

When Your Client Cannot Get His/Her Prescription Medications Under Medicare Prescription Drug Coverage

The Medicare prescription drug coverage program has several different tracks for clients to follow in order to obtain coverage for their prescriptions. The first stages of the appeals and grievance processes largely involve paper reviews, rather than hearings at which advocates can represent their clients at in-person settings. Nevertheless, advocates' assistance, along with cooperation from the client's physician, will be crucial to getting clients the medications that they need. Besides the federal laws and regulations, advocates should look to the CMS Prescription Drug Manual, Chapter 18 (available at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDManualAppeals_11.30.05.pdf for guidance on appeals and grievances. References on the charts are to Title 42 of the Code of Federal Regulations unless otherwise noted.

First steps:

- **Ensure that your client has Medicare and is enrolled in a Medicare prescription drug plan (PDP) or a Medicare Advantage drug plan (MA-PD).** With the client's consent and identifying information, an advocate should be able to confirm this at www.medicare.gov or by calling 1-800-MEDICARE. These resources should also be able to tell whether your client is enrolled in the low-income subsidy ("extra help.")
- **Make sure that the medication is not among the types of medications excluded from Medicare Part D coverage.** These medications include: benzodiazepines, barbiturates, drugs for anorexia, weight loss or weight gain, fertility drugs, drugs for cosmetic purposes or hair growth, medications for cough and cold symptoms, over-the-counter medications, and vitamins and mineral products (unless prescribed for prenatal purposes.) If the client also has Medi-Cal coverage, most of these medications continue to be covered by Medi-Cal.
- **Obtain the client's consent to his/her medical information with a HIPAA-compliant consent form.** You will likely need to speak to the client's prescribing physician and perhaps to other medical professionals that the client sees. Because the physician's willingness to cooperate in the appeal process will be crucial, you should contact the physician early on to gauge the physician's willingness to help and to find out whether the most expedient way to ensure your client's health actually may be to obtain a prescription for another drug which the client's PDP or MA-PD will cover without problems. You may also need to view the client's medical history to document his/her need for the medication. You will also need CMS form CMS-1696 (or its equivalent) from the CMS Web site to communicate with the PDP.
- **Find out from the client what s/he was told at the pharmacy.** Was the client told that the particular medication is not on the PDP's formulary? Was the client told that the pharmacy is not in the PDP's network? Was the client told that s/he cannot get the quantity requested? Finding out what happened at the pharmacy will be crucial to deciding which track you should follow.

Using this set of flowcharts:

On the next page you will see various types of problems that may arise and cause your client to be denied coverage for her prescription. Locate that problem that best fits your client's situation, and turn to the indicated flowchart and/or appendix.

These flowcharts are a joint project of the National Senior Citizens Law Center and the National Health Law Program. If you have client stories to help improve the Medicare Part D appeals/grievance processes, please contact us for assistance. If you have comments or suggestions for improving this document, please contact Randy Boyle at the National Health Law Program, at boyle@healthlaw.org.

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GO TO CHART A and review APPENDIX 1 if:

Your client is unable to get coverage for his/her prescription drug because:

The prescription drug is not on the PDP or MA-PD formulary.

The prescription drug is determined to not be medically necessary.

The client is seeking the drug through an out-of-network pharmacy.

The plan says that the drug is excludable under Part D, but it should not be excludable.

Your client was told that s/he must try other medications first (e.g. the PDP is applying step-therapy).

The plan will not approve the drug in the dosage that the physician prescribed.

The client was taking a medication which the plan has removed from its formulary

or which the plan has moved to a higher co-payment tier.

The plan failed to make a coverage determination in a timely manner, and delay would adversely affect the client's health.

The client disagrees with the amount of cost-sharing that s/he is being charged.

OR

GO TO CHART B if: Your client has one of these problems:

The PDP takes too long to approve coverage or make a coverage decision.

The PDP did not send a written denial notice.

Enrollment into or disenrollment from a PDP was not done in a timely manner.

The client has trouble communicating with the PDP (e.g. phone lines are clogged, PDP does not speak the client's primary language.)

The client wishes to complain about customer service at the PDP or at a network pharmacy.

The client has trouble understanding how to access his/her prescription drug benefits.

The client wishes to complain about the PDP's marketing practices.

The client has troubles with the pharmacy such as: (1) The pharmacist incorrectly said that the medication is not covered and asked that

Your client pay for the medication out-of-pocket, or (2) The medication was of poor quality or was past the expiration date

CHART A

Request for a Coverage Determination (Appeals and Exceptions Process)

Preliminary Considerations:

1. Does the client have other prescription drug options? If the client is able to take another medication, including a generic, which is on the prescription drug plan’s formulary, obtaining a new prescription from the prescribing physician may be the best course of action.
2. Can the client switch plans without a treatment interruption? If the client is a dual eligible or in a Medicare Savings Program, s/he may be able to change to a plan that covers his/her prescription drugs. However, this change will not take effect until the first of the next month.

Denial at the pharmacy—the pharmacy must post or distribute a standard notice. [§ 423.562(a)(3)].

Step 1: Start the appeals/exception process: Call or fax request for an exception to the PDP or MA-PD. CMS has no standard form for this request, but each plan sponsor may develop its own form. Enrollee, enrollee’s appointed representative, or physician may make the request. [§ 423.566(c)]. Actions that are appealable under the “coverage determination” process listed at § 423.566(b). Criteria for exceptions are outlined in Appendix I.

Is it necessary to expedite the request because applying the standard timeframe “may seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function?” [§ 423.570(c)(3)(i), (ii)].

YES

Oral or written request to expedite the determination by enrollee or physician. § 423.570(a),(b). Payment for Part D drugs already furnished may not be expedited. [§ 423.570(a)].

DENIED

APPROVED

Enrollee may file an expedited grievance with the plan (See Chart B) or resubmit request for expedited determination. Otherwise, the request follows the Standard Process. §§423.570(d)(2)(i-iv)

NO

Standard Process (42 C.F.R. §§ 423.566-423.568): Plan has 72 hours—from receipt of physician’s supporting statement [§ 423.568(a)]--to issue a determination.

Expedited Process (42 C.F.R. §§ 423.570, 423.572) Plan has 24 hours to issue a determination. Plan may give oral notification, followed by written confirmation within 3 calendar days. Plan must notify enrollee (and prescribing physician, as appropriate) within 24 hours of the request, or for an exceptions request, the physician’s supporting statement. [§ 423.572(a)].

Proceed to next page

CHART A (continued)

Plan makes a coverage determination within the timeframes. [§ 423.568(b)].

Determination is binding on the plan and the enrollee unless appealed. [§ 423.576]

The plan sponsor may reopen and revise the coverage determination. [§ 423.634(a)], which is appealable as well. [§ 423.634(c)].

Plan does NOT inform the enrollee of the coverage determination within the timeframes:

- Failure constitutes an adverse decision. [§ 423.568(e)]
- Plan must forward the request to the IRE within 24 hours of timeframe's expiration. *Id.* [Skip redetermination process below and proceed to IRE reconsideration process on page 6.]

Plan denial. Requirements for denials:

- Denials, in whole or in part, must be in writing, using approved language. [§ 423.568(c),(d)].
- Must advise an enrollee of his/her right to a redetermination, including the right to an expedited redetermination and a description of the rest of the appeals process. [§ 423.568.(d)].

Plan approval:

- Plan must notify enrollee (and prescribing physician, as appropriate) within 72 hours of the request, or for an exceptions request, the physician's supporting statement. [§ 423.568(a)].

Step 2: Redetermination Process: [42 C.F.R. §§ 423.580-423.590]

- If request denied in whole or in part; or
- If a determination, redetermination, reconsideration by an IRE, an ALJ decision, or the MAC issues a decision that is final and binding, the plan may reopen and revise its original determination. [§ 423.634(a)], which is appealable. [§ 423.634(c)].

Standard Redetermination:

- Enrollee has 60 days from coverage determination to file for a redetermination. [§ 423.582(b)].
- Plan may extend the 60 days limit for good cause. [§ 423.582(c)(1)]. This request must be in writing and state reasons for untimely filing. [§ 423.582(c)(2)].
- Request must be in writing, unless the plan adopts a policy for accepting oral requests. [§ 423.582(a)].

Expedited Redetermination:

- Enrollee or prescribing physician may request, in writing or orally. [§ 423.584(a),(b)].
- Requests for payment of drugs already furnished may not be expedited. [§ 423.584(a)].
- Must provide an expedited redetermination if the plan sponsor or the physician determines that following standard timeframe "may seriously jeopardize the life or health or the enrollee or the enrollee's ability to regain maximum function." [§ 423.584(c)(2)(i), (ii)].

Proceed to next page

CHART A (Continued)

Plan accepts request for expediting redetermination:

- Plan sponsor must give notice of its decision to the enrollee (and the prescribing physician, as appropriate) “as expeditiously as the enrollee’s health condition requires but no later than 72 hours after receiving the request.” [§ 423.590(d)(1)].
- Plan sponsor may request additional information within 24 hours of the initial request for expedited redetermination. Plan sponsor still must meet timeframe. [§ 423.590.(d)(2)].

Plan denies request for expediting review:

- Plan must make redetermination within timeframes of a standard redetermination, provide the enrollee with prompt oral notice of the denial, explain the standard process, inform the enrollee of the right to file an expedited grievance (with an explanation and timeframes for that process—see Chart B), inform the enrollee of the right to resubmit the request for an expedited redetermination with the prescribing physician’s support, and deliver written notice of this denial within 3 calendar days. [§ 423.584(d)].
- Failure to meet the expedited timeframe is deemed an adverse redetermination. The plan must forward the request to the IRE within 24 hours of expiration of the expedited timeframe. [§423.590(e)]. [Skip Standard Redetermination to IRE process on page 6.]

Standard Redetermination:

- Plan sponsor must notify enrollee in writing, “as expeditiously as the enrollee’s health requires” but no later than 7 days after receiving request for standard redetermination. [§ 423.590(a)(1), (2), note also § 423.590(b)(2).].
- If redetermination is completely favorable to enrollee, the plan sponsor must effectuate it within the same time period. [§§ 423.590(a)(1), 423.636(a)(1)].
- If redetermination in favor of the enrollee concerns a request for payment, the plan sponsor must authorize payment within 7 days and make payment within 30 days of receiving the request for redetermination. [§§ 423.590(b)(1), 423.636(a)(2)].
- If plan sponsor fails to provide a redetermination within the 7 day timeframe, the plan sponsor must forward the request to the IRE within 24 hours of the expiration of the 7 day period. [§ 423.590(c)].
- The plan sponsor may reopen and revise the redetermination. [§ 423.634(a)]. Revised redeterminations may be appealed. [§ 423.634(c)].

Form & Content of Adverse Redetermination Notices [423.590(g)]

- Use approved language in a readable and understandable form;
- State the specific reasons for the denial;
- Inform the enrollee of the right to IRE reconsideration;
- Adverse drug coverage redeterminations: Describe both standard and expedited reconsideration processes and the rest of the appeal process;
- Adverse payment determinations: Describe the standard IRE reconsideration process and the rest of the appeal process.
- Comply with any other CMS notice requirements.

If still denied, continue to next page ↓

CHART A (Continued)

Reconsideration by an Independent Review Entity (IRE) [§ 423.600]

- Enrollee must file for IRE reconsideration within 60 days of the date of the redetermination. [§ 423.600(a)].
- IRE is required to solicit the views of the prescribing physician. Physician's views may be oral or in writing, but must be included in IRE's record. [§ 423.600(b)].
- IRE's reconsideration must be conducted as expeditiously as the enrollee's health requires, but must not exceed timeframes for a redetermination under § 423.590 (Standard: 7 calendar days, Expedited: 72 hours, starting from date of request for IRE.) [§ 423.600(d)].
- CMS will contract with a private entity to perform IRE reconsiderations.

IRE Reconsideration of a non-formulary drug [§ 423.600(c)]

- 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 non-formulary drug, would have adverse effects for the individual, or both."
- This includes exceptions based on cost utilization tools.

IRE Reconsideration of Denial of Coverage Based on a Lack of Medical Necessity [§ 423.600(e)]

- The "reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsideration need not, in all cases, be of the same specialty or subspecialty as the prescribing physician."

Reconsideration by IRE [Notice: § 423.602, Effect of a reconsideration: § 423.604]

- IRE must send notice to the enrollee and the plan sponsor and a copy to CMS.
- Must contain specific reasons for the IRE's decision in understandable language.
- Must describe the procedures required to obtain an ALJ hearing.
- Must comply with any other CMS requirements.
- If the reconsideration is adverse (i.e. does not completely reverse an adverse redetermination), the notice must inform the enrollee of the right to an ALJ hearing if the amount in controversy meets the threshold requirement under §423.610.
- The reconsideration determination is binding on both the enrollee and the plan sponsor, unless the enrollee files for an ALJ hearing.
- The IRE may reopen and revise the reconsideration. [§ 423.634(a)]. Revised reconsiderations may be appealed. [§ 423.634(c)].

If still denied, continue to next page

CHART A (Continued)



Hearing before an Administrative Law Judge (ALJ) [§§ 423.610, 423.612, 422.600, 422.602]

- Enrollee must file request for hearing within 60 days of date of IRE reconsideration decision notice, unless ALJ extends the time. [§ 422.602(b)].
- Enrollee must file a written request with the entity specified in the IRE's reconsideration notice.
- The amount in controversy must be met (at least \$110 in 2006). The ALJ dismisses the request if it does not meet this amount. [§ 422.602(d)(1)]. If after the hearing begins, the ALJ discovers that the amount in controversy is not met, s/he discontinues the hearing and does not rule on the substantive issues. [§ 422.602(d)(2)].
- Aggregating appeals to meet the amount in controversy:
 - All appeals must have been previously considered by the IRE.
 - The ALJ must list all of the aggregated appeals and each must meet the ALJ filing requirements.
 - The appeals involve the delivery of prescription drugs to the same enrollee. Value is determined by the projected costs to the beneficiary for refills prescribed during the plan year, **OR**
 - The appeals involve the same prescription drug for two or more enrollees.
- If an enrollee is dissatisfied with the ALJ decision, s/he may request a MAC review. [§ 422.608].
- The ALJ may reopen and revise the decision. [§§ 423.634(a), 422.616(a)]. Revised decisions may be appealed. [§§ 423.634(c),



Medicare Appeals Council (MAC) Review [42 C.F.R. §§ 423.620, 422.608, 405.1100-405.1140]

Request for review by the MAC is made by using form DAB-101, available at: <http://www.hhs.gov/dab/DAB101.pdf>. Appeals must be filed within 60 days of the ALJ decision or dismissal. A beneficiary may establish good cause for an extension of this time. [§§ 405.942(b)(2), (b)(3)]. The MAC undertakes a *de novo* review of the ALJ decision. [§ 405.1100(c)]. Note: The Medicare Part D regulations contain almost nothing about this level of review. Refer instead to the code sections at the beginning of this box. The MAC may reopen and revise its decision. [§ 423.634(a)]. Revised decisions may be appealed. [§ 423.634(c)].



Judicial Review [42 C.F.R. §§ 423.630, 422.612]

- The enrollee may request judicial review in U.S. district court if:
 - The MAC denied the enrollee's request for review; **and**
 - The amount in controversy is met (\$1090 in 2006).

END OF CHART A

CHART B

Prescription Drug Plan Grievances

Each prescription drug plan sponsor must develop its own grievance procedure to dealing with issues other than coverage determinations. The federal regulations contain few requirements for the grievance procedures. Plans may accept written or oral grievances, and CMS has not developed a standard grievance form for plans to use.

Enrollee may file a grievance with the prescription drug plan sponsor [§ 423.564]. The grievance procedure must include:

- Meaningful procedures for timely hearing and resolving grievances between enrollees and the Part D plan sponsor or any other entity or individual through whom the Part D plan sponsor provides covered benefits. [§ 423.564(a)].
- The sponsor must promptly determine and inform the enrollee whether the request is subject to the grievance procedure or the coverage determination appeals process. [§ 423.564(b)].
- Although quality of care issues are processed separately through the Quality Improvement Organization (QIO) procedures, an enrollee may file a grievance regarding quality of care or file with the QIO, or both. [§ 423.564(c)].
- The enrollee may file the grievance orally or in writing. [§ 423.564(d)(1)].
- The enrollee must file the grievance within 60 days of the event or incident that precipitated the grievance. [§ 423.564(d)(2)].
- The sponsor must have an established process to track and maintain records on all grievances. [§ 423.564(g)].

Expedited Grievances: [§ 423.564(f)]: The sponsor must respond to an enrollee's grievance within 24 hours if the complaint involves the sponsor's refusal to grant a request for either an expedited coverage determination or an expedited redetermination, and the enrollee has not yet purchased or received the drug that is in dispute.

Grievance disposition and notification:

- The sponsor must notify the enrollee of its decision "as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days" after the sponsor receives the oral or written grievance. [§ 423.564(e)(1)].
- The sponsor may extend the 30-day timeframe by up to 14 days if:
 - The enrollee requests the extension [§ 423.564(e)(2)]; or
 - The sponsor "justifies a need for additional information and documents how the delay is in the interest of the enrollee." If the sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay. [§ 423.564(e)(2)].
- All grievance submitted in writing must be responded to in writing. [§ 423.564(e)(3)(i)].
- Oral grievances may be responded to orally or in writing, unless the enrollee requests a written response. [§ 423.564(e)(3)(ii)].
- All quality of care grievances must be responded to in writing. The response must also contain a description of how the enrollee may make a written complaint with the QIO. [§ 423.564(e)(3)(iii)].

Appendix I

Advocacy for Coverage under the Exceptions Process

If a client was denied a medically necessary medication because it is not on the plan's formulary or the plan is applying inappropriate cost utilization tools, you may wish to show [generally, 42 C.F.R § 423.578(b)]:

- Medical necessity for the particular drug.
 - Has the client tried and failed other drugs? Obtain evidence of the client's failure on or inability to tolerate alternative medications.
 - Submit documentation of the client's underlying illness or condition.
 - Obtain a written statement from the prescribing physician as to why none of the other formulary drugs would be as effective or would have adverse effects on the enrollee's health or why cost utilization controls (e.g. step therapy or dosage restrictions) would be ineffective or detrimental to the enrollee's health.. [§ 423.578(b)(5)]. [Note: If the physician does not provide this in writing, the plan may require the physician to submit a subsequent written supporting statement. The plan may also require the physician to submit supporting medical documentation as part of the written follow-up. [§ 423.578(b)(6).]
 - A plan sponsor's exception criteria must include:
 - A description of the criteria that the plan sponsor uses to evaluate the prescribing physician's determination [§ 423.578(b)(2)(i)].
 - A process for gathering and comparing medical and scientific evidence of the safety and effectiveness of the requested drug, including safety information generated by an authoritative government body [§ 423.578(b)(2)(ii)].
 - A description of how cost-sharing will apply to a non-formulary drug that is granted an exception. [§ 423.578(b)(2)(iii)].

If a client is seeking to get lower co-payments on a medication included on the formulary [generally, 42 C.F.R. § 423.578(a)]:

- The formulary must be using tiers to manage the drug benefit. [§ 423.578(a)].
- The prescribing physician must provide an oral or written supporting statement of why preferred drugs would not be as effective or would result in adverse consequences for the enrollee. [§ 423.578(a)(2)(i), (a)(4)]. [Note: If the physician does not provide this statement in writing, the plan may require the physician to submit a subsequent written statement demonstrating the medical necessity. The plan may also require the physician to submit supporting medical documentation as part of the written follow-up. § 423.578(a)(5).]
- Exceptions process will not work when:
 - The plan maintains a separate tier for generic drugs. The plan does not need to provide the medication at the generic drug tier's level of cost-sharing. [§ 423.578(a)(6)].
 - The plan maintains a separate tier for high cost and unique items, such as genomic and biotech products. The plan may make these medications exempt from the exceptions process. [§ 423.578(a)(7)].

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