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Centers for Medicare & Medicaid Services
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CENTER FOR DRUG and HEALTH PLAN CHOICE

Date: August 27, 2008

To: All Current and Pending Part D Sponsors

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

Subject: 2009 Part D Readiness Checklist

With the Annual Enrollment Period (AEP) fast approaching, we want to remind Part D sponsors of established requirements critical to ensuring a plan's enrollees receive effective drug coverage in 2009. The 2009 Part D Readiness Checklist (Attachment A) summarizes the key operational requirements as established in existing and new statute, regulations, Part D manual chapters, HPMS memos, applications and other advisory materials. Given the significance of these updates and changes, all Part D sponsors should review this checklist carefully and take the necessary measures to ensure that these key requirements are in place for CY 2009 open enrollment.

Similar to last year, CMS will expect Part D sponsors to perform their own audit of these requirements. At a later date, CMS will provide a timeline to Part D sponsors for reporting these results back to us through a secure information collection website.

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 need additional detail regarding requirements listed in the checklist, please refer to the appropriate CMS guidance or you can contact your account manager.

Attachment A: 2009 Part D Readiness Checklist

A. Systems, Data & Connectivity

- ☐ 1. For New 2009 Sponsors only: Establish connectivity (Gentran or Connect:Direct) with CMS systems for purpose of electronic file transfers. Connectivity methods (Gentran or Connect:Direct), setup instructions and forms are available in the Plan Reference Guide section of the MMA Help website, www.cms.hhs.gov/mmahelp/PRG.
- ☐ 2. For New 2009 Sponsors only: Fulfill all testing requirements established by the Office of Information Services.
(Plan Reference Guide for CMS Part C/D Systems, <http://www.cms.hhs.gov/MMAHelp/PRG/list.asp>)
- ☐ 3. For New 2009 Sponsors only: Register and approve 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.
- ☐ 4. For New 2009 Sponsors only: Register appropriate staff for submitter and representative roles in IACS to ensure active access to CMS user interfaces and file transfer execution to CMS systems.
- ☐ 5. Ensure key staff registers for HPMS access
(<http://www.cms.hhs.gov/AccessToDataApplication/>), bi-weekly CMS Part C & D User Calls and MMA Help Desk Announcements.
- ☐ 6. Update sponsor contact information in HPMS for the 2009 contract year. Changes to any HPMS contacts should be made immediately upon the effective date of the responsibility transfer.
- ☐ 7. Automated TrOOP Balance Transfer: Ensure organization is prepared by September 1, 2008 to initiate testing of new automated TrOOP balance transfer certification process.
(HPMS Memo: 03/18/2008)
- ☐ 8. Automated TrOOP Balance Transfer: Ensure the Part D Sponsor's pharmacy benefits manager (PBM) or other processor is prepared to be certified by November 1, 2008 and be fully prepared to respond to TrOOP Balance Transfer transactions for 2009 beneficiaries on January 1, 2009.
(HPMS Memo: 08/06/2008)
- ☐ 9. Ensure network pharmacies send and are able to accept claim (billing) transactions with
 - o The pharmacy's NPI in all cases, and
 - o A prescriber ID in all cases (which must be the prescriber's National Provider Identifier (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) in the transaction.
(HPMS Memo: 05/01/2008)
- ☐ 10. Demonstrate, or are prepared to demonstrate, the ability to process 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.

Part D sponsors are required to match their LIS data files to the CMS data files. To facilitate the data matching, sponsors are required to submit monthly LIS data files to the CMS contractor, Acumen, LLC for the purpose of analyzing the consistency of the two files.

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Sponsors are responsible for reviewing the Acumen, LLC reports, and resolving all discrepancies identified in those reports. Sponsors must achieve a greater than 95% match rate between their files and those of CMS. (HPMS Memo: 08/30/2006 & 10/30/2006)

- ☐ 11. For New 2009 Sponsors only: Ensure your organization meets Prescription Drug Event (PDE) testing and certification requirements outlined at <http://csscooperations.com/> (follow link, Enroll to Submit PDE). After completing certification, organizations must submit PDEs monthly.
- ☐ 12. Ensure systems and processes are in place to research, correct, and resubmit PDE rejections per CMS guidelines.
(HPMS Memo: 02/26/2008)
- ☐ 13. Ensure data submission and error correction processes are maintained for multiple payment years.
(HPMS Memo: 03/31/2008)
- ☐ 14. Ensure procedures are in place for reconciliation of monthly reports to ensure that PDE data maintained by CMS (which are the basis for Part D Payment Reconciliation) and the Sponsor's internal records correspond. Monthly reports include:
 - o DDPS Cumulative Beneficiary Summary,
 - o PDE Accounting Report, and
 - o Part D Payment Reconciliation Report.

CMS strongly recommends that Sponsors contracting with third parties for PDE submission and reporting also receive copies of monthly reports directly from [CSSCOperations](http://csscooperations.com/) in addition to receiving the reports from the third party.

- ☐ 15. Ensure timely and accurate submission of CY 2009 pricing data for posting on the Drug Plan Finder.

The initial CY 2009 data submission period for live/public pricing data will be September 22 through September 23, 2008 - the data will be published on October 9, 2008 (tentative).
- ☐ 16. Ensure 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, including complying with effectuation and other regulatory requirements.

The new format will include only the first initial of the beneficiary's first name, the beneficiary's full last name, and the last four digits of the beneficiary's health insurance claim number (HICN). A complete HICN will no longer be used in IRE correspondence sent to beneficiaries.
(2009 Call Letter, pg. 69)

B. Best Available Evidence (primary reference documents: HPMS Memo 8/4/2008 and 2009 Call Letter)

- ☐ 1. Ensure 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.
(HPMS Memo: 08/04/2008)

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- ☐ 2. Ensure your organization meets the CMS requirements for accepting specific forms of BAE to establish a beneficiary is institutionalized and qualifies for zero cost-sharing.
(HPMS Memo: 08/04/2008)
- ☐ 3. Ensure your organization provides 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.
(HPMS Memo: 08/04/2008)
- ☐ 4. Implement procedures to accept BAE at point-of-sale and update systems within 48-72 hours of receipt of the documentation, and ensure correct charges of premium, deductible and cost sharing to low-income subsidy beneficiaries.
 - i. In cases involving immediate need (i.e., when the beneficiary has less than 3 days of medication available), sponsors must have a process in place to permit the beneficiary to receive an emergency supply of medication.
 - ii. Sponsors must then update their systems within 48-72 hours to allow the pharmacy to re-submit claims at the corrected cost-sharing level.
(2009 Call Letter, pg. 65; HPMS Memo: 08/04/2008)
- ☐ 5. Ensure your organization follows CMS' new process for assisting individuals without BAE documentation
(HPMS Memo: 08/04/2008)
- ☐ 6. Ensure your organization's websites contain a link to the CMS website BAE page (http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp#TopOfPage) containing CMS policy guidance.
(2009 Call Letter)

C. Reporting (primary reference documents: Prescription Drug Benefit Manual Chapter 5 and CMS website: [Plan Reporting and Oversight](#))

- ☐ 1. Ensure a process is in place to submit all Part D CY 2009 reporting requirements to CMS according to specified timelines.

The CY 2008 Reporting Requirements will remain in effect for CY 2009, and CMS will reconsider whether additional data should be collected in the future. The CY 2008 Reporting Requirements and technical specifications document are available on the [CMS website](http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage) (http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage).
- ☐ 2. For existing sponsors: Ensure all steps have been followed if changing your organization's PBM for the 2009 benefit year as detailed in the 2009 Call Letter.
 - o Update Pharmacy Benefits Manager (PBM) contract(s) to ensure compliance with the December 2007 compliance language.
 - o Prepare to update 4Rx data during the last week in December to reflect the new PBM.

D. Subcontractor Provisions, Contracting, and Oversight (primary reference documents: 42 CFR 423.505 (i)(3)(iv), MIPPA)

- ☐ 1. Submit offshore subcontractor attestation to CMS for each offshore contractor, to the extent applicable.
(HPMS: 07/23/2007 & 09/20/2007)

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- ☐ 2. Ensure contract with PBM is updated to address standard reimbursement update requirement.
 - Identify the type of standard reimbursement used (AWP, ASP, WAC)
- ☐ 3. Ensure that all Home Infusion downstream contracts have been amended to include provision for 24-hour delivery.
(42 CFR 423.120(a)(4)(iv))

The Policy & Technical Regulation issued in final April 5, 2008 requires a Part D plan's contracted home infusion pharmacies include a provision ensuring the delivery of home infusion drugs within 24 hours of discharge from an acute setting, or later if so prescribed.
- ☐ 4. Ensure processes are in place to provide timely payment to pharmacies, as per your contracting terms with pharmacies.
- ☐ 5. Ensure all requirements are followed according to CMS' application, contract, guidance, and other advisory materials.

Recall that the 2009 Part D application/solicitation is binding for contractors that applied using earlier application/solicitation versions.

E. Marketing (primary reference documents: Prescription Drug Benefit Manual Chapter 2, HPMS memos, 2009 Call Letter, and Medicare Improvements for Patients and Providers Act of 2008 (MIPPA))

- ☐ 1. Implement procedures and safeguards to ensure the CMS-approved formulary matches marketed formulary both in print and on the website.
- ☐ 2. Ensure all marketing materials include all necessary information and undergo thorough quality control review prior to submission of marketing materials for CMS review. Sponsors are accountable for the accuracy and completeness of their marketing materials.
(2009 Call Letter)
- ☐ 3. File & Use: Ensure your organization meets the CMS requirement for File & Use of marketing materials. Organizations are required to submit at least 90 percent of the materials that qualify for File & Use under this process. Sponsors may request a manual review of no more than 10 percent of materials that qualify for File & Use.
(HPMS: 04/09/2008)
- ☐ 4. Market CY 2009 benefits to Medicare beneficiaries using CMS-approved and CMS-File & Use accepted marketing materials. CY 2009 marketing may begin no earlier than October 1, 2008.
(Prescription Drug Benefit Manual Chapter 2)
- ☐ 5. For Existing Sponsors: Ensure you cease marketing CY 2008 plans when marketing of CY 2009 plans begins. All CY 2008 plan marketing must cease by October 31, 2008.
(Prescription Drug Benefit Manual Chapter 2)
- ☐ 6. For Existing Sponsors: Ensure members receive the CY 2009 annual benefits notices on time. Due on October 31, 2008:
 - Combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC), and
 - Formulary

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(2009 Call Letter)

NOTE: 800 series only/Employer Direct/Cost sponsors – different deadlines/timeframes

- ☐ 7. Request use of, and sign applicable licensing agreement for, the Medicare Prescription Drug Benefit Program Mark in 2008, if planning to use it during CY2009.
(Prescription Drug Benefit Manual Chapter 2)
- ☐ 8. Ensure your organization abides by the new (as established by MIPPA) and existing prohibitions and limitations on certain sales and marketing activities.
- ☐ 9. Ensure your organization meets the requirements regarding the appointment of agents and brokers and compliance with State information requests under MIPPA.

F. Enrollment/Disenrollment (primary reference documents: Medicare Managed Care Manual Chapter 2 & Prescription Drug Benefit Manual Chapter 3)

- ☐ 1. Ensure an updated CY 2009 paper enrollment form is available for potential enrollees to request enrollment during valid periods.

If allowing enrollment requests through other optional mechanisms such as telephone or internet, the sponsor must obtain appropriate CMS approval as necessary, and must meet all additional requirements per CMS guidance, e.g. must provide evidence of internet receipt, must record and maintain telephone enrollments, etc.
- ☐ 2. Establish/maintain a process to download enrollment on at least a daily basis from the Online Enrollment Center (OEC) [unless your organization has opted out of participating in the OEC].
- ☐ 3. Implement a process 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 calendar days of receiving confirmation of enrollment from CMS.
- ☐ 4. Ensure a process is in place to transmit enrollment and disenrollment transactions to CMS within 7 calendar days of receipt.
- ☐ 5. Implement a process to send individuals an acknowledgment notice within 10 calendar days if you receive the disenrollment request directly from the individual.

If a sponsor only learns of disenrollment from CMS confirmation (e.g. as a result of enrollment with another sponsor), the sponsor must send a notice confirming disenrollment within 10 calendar days of receiving the notice of disenrollment on the Transaction Reply Report (TRR).
- ☐ 6. Ensure the enrollment process allows for appropriate up-front plan 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 TRR (whichever is earliest).
- ☐ 7. Review and process CMS TRR and other MARx reports in a timely and consistent manner, and take appropriate actions to resolve rejections and correct errors.
- ☐ 8. Ensure a process is in place to transmit plan-generated enrollment transactions that include active 4Rx data, and for CMS-generated enrollments, to transmit active 4Rx data on an

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update transaction within 3 business days of availability of the TRR transmitting the enrollments.

- ☐ 9. Establish/maintain processes to request enrollment and disenrollment corrections in accordance with CMS requirements.
- ☐ 10. Ensure systems and processes are in place to ensure referrals to IntegriGuard are made appropriately and are timely.

G. Late Enrollment Penalty (LEP) & Creditable Coverage (primary reference documents: Prescription Drug Benefit Manual Chapters 4 & 18, and HPMS Update Memo 04/11/2008)

- ☐ 1. Ensure that beneficiaries receiving Low-Income Subsidy (LIS) are not subject to a Late Enrollment Penalty.

Each year since the beginning of the Medicare prescription drug program, CMS has operated under the Medicare payment demonstration entitled "Elimination of the 2006 Late Enrollment Penalty", such that Medicare beneficiaries who qualify for the low-income subsidy for Medicare prescription drug coverage were able to enroll in a Medicare prescription drug plan with no penalty. This demonstration has been made permanent by section 114 of the MIPPA. This provision will become effective January 1, 2009, when the demonstration ends.
- ☐ 2. Ensure, for enrollments received on or after June 1, 2008, use of the model Late Enrollment Penalty (LEP) Attestation and model notice to remind enrollees of the need to submit a timely attestation if they have prior creditable prescription drug coverage (serving as a "final notice" that an LEP will be imposed if enrollee does not return attestation for or call their plan with this information by the stated deadline).
(Part D Manual Chapter 4 and HPMS Memo Update: 04/11/2008)
- ☐ 3. Ensure procedures are in place to accept and process State Pharmaceutical Assistance Programs (SPAPs) attestations of creditable coverage on their members' behalf.
(Prescription Drug Benefit Manual Chapter 4)
- ☐ 4. Ensure 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.
(Prescription Drug Benefit Manual Chapter 4)

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

H. Coordination of Benefits (COB) (primary reference document: Prescription Drug Benefit Manual Chapter 14)

- ☐ 1. Establish/maintain systems and procedures to regularly (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 MBD for COB purposes.

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- ☐ 2. Establish/maintain systems and procedures for at least weekly COB data report/file processing. Sponsors are required to not only receive COB information but also to apply it to their system(s).

I. Claims Process/Transition/Point of Sale (POS) (primary reference documents: Prescription Drug Benefit Manual Chapters 5 & 6)

- ☐ 1. Ensure staff is trained on the transition policy and any related information systems necessary to accommodate administration of the transition policy.
(Prescription Drug Benefit Manual Chapter 6)

This includes implementation of policies and procedures necessary to override any non-safety-related drug claims edits (other than B vs. D and non-Part D drug edits) or otherwise ensure these are readily resolvable at point of sale for transition supplies.
- ☐ 2. Ensure 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.
(Prescription Drug Benefit Manual Chapter 6)
- ☐ 3. Establish a system and system support staff to ensure that claims (including appropriate transition supply claims) can be filled at Point of Sale for all enrollees.
(Prescription Drug Benefit Manual Chapter 5)
- ☐ 4. Revise payment systems, as applicable, to ensure they are set up to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount.
(Prescription Drug Benefit Manual Chapter 5)
- ☐ 5. Ensure/Guarantee 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 had declared a public health emergency.

It is the sponsor's responsibility to proactively monitor the FEMA website on an ongoing basis.
(Prescription Drug Benefit Manual Chapter 5)
- ☐ 6. If you use a standard for reimbursement of pharmacies based on cost of a drug, ensure processes are in place to update the standard not less frequently than every seven days beginning with an initial update on January 1 of each year, beginning 2009.
(MIPPA Section 173)
- ☐ 7. Ensure procedures are in place to provide vaccine administration per Part D Manual Chapter 6.

J. Customer Service

- ☐ 1. Ensure 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.
Part D sponsors must meet CMS standards for timely call center performance.

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- i. Beneficiary call center requirement during the Annual Enrollment Period plus 60 days: 8:00 AM to 8:00 PM seven days a week in all regions where the sponsor offers Part D.
 - ii. Pharmacy technical support requirement: Open if any network pharmacy is open. Sponsors whose pharmacy networks include 24-hour pharmacies must operate their pharmacy technical help call centers 24 hours a day.
- ☐ 2. Ensure that after the first 60 days of 2009 until the next annual enrollment period, call centers will remain open until 8:00 PM in all regions where the sponsor offers Part D.
 - i. Beneficiary call center requirement after the first 60 days of 2009: 8:00 AM to 8:00 PM in all regions, Monday through Friday, with permission to use alternative technologies to meet the customer service call center requirements for Saturdays, Sundays and holidays.
 - ii. Pharmacy technical support requirement: Open if any network pharmacy is open. Sponsors whose pharmacy networks include 24-hour pharmacies must operate their pharmacy technical help call centers 24 hours a day.
- ☐ 3. Ensure your organization develops appropriate member services and pharmacy help desk scripting to identify cases involving BAE and to allow callers either to submit BAE or request assistance with acquiring BAE.
(HPMS Memo: 08/04/2008)
- ☐ 4. Ensure your organization follows the procedures outlined in the Complaints Tracking Module (CTM) Plan Standard Operational Procedure at all times.
(HPMS Memo: 07/28/2008, Attachment A, *Complaints Tracking Module (CTM), Standard Operational Procedure, Medicare Advantage (MA) Organization and Prescription Drug Plan (Part D) Sponsor Users*)
- ☐ 5. Implement processes to ensure timely resolution of beneficiary complaints, dependent upon issue level of complaint.
(HPMS: 07/28/2008 Attachment A, *Complaints Tracking Module (CTM), Standard Operational Procedure, Medicare Advantage (MA) Organization and Prescription Drug Plan (Part D) Sponsor Users*)

Note: Issue Level Definitions from HPMS memo 07/28/2008, Attachment A, Section K of CTM Standard Operational Procedure

- o For MA, an immediate need complaint is defined as a complaint where a beneficiary has no access to care and an immediate need for care exists. Sponsors are required to resolve these complaints within 2 calendar days.
- o For Part D, an immediate need complaint is defined as a complaint that is related to the beneficiary's need for medication where the beneficiary has 2 or less days of medication left. Sponsors are required to resolve these complaints within 2 calendar days.
- o For MA, an urgent complaint involves a situation where the beneficiary has no access to care, but no immediate need exists.
- o For Part D, an urgent complaint is defined as a complaint that is related to the beneficiary's need for medication where the beneficiary has 3 to 14 days of medication left.
- o CMS reserves the right to classify any complaint that does not fit the above definition to "Immediate Need" or "Urgent" should the complaint be egregious in nature.