

General PACE/Part D Implementation Issues

As we move into the latter part of the year, organizations are hard at work with Part D implementation preparations. CMS continues to release new implementation guidance to PDPs, MA-PD plans, and PACE organizations via training conferences, user group calls, and HPMS notices. Because PACE organizations are being treated similarly to MA-PD plans for purposes of Part D, the guidance is generally addressed to MA-PD plans with the expectation that PACE organizations will also comply. Yet, because a large portion of the Part D regulation has been waived on behalf of PACE organizations it is often necessary to further clarify the MA-PD guidance on behalf of PACE.

Several of the most recent questions raised by PACE organizations and CMS responses are included below. As always, if you have additional questions about the applicability of CMS Part D guidance to your PACE organization, please contact Brenda Hudson at:

<mailto:Brenda.Hudson@cms.hhs.gov>

Thank you for your diligent efforts in implementing Part D into your organization.

Brenda Hudson

Question:

During the 9/7/05 CMS User Group call a reference was made to connectivity testing that should occur sometime this month. What does this mean for PACE organizations?

Answer:

Plans that will be sending data directly (not using a third party) to CMS are required to test their connectivity - essentially we are just making sure they are preparing to send/receive files. If they have a T1 line and will use Connect:Direct to transfer files, the test is an actual exchange of an empty file, just to make sure the setup/configuration has been completed properly and everything seems to be working. For plans that will use Secure FTP or their Internet web browser to send files, they must complete some setup that will allow them to get to a login screen and send a screen shot of that login screen to us. This provides us with some assurance that they have started preparing their systems for day one.

Question:

During the 9/7/05 CMS User Group Call plans were told to list their primary point of contact for systems plan testing. What does this mean for PACE organizations?

Answer:

The CSMM help desk (AKA MMA Technical Help Desk) is collecting primary points of contact for each organization's overall testing effort, which could in some cases be the same as the 'systems contact' in HPMS, but in many cases will be a different testing coordinator. Plans were asked to send an email to mmahelp@cms.hhs.gov with the name, phone number, and email address of their testing contact, and all associated contract numbers, and any third parties/subcontractors they intend to use, and for what function.

Question:

During the 9/7/05 CMS User Group Call a reference was made to "Plan Data Preview". What does this mean for PACE organizations?

Answer:

The data preview is only for the PDPs and MAPDs that will be included on the plan finder site. As always, this excludes PACE and employer plans.

Question:

CMS will conduct a one day Compliance Conference for Prescription Drug Plans and Medicare Advantage Plans at the Renaissance Harbor Place Hotel in Baltimore, Maryland on September 28, 2005. Should PACE organizations attend?

Answer:

We recognize that it may not be feasible for small organizations such as PACE to attend. However, much of the content presented will be relevant to PACE organizations such as: the CMS organizational structure and responsibilities. PACE organizations should be aware that under Part D, they will be submitting materials to many components within CMS. It will be useful for PACE organizations to familiarize themselves with the various components of CMS and their associated Part D requirements. Some of these requirements include: formulary compliance (for those PACE organizations with formularies), CMS reporting requirements and CMS data uses, and the role of Medicare Drug Integrity Contractors (MEDICS).

We encourage those organizations that are unable to attend to visit the conference website at:

<http://cms.c2ti.com> in the days preceding the conference in order to obtain conference materials, including presentations from CMS Part D compliance experts.

Question:

PACE organizations that have elected to utilize formularies are unclear as to what is required of them in terms of notifying participants of formulary changes and other formulary related marketing requirements.

Answer:

PACE organizations have received a waiver of the Part D marketing requirements outlined in section 423.50 of the regulation as well as the dissemination of Part D plan information located in section 423.128. However, those organizations that submitted formularies are required to adhere to Part D formulary requirements as outlined in section 423.120(b) of the regulation.

Specifically, these organizations must:

- Develop a Pharmacy and Therapeutic Committee
- Provide an Adequate Benefit
- Provide a Transition Process
- Organizations are limited to changing therapeutic categories and classes other than at the beginning of each plan year
- Provide Notice Regarding Formulary Changes
- Limit formulary changes
- Educate Providers and Patients Concerning Formulary

The MMA did not exempt PACE organizations from the original requirement of providing participants with all necessary services (including prescription drugs). As a result, we anticipate the provision of a generous formulary and a very limited need on the part of PACE organizations to make mid-year changes to therapeutic categories, classes of drugs, or formularies in general. PACE organizations that have elected to use formularies must adhere to the requirements outlined in section 423.120(b).

Question:

When should PACE organizations expect to receive their Part D contracts?

Answer:

PACE organizations that receive final approval to provide Part D will be receiving an appendix to their PACE program agreement in Fall 2005.