

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



CENTER FOR BENEFICIARY CHOICES

MEMORANDUM

TO: Medicare Prescription Drug Plan Applicants

FROM: Bob Donnelly, Director, Medicare Drug Benefit Group

RE: Timeline and Process for Issuing Determinations on PDP Applications

DATE: May 9, 2005

This communication provides Medicare Prescription Drug Plan (PDP) applicants with information on CMS' timeframe for review and approval of applications. This year of Part D pre-implementation is also a year of challenges – for you as our partners in Medicare Part D and for CMS. In our design and review of the Part D application, we endeavored to provide flexibility in timeframes, thereby increasing the opportunity for you to meet the requirements of Part D sponsors.

The Part D application is clear that applicants who cannot meet either the licensure waiver or pharmacy access requirements at the time of the application can provide later submissions. State licensure waiver packages must be sent to CMS no later than June 1, 2005. Applicants that did not have an adequate Part D pharmacy network by the application deadline in March, 2005 are given the opportunity to resubmit their pharmacy network analysis on August 1, 2005. Additional guidance on submitting these pharmacy access analyses will be provided in early June 2005.

As we conduct the Part D application reviews, we have notified applicants of incomplete and/or deficient sections of the application along with target dates to resubmit the information. As noted on the attached timeline, any such resubmitted information **must be completed and submitted to CMS no later than COB June 1, 2005.**

For applicants who meet all sections of the application (with the exceptions of follow-up on licensure waivers and/or the August 1 pharmacy access submission), CMS will issue conditional approval letters. These letters will be issued prior to June 6, 2005 – the date that bid submissions are due. For applicants that have deficiencies in their applications on June 1, 2005 other than these areas of licensure and/or pharmacy network, a letter of intent to deny will be issued.

Applicants that receive a letter of intent to deny may attempt to cure within 10 days the deficiencies identified by CMS. If the additional documentation proves satisfactory, these

applicants will receive conditional approval letters. Such applicants may also request a formal denial or withdraw their applications.

By mid-September, we plan to send contracts to those applicants that have met all of the application requirements and whose bids we have accepted subsequent to the negotiation process. At that time, entities that fail to meet licensure waiver and/or pharmacy network requirements will receive a letter of intent to deny; similarly, entities whose bids are not accepted will be sent letters that explains the basis for the denial.

In making this announcement, we wish to clearly state the implications of this review process. Allowing PDP applicants additional time to complete and satisfy the licensure waiver and pharmacy access requirements could impact applicants' ability to appeal application denials in time to participate in contract year 2006. Regulations at 42 CFR Part 3422, Subpart N, allow applicants to seek three levels of administrative review of application denials. Those regulations further provide that entities seeking to appeal a denial must receive a favorable determination on appeal by July 15th in order for the contract to be effective on January 1 of the following year. Accordingly, PDP applicants that take advantage of the extended time frame for submitting their licensure waiver packages, and who do not demonstrate pharmacy access compliance until the August 1, 2005 follow-up submission, could be unable to participate in the 2006 contract year if CMS determines their applications are insufficient. This will be the case even if the applicant prevails under the appeals procedures of subpart N of the regulation. A favorable re-determination on appeal received after July 15, 2005 would render the applicant qualified to contract as a Part D sponsor for the 2007 contract year (although the applicant would still need to submit a bid for 2007).

Each entity must assess its own interests in choosing how to proceed. The best approach is to address all application requirements prior to the end of May 2005 (except the follow-up pharmacy access requirements, which are due August 1, 2005). CMS will not necessarily know by June 6 (when bids are due) if an applicant's licensure waiver package is sufficient, depending on when it is sent. Additionally, applicants who could not fully demonstrate Part D pharmacy access in their initial applications were provided the opportunity to provide a follow up analysis on August 1, 2005. However, for these applicants, CMS will not know by June 6 whether the applicant meets pharmacy access requirements, as the review will not occur until August 2005.

Applicants who receive a letter of conditional approval pre-June 6, 2005 should work with CMS through the licensure waiver approval process, and to build their pharmacy networks and provide the submission due August 1, 2005. Some may wish to request a formal denial to enable them to pursue a formal appeal under Subpart N in the hopes of gaining a favorable re-determination prior to the July 15, 2005 cut-off. We will issue formal denials in lieu of conditional approvals if requested. Others may choose to withdraw their applications

CMS is very pleased with the industry's response to the Part D drug benefit solicitation. We appreciate your cooperative spirit in this extraordinary year, and remain committed to working with applicants to ensure that beneficiaries have quality drug benefit choices.

Please contact Scott Nelson at 410-786-6604, or Marla Rothouse at 410-786-8063 if you have questions about this timeline and process for PDP applications.

Attachment: PDP Plan Application Timeline

Attachment 1

2006 Medicare Part D Prescription Drug Application Timeline

March 23, 2005	Receipt of PDP Applications
April 22, 2005	Receipt of drug plan formularies
May 6, 2005	CMS releases Memo and Timeline to PDP Applicants
June 1, 2005	Last day for applicants to send licensure waiver packages to CMS
June 1-6, 2005	CMS sends "Status of Application" letters to PDP applicants. An applicant can receive either a letter of intent to deny or a conditional approval. Conditional approvals will be granted only to applicants whose remaining open issues (if any) are review of the licensure waiver packages sent by June 1, 2006 and/or receipt of the follow up pharmacy access analyses by August 1, 2005. The conditional approval letters will indicate steps that remain to be completed by the plan, such as bid submission and successful negotiation of pricing, benefits, and cost-sharing. All other deficiencies (other than the licensure waiver and pharmacy access issues identified above) will result in a letter of intent to deny indicating that the applicant has 10 days to cure the deficiencies, and steps to seeking appeals rights.
June 6, 2005	PDP plan bids are due.
July 15, 2005	Last date to receive a favorable re-determination under the appeals process
August 1, 2006	Follow-up pharmacy access analyses due.
August 26, 2005	Deadline for CMS review of State licensure and pharmacy networks. CMS begins to issue letters of intent to deny for insufficient evidence of State licensure or pharmacy access. Applicants may withdraw their application.
September 1, 2005	CMS begins to sign contracts for successful applicants who also have approved bids.
September 14, 2005	Last date for signing contracts. Date by which all contract approvals are due to HPMS. Last date to finalize variable pages in "Medicare and You".