DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

DATE: March 17, 2006

Memorandum To: All Part D Sponsors

Subject: Next Steps on Formulary Transition Policies

From: Gary Bailey, Deputy Director, Center for Beneficiary Choices

On February 2, CMS issued guidance calling for a one-time, across the board extension of the transition period to March 31 for those individuals who were enrolled with effective coverage dates of January 1 or February 1. According to our guidance, individuals enrolling March 1 or later should generally be provided with the customary 30-day transition period. The transition period has been successful in ensuring that enrollees are provided immediate access to necessary drugs at the point of service. We appreciate your cooperation during this initial implementation.

As the initial transition period ends on March 31 for those early enrollees, I would like to take this opportunity to remind you of the critical importance of aggressively implementing policies and processes that ensure your enrollees have access to appropriate transitions from their previous prescription drug coverage. The purpose of the transition process is not simply to provide a temporary supply of non-formulary drugs during a certain period of time but, rather, to provide your enrollees with sufficient time to work with their health care providers to switch to a therapeutically appropriate formulary alternative or to request a formulary exception on the grounds of medical necessity. At the same time, it is vital that your enrollees be given clear guidance regarding how to proceed after a temporary fill is provided so that an appropriate and meaningful transition can be effectuated before the end of the transition period.

We are asking plans to ensure that they have provided their enrollees who have used a transition benefit with the appropriate assistance and information necessary to enable them to better understand the purpose of the transition. Steps that you should consider to ensure a meaningful transition include:

- Analyzing claims data to determine which of your enrollees require information about their transition supply.
- Contacting those enrollees to ensure they have the necessary information to enable them to switch to a formulary product or as an alternative to pursue necessary prior authorizations or formulary exceptions.
- Increasing staff capacity to respond to an anticipated increase in the volume of formulary exceptions requests.

- Increasing call center capacity, including pharmacy help lines, to respond to an anticipated increase in call volume from affected enrollees regarding your transition process.
- Making arrangements to continue to provide necessary drugs to an enrollee by extending the transition period, on a case-by-case basis, if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period. For example, in the event that some of your enrollees were enrolled in two plans at the same time and have been re-enrolled into your plan, we would expect you to provide a new 30 day transition period in cases where the individual is presenting at a contracted pharmacy under your plan for the first time.

We understand that many of you have systems in place to trigger a written notice to a member when a plan provides a transitional first fill of a non-formulary drug, and others still may provide instructions – including instructions to contact the plan for further information – through your contracted pharmacies. While plans have flexibility to provide this information in a variety of forms, the instructions to the enrollee must, at a minimum, explain:

- That the transition supply provided is temporary and may not be refilled unless a formulary exception is approved;
- That the enrollee will need to work with the plan as well as his or her health care provider to identify appropriate therapeutic alternatives that are on the plan's formulary and that will likely reduce his or her costs;
- That the member has the right to request a formulary exception, the timeframes for processing the exception, and the member's right to request an appeal if the plan issues an unfavorable decision; and
- The plan's procedures for requesting a formulary exception.

Attachment I to this memorandum is a model letter you may use to provide information about your transition processes to affected enrollees. Plans using the model may submit the letter under the file and use certification process. Please note that use of this model letter is not required, but use of an alternative notice will require marketing review and will be subject to a 45-day review process. We will honor transition notices currently in use and previously approved during marketing review prior to the release of this memorandum.

Plans that need to submit new transition notices must submit them under the following marketing material category and code:

- Category: Special Materials
- Code #: 7004 2006 Transition notice

If enrollees or prescribing physicians request formulary exceptions, the requests must be processed in accordance with Chapter 18, sections 30, 30.1, 30.1.2, 40, and 50 of the Prescription Drug Benefit Manual. I urge you to continue to streamline your exceptions and appeals processes in order to further ensure a smooth transition process for your enrollees. As part of your process, you must make available any exceptions and appeals standard forms to your enrollees, as well as to providers, via U.S. mail upon request, fax, and Internet. Plans also

have the option of accepting phone requests for exceptions and appeals and must do so for expedited exceptions requests.

While all of you have committed to provide an initial 30-day supply for new enrollee transitions after March 1, we expect that you will use sound judgment to extend that temporary coverage in certain situations in which a longer transition may be required for valid medical reasons. Applied on a case-by-case basis, such extensions may provide enrollees in special situations with the time they need to effectively transition to a formulary drug or to request a formulary exception.

Attachment II to this memorandum is a document entitled "Important Reminders about Part D Coverage Determinations & Appeals." This document reiterates established policies on processing coverage determinations and appeals as set out in Chapter 18 of the *Medicare Prescription Drug Coverage Manual* and provides clarification on several issues that have been raised since the inception of the prescription drug program.

Also attached to this memorandum is a spreadsheet we will be using to track the processes you have put into place for effectuating a meaningful transition for your enrollees. We are also requesting that you report counts of prescriptions that you have provided under your transition policy, the number that have been switched to your formulary, the number under coverage determination and reconsideration, and the status of IRE reconsiderations due to not meeting the timelines. Please submit to CMS by COB March 24 your completed spreadsheet. Please zip the file and send your reply to drugbenefitimpl@cms.hhs.gov and include in the subject line "Transition process spreadsheet: <insert organization name>."

Please feel free to contact your account manager if you have additional questions.

Attachment I

Dear <Beneficiary Full Name>,

Please keep this letter for your records. You are getting this letter because you recently filled a prescription <for *insert prescription if known*> *<that was not on our list of covered drugs (called a formulary)*> /*<that was subject to a prior authorization requirement that you did not meet*>. This last fill of that prescription was a temporary solution. You now need to work with us or your doctor to change your prescription to one that we cover. If that isn't possible, you must request an exception from us for this prescription.

How do I change my prescription?
You can ask us if we cover another drug used to treat your medical condition. If we cover another drug for your condition, you can ask your doctor if this drug is an option for you. If your doctor tells you that another drug we cover isn't medically appropriate for treating your condition, you have the right to request an exception from us < *to cover your current prescription or insert prescription if known*>.

How do I request an exception?
The first step in requesting an exception is for you or your prescribing doctor to contact us. *<Provide the necessary address, fax number, and phone number>*.

Your doctor must submit a statement supporting your request. The doctor's statement must demonstrate that the requested drug is medically necessary for treating your condition. Once the physician's statement is submitted, we must notify you of our decision no later than 24 or 72 hours, depending on whether the request is an expedited request or a standard request. Your request will be expedited if we determine, or your doctor tells us, that your life, health, or ability to regain maximum function may be seriously jeopardized by waiting for a standard request.

What if my request is denied?
If your request is denied, you have the right to appeal and ask us to review our decision. You must request this appeal within 60 calendar days from the date of our first decision. <*You must file a standard request in writing* or *we accept standard requests by telephone and in writing. We accept expedited requests by telephone and in writing. Provide the necessary address, fax number, and phone number*>.

What if I have questions about this letter?
If you have questions about this letter, please call our customer service number at <*insert phone and TTY/TDD number*> from <*insert customer service hours of operation*>.

Sincerely,
<Plan Representative>

<Material ID number>

Attachment II: Important Reminders about Part D Coverage Determinations & Appeals

Issue: Distribution/Posting of Standardized Pharmacy Notice

Reminder: Plans **must** arrange with their network pharmacies to distribute or post the standardized Pharmacy Notice ("Medicare Prescription Drug Coverage and Your Rights"). See: 42 CFR §423.562(a)(3). The purpose of the Notice is to provide an enrollee with information about how to contact his or her Part D plan to obtain a written coverage determination when a prescription is not filled as written by the prescribing physician. The notice also reminds enrollees about certain rights and protections related to their Medicare drug benefits.

Resources: The standardized Pharmacy Notice is contained in Appendix 5, Chapter 18 of the *Medicare Prescription Drug Benefit Manual*, which can be found under "Downloads" at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/06_RxContracting_EnrollmentAppeals.asp

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Issue: Statutorily Excluded Drugs

Reminder: In general, complaints about statutorily excluded drugs should not be processed as coverage determinations. However, in some cases, an enrollee may use the coverage determination process to argue that a drug is not statutorily excluded, is not statutorily excluded for a specific indication, or is covered by the plan as a supplemental benefit. Conversely, if an enrollee is not disputing that a drug is excluded, but has a question or general complaint about an excluded drug not being covered, plans should process the transaction as an inquiry or a grievance. CMS is developing a model Notice of Inquiry Regarding an Excluded Drug that plans may use when a plan sponsor receives an inquiry for an excluded drug.

Resources: List Serve message of February 28 entitled "Excluded Drugs."
Section 20.2.4, Chapter 18, *Medicare Prescription Drug Benefit Manual*. The revised version of Chapter 18 will be posted in early April 2006.
The model Notice of Inquiry Regarding an Excluded Drug will be contained in Appendix 12, Chapter 18 of the *Medicare Prescription Drug Benefit Manual*.

Issue: Distinguishing PA Requests from Exception Requests

Reminder: Plans must properly distinguish cases where an enrollee/physician is attempting to demonstrate that they have met prior authorization (PA) requirements associated with a formulary drug from cases where an enrollee/physician is asking for an exception to the PA requirements associated with a formulary drug. The former request should be processed as a coverage determination and the latter request should be processed as a formulary exception since the enrollee/physician is asking for an exception to the application of a cost utilization management tool.

Where an enrollee/physician is attempting to satisfy a PA requirement and the plan has a PA form available for seeking prior authorization for the requested drug, the plan should promptly provide the physician with the necessary PA form(s). Cases where an enrollee/physician is attempting to satisfy a PA requirement should be processed as a coverage determination request. In other words, the plan must notify the enrollee (and the prescribing physician involved, as appropriate) of its decision no later than 24 hours after receiving the request for expedited cases and no later than 72 hours after receiving the request for standard cases.

Where an enrollee/physician is seeking an exception to a PA requirement, the prescribing physician must submit a statement to support the request consistent with the requirements set forth in 42 CFR 423.578(b)(5). As with other exception requests, the plan must notify the enrollee

(and the prescribing physician involved, as appropriate) of its decision no later than 24 hours after receiving the physician's supporting statement for expedited cases and no later than 72 hours after receiving the physician's supporting statement for standard cases.

Finally, if an enrollee/physician asks for coverage for a non-formulary drug, the plan should contact the enrollee/physician and explain the need for a supporting statement in order to process the request. The request should be properly processed as a formulary exception request and not as a PA request since PA requirements do not apply to non-formulary drugs.

Resource: Section 30.1, Chapter 18, *Medicare Prescription Drug Benefit Manual*

Issue: Timely Processing of PA requests

Reminder: If a physician is requesting prior authorization of a drug and is attempting to show that the PA requirements have been satisfied (as opposed to requesting an exception to the PA requirements), the plan must process the request within the same timeframes that apply to all coverage determination requests (as expeditiously as the enrollee's health requires, but no later than 24 hours for expedited cases and 72 hours for standard cases).

Resource: Section 30.1, Chapter 18, *Medicare Prescription Drug Benefit Manual*

Issue: Timeframes for Processing Coverage Determinations

Reminder: In all cases, plans must notify enrollees of initial coverage determinations as expeditiously as the enrollee's health condition requires. In expedited cases where applying the standard timeframe may seriously jeopardize the life or health of the enrollee, the plan must notify the enrollee of its decision no later than 24 hours after receiving the request or, for cases involving exception requests, no later than 24 hours after receiving the prescribing physician's supporting statement. In cases where the standard timeframe is applied, the plan must notify the enrollee of its decision no later than 72 hours after receiving the request or, for cases involving exception requests, no later than 72 hours after receiving the prescribing physician's supporting statement. If a plan fails to meet these timeframes, it **must** forward the case to the Part D QIC within 24 hours of the expiration of the timeframe. Plans should not auto-forward cases to the Part D QIC if the timeframe has not expired or if the plan has already issued a decision.

Note: If a coverage determination request involves an exception, the plan's timeframe begins when the plan receives the prescribing physician's supporting statement. The physician may provide either a written or an oral supporting statement. If the physician provides an oral supporting statement, the plan may require the physician to subsequently provide a written supporting statement demonstrating the medical necessity of the drug. The plan must be explicit about the supporting statement requirements and, if the plan requires additional supporting medical documentation, it must clearly identify the type of information that must be submitted.

Resource: Sections 30.2.1, 30.2.2, 40.2, 40.4, 50.4, and 50.6, Chapter 18, *Medicare Prescription Drug Benefit Manual*

Issue: Timeframes for Processing Redeterminations

Reminder: In all cases, plans must notify enrollees of redetermination decisions as expeditiously as the enrollee's health condition requires. In expedited cases where applying the standard timeframe may seriously jeopardize the life or health of the enrollee, the plan must notify the enrollee of its decision no later than 72 hours after receiving the request. In cases where the standard timeframe is applied, the plan must notify the enrollee of its decision no later than 7 days after receiving the request. If a plan fails

to meet these timeframes, it **must** forward the case to the Part D QIC within 24 hours of the expiration of the timeframe. Plans should not auto-forward cases to the Part D QIC if the timeframe has not expired or if the plan has already issued a decision.

Resource: Sections 70.7, 70.7.1, 70.8.1, and 70.8.2, Chapter 18, *Medicare Prescription Drug Benefit Manual*

Issue: Auto-forwarding Cases to the Part D QIC

Reminder: When a plan fails to notify an enrollee of a coverage determination or redetermination within the applicable timeframe, the plan must auto-forward the case to the Part D QIC, Maximus, within 24 hours of the expiration of the timeframe. In all cases, enrollees must be notified of decisions as expeditiously as their health requires, but no later than 24 hours for expedited coverage determinations and 72 hours for standard coverage determinations. Enrollees must be notified of redetermination decisions no later than 72 hours for standard cases and no later than 7 days for standard cases. If a coverage determination request involves an exception, the plan's timeframe is tolled until the plan receives the prescribing physician's supporting statement. Plans should not auto-forward cases to the Part D QIC if the timeframe has not expired or if the plan has already issued a decision. Cases that are improperly auto-forwarded to the Part D QIC because the plan's adjudication timeframe has not expired will be remanded to the plan for proper processing.

Resources: Sections 40.4 and 70.10, Chapter 18, *Medicare Prescription Drug Benefit Manual*
Section 5, *Part D QIC Reconsideration Procedures Manual,* www.MedicarePartDAppeals.com

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Issue: Prompt Submission of Case Files to the Part D QIC

Reminder: When a Part D plan receives a request for a case file from the Part D QIC, the plan must forward the complete case file to the Part D QIC within 24 hours of the request for expedited cases and within 48 hours of the request for standard cases. Failure to promptly forward the complete case file to the Part D QIC may result in unnecessary delays in the Part D QIC's ability to begin processing the reconsideration request. The Part D QIC is also subject to short adjudication timeframes and must notify enrollees of decisions within 72 hours (expedited cases) or 7 days (standard cases).

Part D plans must use the *Reconsideration Case File Transmittal Form* developed by the Part D QIC and be certain to include the plan's contract number, plan ID number, and formulary ID number.

Resources: The *Reconsideration Case File Transmittal Form* can be downloaded from:
www.MedicarePartDAppeals.com
Section 70.20, Chapter 18, *Medicare Prescription Drug Benefit Manual*
Section 5, *Part D QIC Reconsideration Procedures Manual*

Issue: Part D QIC Information on Redetermination Notices

Reminder: Plans must include the Part D QIC filing information on the Redetermination Notice/Denial of Medicare Prescription Drug Coverage, including the Part D QIC's fax number. Including the fax number will facilitate an enrollee's ability to quickly request a reconsideration. CMS has developed a model Request for Reconsideration form that plans must include with each adverse Redetermination Notice. This model Request for Reconsideration will be included in the revised Chapter 18 of the *Medicare Prescription Drug Benefit Manual*. In addition, the model Redetermination Notice is being revised and will also be included in the revised Chapter 18 of the *Medicare Prescription Drug Benefit Manual.*

Resource: Maximus contact information, including filing locations (address/fax), is set forth on page one of the *Part D QIC Reconsideration Procedures Manual* at www.MedicarePartDAppeals.com

The model Request for Reconsideration form and revised model Redetermination Notice will be contained in Appendix 13, Chapter 18 of the *Medicare Prescription Drug Benefit Manual*. The revised version of Chapter 18 will be posted in early April 2006.

Issue: Availability/Accessibility of Plan Prior Authorization Forms

Reminder: Where an enrollee/physician is attempting to satisfy a PA requirement and the plan has a PA form applicable to the requested drug, the plan should promptly provide the physician with the necessary PA form(s). Plans should make every reasonable effort to provide prescribing physicians with clear instructions on what information is needed to make timely coverage determinations and should provide physicians with any applicable forms that the plans have available. Plans should make these forms readily available, such as by posting all such forms on a webpage dedicated to PA/exceptions/appeals issues. CMS will work with plans to provide links to these web pages.