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MEMORANDUM

Date: September 29, 2006

To: All Part D Sponsors

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

Subject: Single State Licensure Waivers for 2008 – Submission of State Application

If you are submitting a new application to become a Prescription Drug Plan (PDP) sponsor with the contract beginning January 1, 2008, CMS can no longer grant "special waivers" of the risk bearing license requirement pursuant to 42 CFR §423.410(d). Special waivers for PDP sponsors requesting a service area expansion for 2008 which includes states that don't currently hold a risk license also won't be granted. If you need to submit a waiver for one of these situations, you will need to apply for a licensure waiver on the basis of the authority provided under 42 CFR §423.410(b) or (c).

In order for CMS to grant a state licensure waiver pursuant to 42 CFR §423.410(b), the waiver applicant must demonstrate that by the time the waiver application is submitted to CMS, either

- 1) The State has already had a substantially complete license application for 90 days and has not made a determination, or
- 2) The State has denied the license application for one of the reasons specified in 42 CFR §423.410(b)(2) through (b)(4).

In order to apply for a CMS waiver based on the ground that a State did not act within 90 days of receiving a substantially complete application, the State must receive any new State license applications no later than December 1, 2006. This will help ensure that States have time to confirm "the receipt and completeness of the application" which is necessary to establish that the 90-day period has been met. If you file the application by December 1, 2006, it will allow the State time to process the application and either approve or deny it.

The specific grounds for licensure waivers for 2008 are below:

1. The State hasn't completed action on a licensing application within 90 days of the date of the State's receipt of a substantially complete application. 42 CFR 423.410(b)(1).
2. The State doesn't have a licensing process in effect with respect to PDP sponsors. 42 CFR 423.410(c).
3. The State has denied the license application on the basis of one of the following: (a) material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or (b) the

- State requires, as a condition of licensure, the Applicant to offer any product or plan other than a PDP. 42 CFR 423.410(b)(2).
4. The State has denied the licensure application, in whole or in part, for one of the following reasons: (a) on the basis of the Applicant's failure to meet solvency requirements that are different from the CMS solvency standards; or (b) the State has imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the information or documentation requirements in the CMS solvency standards. 42 CFR 423.410(b)(3).
 5. The State has denied the licensure application on the basis of grounds other than those required under Federal law. 42 CFR 423.410(b)(4).

Any questions regarding this issue, including the documentation requirements for 2008 waivers, should be directed to Joseph Millstone (joseph.millstone@cms.hhs.gov) or Aaron Eaton (aaron.eaton@cms.hhs.gov).