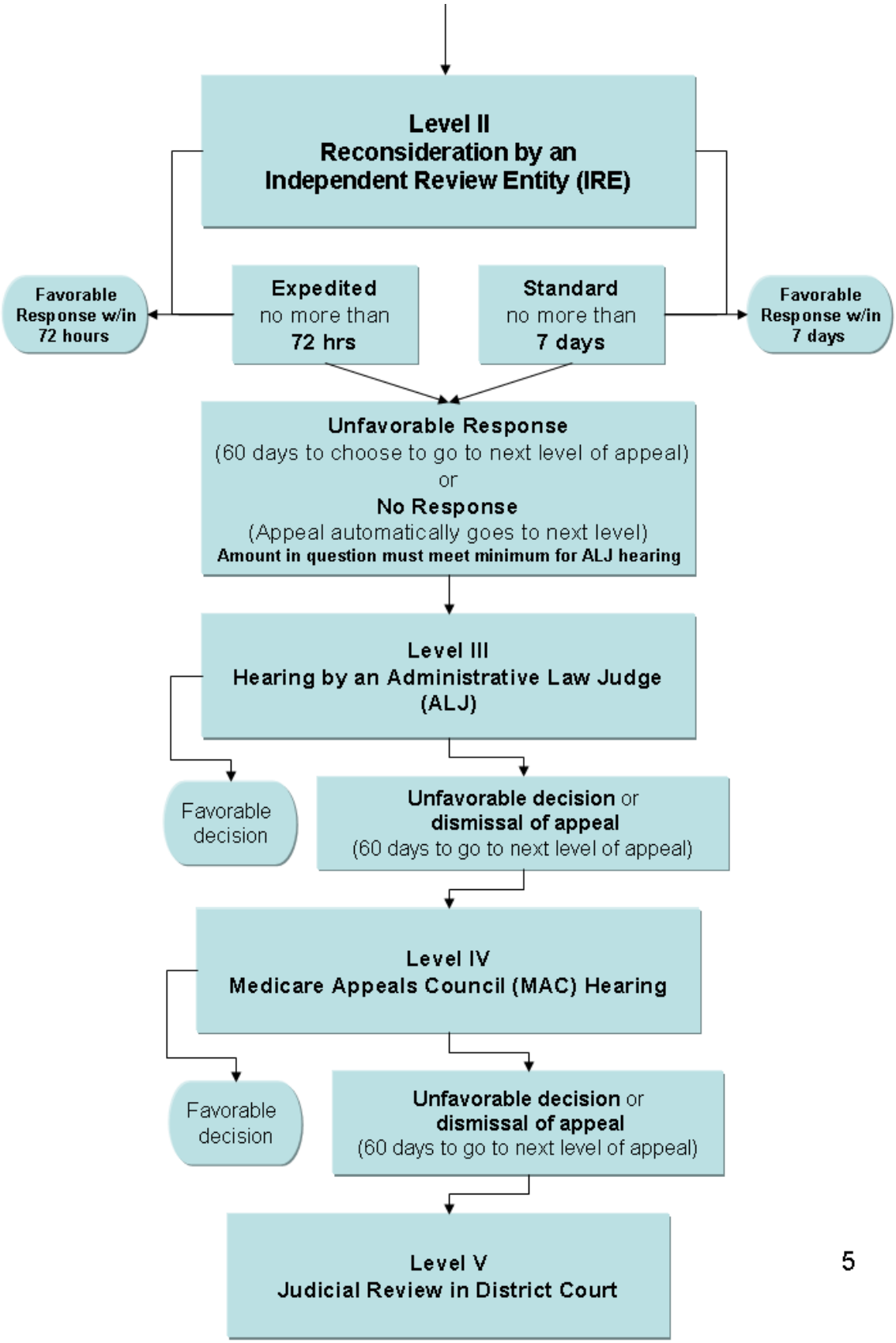
The following pages provide details on each level of appeal.

3

How an Appeal Proceeds



4



5