



## CENTER FOR DRUG and HEALTH PLAN CHOICE

**Date:** November 5, 2008  
**To:** All Part D Sponsors except PACE organizations  
**From:** Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group  
**Subject:** 2009 Part D Readiness Checklist Assessment Tool Request

On August 27, 2008, CMS released the 2009 Part D Readiness Checklist. The annual Readiness Checklist reminds Part D sponsors of established requirements critical to ensuring a plan's enrollees receive effective drug coverage in 2009. We asked that Part D sponsors review the checklist and take all necessary measures to ensure that these key requirements are in place for CY 2009 open enrollment and a smooth transition to the 2009 contract year.

Similar to last year, we are once again asking all Part D sponsors to report back to us the results of their readiness activities. Per the instructions below, please access the electronic version of the 2009 Part D Readiness Checklist Assessment Tool to relay the current status of your preparations for 2009. The assessment contains two updates: (1) a question was added regarding Explanation of Benefits (EOB), and (2) the Annual Notice of Change (ANOC) question was expanded. For your convenience, a hard copy of the Readiness Checklist Assessment Tool is attached to this memo; however, we will only accept electronic submissions. Note: The August 27<sup>th</sup> version of the checklist includes the resource documents and references for the key requirements. Organizations that offer both individual and employer-group products should answer in the context of their readiness for their individual market product line(s).

Simultaneous to the release of this memo, CMS is sending an email from [DrugBenefitImpl@cms.hhs.gov](mailto:DrugBenefitImpl@cms.hhs.gov) to each Compliance Officer with the link to the 2009 Part D Readiness Checklist Assessment Tool. Please click on the link in that email to complete and submit the tool electronically to CMS.

We are aware that some organizations will not receive the email due to firewall constraints. If your organization's Compliance Officer did not receive the email notification, or if it is more convenient for you, paste the following link into your web browser to access and complete the tool:

<http://vovici.com/wsb.dll/s/11dc4g38a78>

Please note that your organization's Unique ID for accessing the tool is your CMS contract number (e.g., S1234/H1234). For security reasons, you must also enter your organization's Compliance Officer's email address in the password field. Organizations with more than one contract number may complete the tool once for each contract number, or alternatively, if responses are identical across contract numbers you will have the option (within the online tool) of submitting a list of the other contract numbers to which your responses apply.

CMS strongly recommends that organizations print their responses prior to moving to the next page. Once you submit your responses on the last page, you will not have the opportunity to return to correct, update, or print your original responses. However, if you reenter and resubmit your complete set of responses, CMS will use the latest submission up until the deadline as your official version. Unlike previous years, CMS will not email a copy of your responses.

Please submit the 2009 Part D Readiness Checklist Assessment Tool by close of business on **November 21, 2008**.

Thank you in advance for taking the time to complete the tool. CMS is very pleased to continue working with the industry to provide prescription drug coverage to Medicare beneficiaries. We appreciate your cooperative spirit and remain committed to working with Part D sponsors to ensure that beneficiaries have continued access to Part D drugs during the upcoming year.

If you have any questions about the 2009 Part D Readiness Checklist, please contact Linda Anders at [Linda.Anders@cms.hhs.gov](mailto:Linda.Anders@cms.hhs.gov) or your Account Manager.

Thank you.

## 2009 Part D Readiness Checklist Assessment Tool

*NOTE: For your convenience, a hard copy of the Readiness Checklist is below; however, we will only accept electronic submissions as described in the attached memo.*

Please submit this 2009 Part D Readiness Checklist Assessment by November 21, 2008. Thank you!

### Organization Status for CY 2009

- My organization is a NEW Part D Sponsor beginning in CY 2009 (my organization does not have any Part D contracts of any type operational in CY 2008)
- My organization is an EXISTING Part D Sponsor with at least one active CY 2008 contract

Note: You will be presented with questions specific to whether your organization is a New or Existing Part D Sponsor.

### Connectivity

1. For New 2009 Sponsors only: **Have you established connectivity (Gentran or Connect:Direct) with CMS systems for purpose of electronic file transfers?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

2. For New 2009 Sponsors only: **Have you fulfilled all testing requirements established by the Office of Information Services?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

3. For New 2009 Sponsors only: **Have you registered an approved External Point of Contact (EPOC) in Individuals Authorized Access to CMS Computer Services (IACS) per the User Guide available from the MMA Help website, [http://www.cms.hhs.gov/MMAHelp/07\\_IACS.asp#TopOfPage?](http://www.cms.hhs.gov/MMAHelp/07_IACS.asp#TopOfPage?).**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

4. For New 2009 Sponsors only: **Have you registered appropriate staff for submitter and representative roles in IACS to ensure active access to CMS user interfaces and file transfer execution to CMS systems?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

5. For New 2009 Sponsors only: **Has your organization met Prescription Drug Event (PDE) testing and certification requirements outlined at <http://csscooperations.com/>?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

## **Systems & Data**

1. **Are key staff registered for:**

- a) HPMS access (<http://www.cms.hhs.gov/AccessstoDataApplication/>),
- b) Bi-weekly CMS Part C & D User Calls, and
- c) MMA Help Desk Announcements?

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

2. **Have you ensured contact information in HPMS is current, and that you have procedures to update the information as applicable?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

3. **Was your organization's Financial Information Report (FIR) processor(s) certified by November 1st per the Automated TrOOP Balance Transfer requirements?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**4. Is your organization fully prepared to respond on January 1, 2009 to TrOOP Balance Transfer (TBT) transactions for 2009 beneficiaries?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**5. Has your organization ensured that your network pharmacies will send, and your organization will be able to accept, electronic transactions with:**

**a) The pharmacy's National Provider Identifier (NPI) in all cases, and**

**b) A prescriber ID in all cases** (which must be the prescriber's NPI whenever known, and when not available, another non-NPI identifier such as a DEA number or state license number - as permitted under state law)?

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**6. Has your organization demonstrated, or is it prepared to demonstrate, the ability to process the bi-weekly deemed Low Income Subsidy (LIS)/ Premium Data file received from CMS, and upload the LIS contract file data to the Acumen LIS match rate website?**

- Yes
- No
- Not Applicable - My organization's service area is limited to the U.S. Territories and LIS is not applicable

If no, please explain and include your expected readiness date: \_\_\_\_\_

**7. Are processes in place to research, correct, and resubmit PDE rejections per CMS guidelines?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**8. Have you ensured that data submission and error correction processes are/will be maintained for multiple payment years?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**9. Have you ensured procedures are in place for reconciliation of monthly reports to ensure that PDE data maintained by CMS and the sponsor's internal records correspond?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**10. Did you submit accurate CY 2009 pricing data for posting on the Drug Plan Finder?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**11. Have you ensured systems and operations are in place to accommodate, by January 1, 2009, the new independent review entity (IRE) correspondence format for purposes of tracking and processing appeals?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

## **Best Available Evidence**

**1. Have you ensured your organization meets CMS requirements for accepting specific forms of Best Available Evidence (BAE) to establish the subsidy status of a full benefit dual eligible beneficiary?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**2. Have you ensured your organization meets the CMS requirements for accepting specific forms of BAE to establish a beneficiary is institutionalized and qualifies for zero cost-sharing?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**3. Have you ensured your organization will provide beneficiaries access to covered Part D drugs at the reduced cost-sharing level as soon as one of the specific forms of BAE is presented?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**4. Are procedures in place to:**

**(a) Accept BAE at point-of-sale,**

**(b) Update systems within 48-72 hours of receipt of the documentation, and**

**(c) Ensure correct charges of premium, deductible and cost sharing to low-income subsidy beneficiaries?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**5. Does your organization have a process in place for assisting individuals who claim to be low income subsidy eligible based on being full- or partial-dual eligibles but who cannot provide the documentation?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**6. Does your organization's website include a link to the BAE page on the CMS website?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

## **Reporting**

**1. Have you ensured a process is in place to submit all Part D CY 2009 reporting requirements to CMS according to specified timelines?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

2. For Existing Part D Sponsors only: **If your organization is changing first tier, downstream, and related entities for any key Part D function (i.e. adjudication and processing of claims) for CY 2009, have you followed all steps in the 2009 Call Letter, including updating contract(s) and preparation to update 4Rx the last week in December to reflect the new information?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

### **First Tier, Downstream, Related Entity Contracting and Oversight**

1. **Have you submitted the offshore subcontractor attestation to CMS for each offshore contractor, to the extent applicable?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

2. **Has your organization ensured that first tier, downstream, and related entities' contracts have been amended to include the standard reimbursement update, if applicable?**

- Yes
- No
- Not Applicable - My organization does not use a prescription drug pricing standard for pharmacy reimbursement

If no, please explain and include your expected readiness date: \_\_\_\_\_

If yes, please provide the source of the reimbursement standard used/to be used by your organization. \_\_\_\_\_

3. **Do your executed Home Infusion pharmacy contracts include a provision for delivery within 24-hours of discharge from an acute setting, or later if so prescribed?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

4. **Are processes in place to provide timely payment to pharmacies, per your contracting terms with network pharmacies?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_



**5. Have you ensured all requirements for CY 2009 are in place and will be followed according to CMS' contract, 2009 application(s), Prescription Drug Benefit Manual, guidance, and other advisory materials?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

## **Marketing**

**1. Has your organization implemented procedures and safeguards to ensure the CY 2009 CMS-approved formulary matches marketed formulary both in print and on your organization's website?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**2. Do your marketing materials include all required information and did the materials undergo thorough quality control prior to submission to CMS for review?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**3. Does your organization meet the CMS requirement of submitting at least 90 percent of the materials that qualify as File & Use under this process?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**4. Is your organization marketing CY 2009 benefits to Medicare beneficiaries using CMS-approved and CMS-File & Use accepted material?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**5. Did your organization request use of and sign the applicable licensing agreement for the Medicare Prescription Drug Benefit Program Mark, if using the Mark in CY 2009?**

- Yes
- No

- Not Applicable - Not using the Medicare Prescription Drug Benefit Program Mark in CY 2009

If no, please explain and include your expected readiness date: \_\_\_\_\_

**6. Is your organization in compliance with existing and new (as established by MIPPA and subsequent CMS regulations) prohibitions and limitations on certain sales and marketing activities?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**7. Is your organization using the model Explanation of Benefits (EOB), or an approved non-model EOB, that fully implements ALL required elements?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**8. For Existing Part D Sponsors only: Did your organization cease marketing CY 2008 plans when marketing of CY 2009 plans began? All CY 2008 plan marketing must have ceased by October 31, 2008.**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**9. For Existing Part D Sponsors only: Did members receive the CY 2009 annual benefits notices on time? CMS requires enrollees receive the ANOC/EOC and formulary no later than October 31st.**

- Yes – SKIP TO Question #12
- No – CONTINUE TO Question #10

**10. For Existing Part D Sponsors only: The annual benefit notices were not received by beneficiaries by October 31, 2008 due to:**

- Late Mailing
- Initial annual benefits notices were inaccurate/incorrect and a subsequent mailing was received later than October 31<sup>st</sup>
- Other (please specify) – \_\_\_\_\_

CONTINUE TO Question #11

11. For Existing Part D Sponsors only: **Provide the date the annual notices were received by beneficiaries.**
- 

SKIP TO Next Section "Enrollment & Disenrollment"

12. For Existing Part D Sponsors only: **Were the annual benefits notices accurate/correct the first time, requiring no subsequent mailing?**

- Yes – SKIP TO Next Section "Enrollment & Disenrollment"
- No – CONTINUE TO Question #13

13. For Existing Part D Sponsors only: **Provide details of the initial annual benefits notices' inaccuracies and the corrections made. Include the date the corrected materials were received by beneficiaries.**
- 

CONTINUE TO Next Section "Enrollment & Disenrollment"

## **Enrollment & Disenrollment**

1. **Have you ensured a current CY 2009 paper enrollment form is available for potential enrollees to request enrollment during valid periods?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

2. **Do you have an established process to download enrollment on at least a daily basis from the Online Enrollment Center (OEC)?**

- Yes
- No
- Not Applicable - My organization opted out of participating in the OEC for 2009

If no, please explain and include your expected readiness date: \_\_\_\_\_

3. **Do you have processes in place to send individuals an acknowledgment notice within 10 calendar days of receiving an enrollment request from that individual, as well as a confirmation notice within 10 days of receiving a confirmation of enrollment from CMS?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**4. Do you have a process in place to transmit enrollment and disenrollment transactions to CMS within 7 calendar days of receipt?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**5. Do you have a process in place to send individuals an acknowledgment notice within 10 calendar days if you receive the disenrollment request directly from the individual?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**6. Have you ensured the enrollment process allows for appropriate up-front denial or CMS rejection in accordance with CMS requirements, e.g. providing beneficiary notices within 10 days of receipt of enrollment request or CMS rejection notice via weekly or monthly Transaction Reply Report (TRR), whichever is earliest?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**7. Have you ensured that CMS TRR and other Medicare Advantage Prescription Drug System (MARx) reports are/will be reviewed and processed in a timely and consistent manner, and that appropriate actions to resolve rejections and correct errors are/will be taken?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**8. Do you have a process in place to transmit active 4Rx data for:**  
**(a) Plan-generated enrollment transactions, and**  
**(b) CMS-generated enrollments via an update/72 transaction within 3 business days of availability of the TRR transmitting the CMS enrollments?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**9. Do you have an established process in place to request enrollment and disenrollment corrections in accordance with CMS requirements?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**10. Have you ensured systems and processes are in place to provide appropriate and timely referrals to IntegriGuard?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

### **Late Enrollment Penalty (LEP) and Creditable Coverage**

**1. Have you ensured processes are in place so that beneficiaries receiving Low-Income Subsidy (LIS) are not subject to a Late Enrollment Penalty?**

- Yes
- No
- Not Applicable - This contract's service area is limited to the U.S. Territories & LIS is not applicable

If no, please explain and include your expected readiness date: \_\_\_\_\_

**2. Is your organization using the model Late Enrollment Penalty Attestation and model notice to remind enrollees of the need to submit a timely attestation if they have prior creditable prescription drug coverage?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**3. Do you have a process in place to accept State Pharmaceutical Assistance Programs (SPAPs) attestations for creditable coverage on their members' behalf?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**4. Have you ensured processes are in place to allow beneficiaries or their authorized representatives to complete\* the entire creditable coverage attestation over the telephone, including documentation of the call and ensuring that it captures all of the requisite elements of the attestation and amend the beneficiary's record?**

**\* This telephonic option is only available after your organization has mailed the attestation form to the member.**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

## **Coordination of Benefits (COB)**

- 1. Do you have established systems and processes to regularly (i.e. upon enrollment and once annually thereafter) survey plan enrollees regarding any other prescription drug coverage they may have and report that information - including, if known, any Rx identifiers (RxBIN, PCN, RxGRP, and RxID) - to the COB Contractor so that it can be validated, captured, and maintained in Medicare Beneficiary Database (MBD) for COB purposes?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

- 2. Do you have established systems and processes for at least weekly COB data report/file processing?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

## **Claims Process/Transition/Point of Sale (POS)**

- 1. Is your staff trained on the transition policy and any related IT systems necessary to accommodate administration of the transition policy?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

- 2. Have you ensured systems are in place to continue to provide necessary drugs to an enrollee via an extension of the transition period, on a case-by-case basis, to the extent that his or her exception request or appeal has not been processed by the end of the minimum transition period?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**3. Does your organization have systems and staff in place to ensure that claims (including appropriate transition supply claims) can be filled at Point of Sale for all enrollees?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**4. Are your organization's systems set up to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**5. Does your organization have systems in place to ensure immediate refills of Part D medications to any beneficiary located in an "emergency area," defined as the area in which the President has declared a major disaster or Secretary of the Department of Health & Human Services has declared a public health emergency?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**6. Have you ensured procedures are in place to provide vaccine administration per Part D Manual Chapter 6?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

## **Customer Service**

**1. Have you ensured that call centers will be staffed appropriately to handle increased call volume during the annual enrollment period and the first 60 days of 2009 operations?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**2. After the first 60 days of CY 2009 until the next annual enrollment period, have you prepared to have call centers remain open until 8:00 p.m. in all regions where the sponsor offers Part D?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**3. Have you ensured call centers are able to accommodate non-English speaking beneficiaries?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**4. Does your organization have appropriate member services and pharmacy help desk scripting so Customer Service Representatives are able to identify cases involving BAE and to allow callers either to submit BAE or request assistance with acquiring BAE?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**5. Have you ensured your organization follows/will follow, at all times, the procedures outlined in the Complaints Tracking Module (CTM) Plan Standard Operational Procedures?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_

**6. Have you implemented processes to ensure timely resolution of beneficiary complaints, dependent upon issue level of complaint?**

- Yes
- No

If no, please explain and include your expected readiness date: \_\_\_\_\_



## **Apply Responses to other Part D contracts**

- 1. Organizations with more than one Part D contract have the option of completing the Readiness Assessment online one-time and apply those responses to your other Part D contracts when all responses are IDENTICAL.**
    - Apply the responses from this online submission to other contracts (when responses are IDENTICAL – SKIP TO Question #2
    - Complete individual submissions by contract number (when only one Part D contract exists, or responses will differ by contract number) – SKIP TO End
  - 2. Please apply these 2009 Readiness Assessment responses to the following contracts (responses are IDENTICAL):**
- 

## **End**

**Thank you for taking time to complete the CY 2009 Medicare Part D Readiness Assessment.**

**When you have completed all responses, click "Submit CY 2009 Part D Assessment Now" below.**

**Note: Once you click the submit button below, you cannot return to edit or print this set of responses. CMS will use the latest submission as the official version when more than one submission is received for a specific contract number. This will allow you to make corrections to your submission after you click the submit button.**

**Contact [Linda.Anders@cms.hhs.gov](mailto:Linda.Anders@cms.hhs.gov) if you have questions.**