DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

Date: September 3, 2010

To: All Medicare Advantage Organizations (MAO) and Prescription Drug Plan (PDP) Sponsors (Excluding Cost, PACE, and Employer Group/800 series plans)

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

Subject: CY 2011 Medicare Advantage and Prescription Drug Plan Readiness Checklist

With the Annual Enrollment Period (AEP) fast approaching, we want to remind organizations of established requirements critical to ensuring beneficiaries receive effective coverage in 2011. The CY 2011 Readiness Checklist (Attachment A) summarizes a selection of key operational requirements as established in existing and new statutes, regulations, manual chapters, Health Plan Management System (HPMS) memos, applications, and other advisory materials. Given the significance of these updates and changes, all organizations should review this checklist carefully and take necessary measures to ensure that these key requirements are in place for CY 2011 open enrollment.

This year, there are two immediate action items in the checklist that your organization will need to respond to by **Friday, October 8, 2010**. See items I.8. and L1. in Attachment A for details.

Similar to previous years, CMS will expect organizations to perform their own audit of the full set of applicable requirements in Attachment A. At a later date, CMS will provide a timeline to organizations for reporting these results back to us through a secure information collection website.

This checklist highlights key topics in a general manner, but it does not include all changes to the Part C and D programs over the past year in great detail. As a reminder, plan sponsors are still ultimately responsible for following all CMS regulations, guidance, and instructions regardless of whether mentioned in this checklist.

CMS is pleased to continue working with the industry to provide health and prescription drug coverage to Medicare beneficiaries. We appreciate your cooperative spirit and remain committed to working with organizations to ensure that beneficiaries have continued access to health care services and prescription drugs during the upcoming year.

If you need additional detail regarding requirements listed in the checklist please refer to the CMS guidance provided in the checklist, contact Linda Gousis at linda.gousis@cms.hhs.gov or

(410) 786-8616 for questions related to the immediate action items in sections I. and L., or you may contact your account manager.

Attachment A

A. Appeals and Grievances

1. Grievances

a. Part D Sponsors. Ensure your organization is correctly implementing CMS grievance requirements. In 2011, CMS will increase oversight of plan grievance procedures. Given recent audit findings on Part D sponsor procedures and operations related to grievances, CMS intends to increase its scrutiny of Sponsor grievance processes and, where necessary, enhance its compliance initiatives in this area. It is critical that sponsors review the guidance provided in Chapter 18 of the Medicare Prescription Drug Benefit Manual. In particular, Section 20 of Chapter 18 provides detailed guidance on how to: distinguish a grievance from a coverage determination request; how to distinguish a grievance from a routine inquiry; procedures for handling a grievance, including decision making timeframes and notice requirements; and procedures for handling misclassified grievances. Sponsors are expected to audit their grievance processes and operations and implement quality improvements, as needed. (Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals)

2. New Requirements from the Policy and Technical Changes Regulations April 2010

a. Medicare Advantage Organizations and Part D Sponsors. In accordance with the final rule published in 75 Fed. Reg. 19678 (April 15, 2010), Medicare Advantage Organizations (MAOs) and Part D sponsors must have policies and procedures in place to ensure compliance with the following regulatory changes:

i. For MAOs. Permit enrollees to make verbal requests for standard organization determinations, except where the request is for payment. (42 C.F.R. § 422.568)

ii. For MAOs. The revised regulations removed the language that an enrollee must disagree with the plan's discontinuation or reduction of a service for the plan's decision to be considered an organization determination. (42 C.F.R. §§ 422.566(b)(4) and 422.568(c))

iii. For Part D sponsors. The revised regulations permit enrollees to make verbal requests for standard coverage determinations, except where the request is for payment. Per subparagraph (c) of this section, when an enrollee makes a request for payment, a sponsor must notify the enrollee of its decision and make payment (when applicable) no later than 14 calendar days after receipt of the request. Other changes include a requirement that sponsors provide written notice of a fully favorable

decision and that such notice explain the conditions of the approval in a readable and understandable form. Initial notice may be provided verbally, so long as a written follow-up notice is sent within three calendar days of the oral notice. (42 C.F.R. § 423.568)

iv. For Part D sponsors. Revised regulations state that if a Part D plan sponsor first notifies an enrollee of an adverse or favorable expedited determination verbally, it must mail a written confirmation to the enrollee within three calendar days of the verbal notice. Fully favorable notices must explain the conditions of the approval in a readable and understandable form. (42 C.F.R. § 423.572(b) and (c))

v. For Part D sponsors, revised regulations state that if a Part D sponsor first notifies an enrollee of an adverse or favorable expedited redetermination verbally, it must mail a written confirmation to the enrollee within three calendar days of the verbal notice. Fully favorable notices must explain the conditions of the approval in a readable and understandable form. (42 C.F.R. § 423.572(b))

3. Provider Payment Dispute Resolution Process

a. Medicare Advantage Organizations. CMS expanded its provider payment dispute resolution process for disputes between non-contracted and deemed providers and Private Fee for Service (PFFS) plans to include disputes between non-contracted providers and all Medicare Advantage plans, cost plans, and PACE organizations. The expansion of the provider payment dispute resolution process does not include Part D claims. (HPMS memo 1/4/2010)

b. Medicare Advantage Organizations. Enrollee appeals of organization determinations and non-contracted provider appeals of fully unfavorable organization determinations (claims) will continue to be handled by the Part C independent review entity, MAXIMUS, and will not be adjudicated under the payment dispute resolution process (a contract with First Coast Service Options, Inc. (FSCO)).

B. Benefits & Beneficiary Protections

1. Revised Manual Chapters

a. Medicare Advantage Organizations. Ensure your organization has reviewed the revised chapter of the **Medicare Managed Care Manual, Chapter 4 Benefits and Beneficiary Protections**, and implemented new policies and clarifications therein, some of which are listed below. (HPMS memos 7/16/2009 and 12/18/2009)

   i. The comprehensive guidance on the criteria for supplemental benefits (Sections 30.1, 30.3), especially with respect to benefits such as the meal benefit. (Section 30.5)
   ii. The updated and complete guidance on the Part C packaged over-the-counter (OTC) benefit. (Section 40)
   iii. Clarification of rules for balance billing. (Section 10.22)
   iv. The updated guidance on the requirement for provision of medical records. (Section 10.8)

b. Part D Sponsors. Ensure your organization has reviewed the revised chapter of the **Medicare Prescription Drug Benefit Manual, Chapter 5 - Benefits and Beneficiary Protections**, and implemented new policies and clarifications therein. (HPMS memo 1/7/2010)

c. Part D Sponsors: Ensure your organization has reviewed the revised chapter of the **Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements**, and implemented new policies and clarifications therein, some of which are listed below. (HPMS memo 3/3/2010)

   i. Clarified that the bundling of services under Part C must be available to enrollees in long term care (LTC) facilities.
   ii. Added a section permitting Part D Sponsors the option of sending transition fill notices to network LTC pharmacies in addition to sending notice to enrollees residing in LTC facilities.
   iii. Clarified transition requirements applying to both drugs removed from a sponsor's formulary as well as drugs that remain on the formulary but now require new prior utilization or step therapy restrictions.
   iv. Added language indicating that beneficiaries must be permitted to have a full outpatient supply available under Part D to continue therapy once their limited Part A supply is exhausted.

d. Part D Sponsors. Ensure your organization has reviewed the revised chapter of the **Medicare Prescription Drug Benefit Manual, Chapter 7 - Quality Improvement and Medication Therapy Management**, and implemented new policies and clarifications therein, some of which are listed below. (HPMS memo 3/3/2010)

i. Expanded and clarified guidance to Part D Sponsors on the maintenance of written policies and procedures on concurrent and retrospective drug utilization review checks.
ii. Updated the Part D Medication Therapy Management Program (MTMP) instructions for enrollment methods, targeting procedures, and MTM services.
iii. Added a section requiring Part D Sponsors to obtain the Prescription Origin Code and report on their prescription drug event (PDE) submissions for new prescriptions.
iv. Clarified how long an "urgent need" complaint should take to be resolved.

2. Advance Directives

a. Medicare Advantage Organizations. Organizations must comply with federal regulations which include maintaining written policies and procedures regarding advance directives for all adult individuals receiving medical care by or through the Medicare Advantage organization. (42 C.F.R. § 422.128)

3. Benefits

a. Medicare Advantage Organizations. Furnish HIV screening to enrollees with high risk profiles and ensure coverage of both standard and the Food and Drug Administration (FDA)-approved rapid screening tests. Plan websites and marketing materials (e.g., Summary of Benefits and Evidence of Coverage) should contain information regarding the screening tests and eligibility for coverage. (HPMS memo 2/1/2010)

b. Medicare Advantage Organizations. Organizations are encouraged to provide Personalized Prevention Plan Services or "annual wellness visits." (Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 553-557 (2010))

c. Medicare Advantage Organizations. If your plan does not offer a visitor/travel benefit to retain enrollees when they are outside of their service area for six to twelve months, then plans must disenroll beneficiaries who are absent from the plan's service area for six months. (HPMS memo 4/30/2010)

4. Coverage Gap Discount

a. Part D Sponsors. Ensure your organization will be able to implement the appropriate guidance consistent with the Affordable Care Act to implement the Medicare Coverage Gap Discount Program for 2011. (HPMS memos 5/21/2010, 5/25/2010, 6/2/2010, and 7/9/2010)

b. Part D Sponsors. Ensure your organization will be able to implement the appropriate gap coverage for 2011 consistent with the Affordable Care Act. (HPMS memo April 16, 2010)

5. Formulary

a. Part D Sponsors. Sponsors should rely on the monthly updates to the Food and Drug Administration (FDA) National Drug Code (NDC) Directory to determine when non-matched NDCs get listed. Sponsors should remove associated point-of-sale (POS) edits once NDCs are listed with the FDA. (HPMS memos 1/13/2010 and 2/3/2010)

b. Part D Sponsors. Part D Sponsors should be prepared to allow overrides of edits on topical ophthalmic products when appropriate to prevent unintended interruptions in drug therapy. (HPMS memo 6/2/10)

6. Home Infusion Pharmacy Network Access

a. Part D Sponsors. Sponsors should actively monitor their Home Infusion (HI) pharmacy networks in order to ensure adequate access consistent with CMS regulations. (HPMS memo 1/26/2010)

7. Pharmacy & Therapeutics Committee – with Judy & Brian

a. Part D Sponsors. Ensure your organization's pharmacy and therapeutics (P&T) committee complies with CMS guidelines. (Prescription Drug Benefit Manual, Chapter 6, 30.1).

b. Part D Sponsors. Ensure that the members of your P&T committee displayed in HPMS are, indeed, the members of your P&T committee who are making clinical decisions for your organization. If your organization operates under a confidentiality agreement with your PBM regarding your P&T committee, ensure that your PBM verifies the P&T members are correct. (Prescription Drug Benefit Manual, Chapter 6, 30.1.3)

8. Quality Improvement Programs

a. Medicare Advantage Organizations. Organizations must conduct chronic care improvement programs in patient populations and quality improvement projects in areas identified by CMS based on a review of current quality performance. (HPMS memo 4/30/2010)

C. Best Available Evidence (BAE) and Low Income Subsidy (LIS)

1. Revised Manual Chapter

a. Part D Sponsors. Ensure your organization has reviewed the revised chapter of the **Medicare Prescription Drug Benefit Manual, Chapter 13 Premium and Cost-Sharing for Low-Income Individuals**, and implemented new policies and clarifications therein, some of which are listed below. (HPMS memo 2/17/2010)

   i. Clarified where plans and beneficiaries may find information regarding appeals of subsidy determinations.
   ii. Added a section on the Part D sponsor's use of the Weekly/Monthly Transaction Reply Report (TRR).
   iii. Clarified the responsibility of Part D Sponsors when beneficiaries are found retroactively eligible for LIS.

2. Best Available Evidence (BAE) Policy

a. Part D Sponsors. Meet CMS requirements for accepting specific forms of Best Available Evidence (BAE) to establish a more favorable low income subsidy status of a full benefit dual eligible beneficiary and beneficiaries who applied to the Social Security Administration (SSA) for the LIS. (HPMS memo 08/04/2008 and 10/16/2008)

b. Part D Sponsors. Meet 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)

c. Part D Sponsors. 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. (HPMS memo 08/04/2008)

d. Part D Sponsors. Implement procedures to accept BAE at point-of-sale, 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. Request manual updates to CMS within 60 days if routine reporting doesn't correct for deemed beneficiaries. (Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.5 and HPMS memo 08/04/2008)

3. Low Income Subsidy Benefit Administration

a. Part D Sponsors. Ensure Part D sponsor applies correct CMS Low Income Subsidy (LIS) levels to enrollees by referring to the Weekly/Monthly Transaction Reply

Report (TRR) to establish the correct premium, cost sharing, and deductible levels with the correct effective dates for prior, current, and prospective enrollees. (HPMS memo 06/09/2009)

b. Part D Sponsors. Be prepared to apply correct CY 2010 benefit parameters (such as cost-share and deductible if applicable) based on low income subsidy (LIS) status in CMS systems or Best Available Evidence (BAE), if more favorable to the beneficiary. (HPMS memo 04/06/2009)

c. Part D Sponsors. Reimburse LIS eligible individuals, or others who have paid or are holding receivables on behalf of the beneficiary, any excess premiums or cost-sharing paid by the individual, including refunding of cost-sharing amounts that were paid during the period of LIS retroactive coverage. Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment. (42 C.F.R. § 423.466 and § 423.800 and HPMS memo 06/09/2009)

d. Part D Sponsors. Make reasonable attempts to notify affected members to advise them of their retroactive liability for higher premiums and cost sharing when LIS is removed. (HPMS memo 06/09/2009)

e. Part D Sponsors. Follow CMS' process for assisting individuals without BAE documentation. Sponsors must develop appropriate member services and pharmacy help desk scripting to identify cases involving a situation in which the BAE policy applies, and to allow callers either to submit BAE, or request assistance with securing BAE, pursuant to CMS requirements. When assisting beneficiaries with securing BAE, Sponsors are required to use the process outlined in Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.5.3. (HPMS memo 08/04/2008)

f. Part D Sponsors. Ensure 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. (Medicare Drug Benefit Manual Chapter 13, Section 70.5 and HPMS memo 08/04/2008)

4. Loss of Low Income Subsidy Data File

a. Part D Sponsors. In response to the Loss of Subsidy Data File (released in December of each year), prepare to set organization's systems to charge the correct premium, deductible, and copayments effective January 1, 2011 as well as sends the appropriate notification to affected beneficiaries. The only exception to this requirement is for those beneficiaries whom the organization confirms are awaiting an SSA determination on an LIS application and have been

granted a grace period by the organization, if applicable. In these situations, organizations should wait until they receive the result of the SSA determination to update their systems. (HPMS memo 11/30/2009)

5. Low Income Subsidy Deeming

a. Part D Sponsors. Follow the changes to the LIS deeming update request process, which includes providing specific information about the deemed beneficiary in an Excel worksheet to IntegriGuard along with the BAE documentation supporting the request to update the beneficiary's deemed status. The BAE documentation must match the "Type of Documentation Supporting Request" field in the Excel worksheet sent to IntegriGuard. (HPMS memo 05/11/2009)

6. LIS History (LISHIST) File

a. Part D Sponsors. Ensure your organization is able to process LIS History (LISHIST) file received from CMS, and upload the LIS contract file data to the Acumen LIS match rate website, https://PartD.ProgramInfo.US/LIS. (HPMS memos 8/30/2006, 10/30/2006, 11/26/2008, and 11/23/2009)
   i. Unless presented with Best Available Evidence (BAE) of a more beneficiary-favorable LIS level, Part D Sponsors are required to match their LIS data files to the CMS data files.
   ii. 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.
   iii. 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.

7. Monthly BAE Monitoring

a. Part D Sponsors. Ensure your organization is prepared to submit Monthly BAE documentation to Acumen each month. The BAE documentation is requested by Acumen for the monitoring project for all beneficiaries for whom sponsors report more favorable LIS benefits through the LIS Match Rate project for the duration of at least four months. (HPMS memo 1/22/2010)

D. Claims Processing and Transition Process

1. Drug Claims

a. Part D Sponsors. 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)

2. Excluded Provider Claims

a. Part D Sponsors. Sponsors must have processes in place to identify and prevent payment of Part D claims at Point-of-Sale (POS) when such claims are for drugs prescribed or dispensed by excluded providers who have been identified by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) on the List of Excluded Individuals and Entities (LEIE). (HPMS memos 1/13/2010 and 3/29/10)

b. Part D Sponsors. Ensure that any prescription drug event (PDE) data related to claims not rejected on/after the effective date of the excluded provider's exclusion are deleted to guarantee the dollars are not inadvertently included in reconciliation. (HPMS memo 3/29/10)

c. Part D Sponsors. Sponsors should use the model letter attached to the 3/29/10 HPMS memo when a sponsor is paying a claim for a Part D covered drug prescribed or dispensed by an excluded provider on the LEIE with a future exclusion effective data and/or to alert the beneficiary that future medication fills will no longer be covered because the prescriber or pharmacy is being excluded from participation in the Medicare program. (HPMS memo 3/29/10)

3. Federal Disaster or Public Health Emergency Declarations

a. Medicare Advantage Organizations and Part D Sponsors. Ensure your organization is prepared to follow CMS guidance regarding pharmacy and provider access during a Federal Disaster or other Public Health Emergency Declaration. (HPMS memos 06/16/2008, 07/20/2009, and Prescription Drug Benefit Manual Chapter 5)

4. Transition Process

a. Part D Sponsors. Sponsor must have a transition process in place for current enrollees who will experience negative changes as a result of revisions to their plan's formulary across contract years (i.e., from CY2010 to CY2011). Sponsors should work aggressively to prospectively transition current enrollees to therapeutically equivalent formulary drugs or work to complete requests for

formulary and tiering exceptions to the new CY2011 formulary prior to January 1, 2011. Sending the Annual Notice of Change (ANOC) is not sufficient to effectuate the transition. (HPMS memo 3/25/2010, 8/27/2010)

b. Part D Sponsors. Ensure enrollees eligible for transition supplies of drugs leave the pharmacy with filled prescriptions. Sponsors must have systems capabilities that allow them to provide a one time, temporary supply of non-formulary Part D drugs (including Part D drugs that are subject to prior authorization or step therapy) in order to accommodate the immediate needs of an enrollee, as well as, to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons. (HPMS memo 8/27/2010)

c. Part D Sponsors. Review the "Part D Transition Policy Reminder" HPMS memo dated 8/27/2010 to ensure that your organization is not conducting one or more of the non-compliant practices described in the memo. (HPMS memo 8/27/2010)

d. Part D Sponsors. Transition process information must be available on the plan website. (HPMS memo 3/25/2010)

e. Part D Sponsors. CMS expects sponsors to fully test how their transition policy works in their claims adjudication system, including pharmacy notification, in order to ensure that the transition policy has been programmed correctly into systems prior to the start of 2011. (HPMS memo 3/25/2010)

f. Part D Sponsors. CMS expects plans to carefully track their transition policy implementation and to take immediate action and notify CMS when they identify problems related to adherence to the Part D transition policy.

g. Part D Sponsors. Ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling. (Prescription Drug Benefit Manual, Chapter 6, 30.4.8)

h. Part D Sponsors. 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)

E. Compliance and Fraud, Waste, and Abuse

1. Compliance Plans

a. Medicare Advantage Organizations and Part D Sponsors. In accordance with new regulations published April 15, 2010 (75 Fed. Reg. 19809-19810 and 19820-19821), MA organizations and Part D sponsors must **adopt** and **implement** an **effective** compliance program that includes measures to prevent, detect, and correct compliance with CMS program requirements as well as measures to prevent, detect, and correct fraud, waste and abuse. The compliance program must, at a **minimum,** include the 7 core element requirements (42 C.F.R. § 422.503(b)(4)(vi) and § 423.504(b)(4)(vi)).

b. Medicare Advantage Organizations and Part D Sponsors. Under the new compliance program requirements, MA organizations and Part D sponsors must be prepared to conduct (i)-(vii) below. Please note that this list highlights some of the new additional requirements and is not all inclusive. Your organization is responsible for ensuring you are prepared to meet all of the CMS compliance program regulatory requirements contained at 42 C.F.R. § 422.503 and § 423.504.

   i. Ensure that policies, procedures and standards of conduct **describe the compliance expectations** as embodied in standards of conduct, implement compliance operations, provide guidance to employees and others for dealing with potential compliance issues, identify how to communicate issues to compliance personnel, describe how issues are investigated and resolved, and include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program. (42 C.F.R. § 422.503(b)(4)(vi)(A) and § 423.504(b)(4)(vi)(A)).

   ii. Ensure that the compliance officer is an **employee of the contracting entity, parent organization or corporate affiliate** and that the compliance officer and compliance committee periodically report compliance issues directly to the governing body of the organization or sponsor on activities/status of the compliance program, including issues identified, investigated and resolved. The **governing body** must (1) be knowledgeable about content and operation of the compliance program and (2) exercise reasonable oversight for implementation and effectiveness of program (42 C.F.R. § 422.503(b)(4)(vi)(B) and § 423.504(b)(4)(vi)(B))

   iii. Establish and implement effective compliance training for the contracting entity's employees, **chief executives or other senior administrators,** managers, **governing body members**, and first tier, downstream and related entities. The training must occur at minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointments of a chief

executive, manager, or governing body member. (42 C.F.R. § 422.503(b)(4)(vi)(C) and § 423.504(b)(4)(vi)(C).

iv. Establish and implement effective lines of communication **ensuring confidentiality** between the compliance officer, members of the compliance committee, employees, managers, **governing body** and first tier, downstream and related entities. These lines of communication must be accessible to all and allow for anonymous and confidential good faith reporting. (42 C.F.R. § 422.503(b)(4)(vi)(D) and § 423.504(b)(4)(vi)(D)).

v. Establish well-publicized disciplinary standards through the **implementation of procedures which encourage good faith participation in the compliance program by all affected individuals.** Standards must articulate expectations for reporting and assisting in resolution of compliance issues, identify non-compliance or unethical behavior, and provide for timely, consistent and effective enforcement of standards when non-compliance or unethical behavior is detected. (42 C.F.R. § 422.503(b)(4)(vi)(E) and § 423.504(b)(4)(vi)(E)).

vi. Establish and implement **an effective system for routine monitoring and identification of compliance risks** which includes internal monitoring and audits and, as appropriate, external audits, in order to evaluate the organization or sponsors compliance with CMS requirements and the overall effectiveness of their compliance programs. (42 C.F.R. § 422.503(b)(4)(vi)(F) and § 423.504(b)(4)(vi)(F)).

vii. Establish and implement **procedures and a system for promptly responding to compliance issues**, investigating potential compliance problems identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence and ensuring ongoing compliance with CMS requirements. (42 C.F.R. § 422.503(b)(4)(vi)(G) and § 423.504(b)(4)(vi)(G)).

2. Fraud, Waste, and Abuse - Payment for Services Not Delivered

a. Medicare Advantage Organizations and Part D Sponsors. Make sure there are procedures in place to combat fraud, waste, and abuse (FWA). An example of a recent fraud is infusion therapy schemes. Procedures for review, approval, and payment for infusion therapy, as well as for the identification of other vulnerable services, must be in place. (HPMS memo 6/1/2010)

F. Contracting, Subcontractor Provisions, and Oversight

1. Contracting Requirements

a. Medicare Advantage Organizations and Part D Sponsors. Ensure all requirements are followed according to CMS' application, contract, guidance, and other advisory materials. Also, recall that the 2011 Part C & D applications/solicitations are binding for organizations that applied using earlier application/solicitation versions. (Annual Contract with CMS)

2. Offshore Subcontracting

a. Medicare Advantage Organizations and Part D Sponsors. For organizations with offshore contractor arrangements, ensure the HPMS Offshore Subcontracting module is up to date regarding the functions offshore subcontractors perform. Within 30 calendar days of signing an offshore contract, submit (via the HPMS module) the offshore subcontractor information and attestation for each offshore contractor. (HPMS memos 07/23/2007, 09/20/2007 and 08/26/2008)

3. State Medicaid Agency Contracts

a. Medicare Advantage Organizations (MAOs). MAOs that will offer new or expanded dual eligible Special Needs Plans (DE SNPs) in CY2011 must ensure they have a contract with their State Medicaid Agency. Ratified contracts were due September 1, 2010 and will be effective on January 1, 2011. (HPMS memos 1/11/2010, 4/6/2010, and 8/19/2010)

G. Coordination of Benefits (COB)

1. Revised Manual Chapter

a. Part D Sponsors. Ensure your organization has reviewed the revised chapter of the **Medicare Prescription Drug Benefit Manual, Chapter 14 - Coordination of Benefits (COB)**, and implemented new policies and clarifications therein, some of which are listed below: (HPMS memo 3/29/2010)
   i. Added a description of the new COB notification requirements which replaces the former COB survey process.
   ii. Incorporated the new workers' compensation Medicare set-aside (WCMSA) data elements into the table of the COB File data elements and added a discussion of the action required when these data elements are reported on a member's COB record.
   iii. Added a discussion of the new limited income newly eligible transition (LI NET) program which replaces the detailed description of the special transition period for retroactive enrollment situations.

2. Coordination of Benefits (COB) Data Report/File Processing

a. Establish/maintain systems and procedures for at least weekly COB data report/file processing. (Medicare Prescription Drug Benefit Manual Chapter 14, Medicare Secondary Payer Manual Chapter 6) and the Plan Communication User Guide (PCUG))
   i. Organizations are required to not only receive COB information but also to apply it to their system(s).
   ii. Organizations utilize the ECRS to send COB updates to CMS (ECRS user guide is available on the CMS website).
   iii. CMS receives daily COB updates from the COBC, and CMS subsequently sends the COB file to the Sponsors.

b. Follow the new coordination of benefits (COB) notification process and request the beneficiary provide new or updated other prescription drug coverage information when the other drug coverage information exists on the COB file. (2010 Call Letter and update via HPMS memo 07/21/2009)
   i. Credible changes to other prescription drug coverage information reported by beneficiaries must be forwarded to the COB contractor (COBC) via Electronic Correspondence Referral System (ECRS). In the preamble to the final policy and technical regulations published in 75 Fed. Reg. 19771 (April 15, 2010), CMS defined "credible" as information that is consistent with conventions for how group health insurance coverage is identified, for instance, information that includes the name and address of the insurance company and the policy identification number. (42 C.F.R. §423.462)

ii. Part D Sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries behalf for a period not to exceed three years from the date on which the prescription for a covered Part D drug was filled. (42 C.F.R. §423.466(b))

c. Interpret the COB file correctly. (2008 Regional Prescription Drug Event Data Technical Assistance Participant Guide, HPMS memo 11/24/2008)
   i. Replace the entire beneficiary record for each changed record. The COB file contains information regarding the beneficiary's other health insurance information (OHI). The OHI is either primary to Medicare, or supplemental to Medicare. If an enrollee's OHI record has been added, changed, or deleted, this will trigger a full replacement of that enrollee's detail (DTL) and subordinate primary (PRM) and supplemental (SUP) records.
   ii. The information on the COB file is collected by the COB contractor (COBC) for establishing payer order. For Medicare Secondary Payer (MSP) purposes, the COBC determines payer order responsibilities avoiding duplication of payment and preventing Medicare from paying primary when it is secondary.

3. Medicare Advantage Maximum Out-of-Pocket

a. Medicare Advantage Organizations. Be prepared to calculate and track out of pocket costs for all Medicare-covered benefits. CMS requires all local Medicare Advantage plans have a maximum out of pocket (MOOP) cap for 2011. (HPMS memos 4/16/2010 and 4/30/2010

4. Nx Transactions

a. Part D Sponsors. Sponsors that intend to change Pharmacy Benefit Managers (PBMs) must have a process in place to ensure that 2010 year Nx transactions (e.g., N_1 and N_2 transactions regarding supplemental claims information) are received by the new PBM. In the alternative, the sponsor may engage the 2010 PBM in 2011 to handle the prior year Nx transactions. (HPMS memo 2/25/2010)

5. True Out Of Pocket (TrOOP) Costs

a. Part D Sponsors. Ensure that prescription drug costs reimbursed by AIDS Drug Assistance Programs (ADAPs) and the Indian Health Service count towards annual True-Out-Of-Pocket (TrOOP) costs when calculating eligibility for catastrophic drug coverage under Part D coverage. (Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 478-479 (2010))

6. TrOOP Balance Transfer Transactions

a. Part D Sponsors. Ensure your organization promptly addresses TrOOP Balance Transfer (TBT) problems identified through the exception reports. Sponsors should successfully resolve identified problems with enrollee automated TBT transaction within 30 days of notification of the problem. (HPMS memo 11/2/2009)

H. Customer Service

1. Complaints Tracking Module

a. Medicare Advantage Organizations and Part D Sponsors. Plan sponsors should be prepared to resolve at least 95% of Complaints Tracking Module (CTM) complaints designated as "urgent" within seven (7) days and resolve at least 95% of CTM complaints designated without an issue level within 30 days. Plan sponsors are urged to make interim contact with beneficiaries if their complaints will take more than seven (7) days to resolve. (HPMS memo 12/28/2009)

2. Customer Service Call Centers

a. Medicare Advantage Organizations and Part D Sponsors. Ensure call centers are able to provide interpreters for non-English speaking and/or reading beneficiaries who have questions about their benefits. (Medicare Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines 30.7 and 80.1 and Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines 30.7 and 80.1)

b. Medicare Advantage Organizations and Part D Sponsors. Ensure that beneficiary call centers will be staffed appropriately to handle increased call volume during the annual enrollment period and the first 60 days of 2011 operations. MAOs and Part D Sponsors must meet CMS standards. (Medicare Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines 80.1 and Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines 80.1)
    i. Until March 1. Beneficiary call center requirement during the Annual Enrollment Period plus 60 days thereafter: 8:00 AM to 8:00 PM seven (7) days a week in all regions where the organization offers Medicare plans.
    ii. After March 1. Beneficiary call center requirement after the first 60 days of 2011: 8:00 AM to 8:00 PM in all regions, Monday through Friday. Organizations are permitted to use alternative technologies to meet the customer service call center requirements for Saturdays, Sundays, and holidays.

3. Customer Service Staff Knowledge

a. Medicare Advantage Organizations and Part D Sponsors. Ensure staff advise new members that have selected premium withhold that it could take up to 90 days for their Social Security deductions for their new plan premiums to begin and they could see premiums for their former plan continue for that period of time. (HPMS memo 12/28/2009)

b. Part D Sponsors. Ensure staff are familiar with the Best Available Evidence (BAE) process and aware of what forms of evidence are considered acceptable proof of Low Income Subsidy (LIS) and how to use the BAE assistance process to verify that an individual has LIS because of their Medicaid status. (HPMS memo 12/28/2009)

c. Part D Sponsors. CMS requires sponsors to accept Late Enrollment Penalty (LEP) telephonic attestations from beneficiaries in order to assist in the effective completion of the attestation process. (Prescription Drug Benefit Manual, Chapter 4)

4. Pharmacy Technical Help Desk Call Centers

a. Part D Sponsors. Ensure that pharmacy technical help desk call centers will be staffed appropriately to handle increased call volume during the annual enrollment period and the first 60 days of 2011 operations. Part D Sponsors must meet CMS standards. (Medicare Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines 80.1.1 and Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines 80.1.1)

b. Pharmacy technical support must be available if any network pharmacy is open. Sponsors that have pharmacy networks with 24-hour pharmacies in their networks must operate their pharmacy technical help call centers 24 hours a day.

I. Enrollment/Disenrollment

1. Revised Manual Chapter

a. Medicare Advantage Organizations. Ensure your organization has reviewed the revised chapter of the **Medicare Managed Care Manual, Chapter 2 - Medicare Advantage Enrollment and Disenrollment**, and implemented new policies and clarifications therein, some of which are listed below. (CMS website http://www.cms.gov/MedicareMangCareEligEnrol/Downloads/FINALMAEnrollmentandDisenrollmentGuidanceUpdateforCY2011.pdf)

2. Certification of Monthly Enrollment and Payment Data

a. Medicare Advantage Organizations and Part D Sponsors. Submit one Certification of Monthly Enrollment and Payment Data for all contracts within 45 days of the date that the monthly reports are available. The attestation letters confirm that the organization has reviewed the enrollment and payment data and that the organization reported enrollment and status information to CMS correctly; reviewed and reported to CMS any discrepancies between the organization's records and CMS monthly membership reports and reply listings, and will follow existing procedures for submitting requests for the correction of discrepancies to the Retroactive Adjustment Processing Contractor. (42 C.F.R. § 422.504(l)(1) and § 423.505(k)(2), and HPMS memos 03/29/2006 & 07/21/2009)

3. Enrollments

a. Medicare Advantage Organizations and Part D Sponsors. Ensure an updated CY 2011 paper enrollment form is available for potential enrollees to request enrollment during valid periods.

b. 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. For 2011, plan sponsors are required to have a tracking mechanism for telephonic enrollments. (Medicare Managed Care Manual, Chapter 2, section 40.1.3, and Prescription Drug Benefit Manual, Chapter 3, section 40.1.3)

4. Enrollment Acknowledgement and Confirmation Notices

a. Medicare Advantage Organizations and Part D Sponsors. 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. (Medicare Managed Care Manual, Chapter 2, 40.4, Prescription Drug Benefit Manual Chapter 3, Section 40.4)

b. Medicare Advantage Organizations and Part D Sponsors. Plan sponsors may also use a combination acknowledgement that accomplishes both purposes within 7 calendar days of confirmation from CMS. (Medicare Managed Care Manual, Chapter 2, 40.4, Prescription Drug Benefit Manual Chapter 3, Appendix 1)

c. Medicare Advantage Organizations and Part D Sponsors. Implement a process to send individuals an acknowledgment notice within 10 calendar days if you receive the disenrollment request directly from the individual. If an organization only learns of disenrollment from CMS confirmation (e.g., as a result of enrollment with another organization), the organization must send a notice confirming disenrollment within 10 calendar days of receiving the notice of disenrollment on the Transaction Reply Report (TRR). (Medicare Managed Care Manual Chapter 2, Section 50.1.4, Prescription Drug Benefit Manual Chapter 3, Section 40.1.4-5)

5. Enrollment and Disenrollment Transactions

a. Medicare Advantage Organizations and Part D Sponsors. Ensure a process is in place to transmit enrollment and disenrollment transactions to CMS within seven (7) calendar days of receipt. (Medicare Managed Care Manual Chapter 2, Section 40.3, Prescription Drug Benefit Manual Chapter 3, Section 40.3)

6. Enrollment Processing

a. Medicare Advantage Organizations and Part D Sponsors. 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. (Medicare Managed Care Manual Chapter 2, Section 60 and Chapter 19, Prescription Drug Benefit Manual Chapter 3, Section 60, and the Plan Communications User Guide)

b. Medicare Advantage Organizations and Part D Sponsors. Ensure your organization has processes in place to submit plan generated enrollments to CMS within seven (7) calendar days of receipt of the completed enrollment request. CMS is monitoring whether sponsors submit enrollments timely and has established a compliance threshold of 90% submitted within seven (7) calendar days. (The lower-than-usual compliance threshold accounts for the fact that some applications may be incomplete upon receipt.) (HPMS memo 7/15/2010)

c. Part D Sponsors. Ensure a process is in place to transmit sponsor-generated enrollment transactions that include active 4Rx data, and for CMS-generated enrollments, to transmit active 4Rx data on an update transaction within 72 hours of availability of the TRR transmitting the enrollments. (42 C.F.R. § 423.32(c))

7. Enrollment Rejections

a. Medicare Advantage Organizations and Part D Sponsors. 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). (Medicare Managed Care Manual Chapter 2, Section 40.2.3 and 40.4.2, Prescription Drug Benefit Manual Chapter 3, Section 40.2.3 and 40.4.2)

IMMEDIATE ACTION ITEM

8. Inform CMS of Significant Enrollment Growth for CY2011

a. Medicare Advantage Organizations and Part D Sponsors. **Notify CMS if your organization will likely experience significant enrollment growth for CY2011.** Significant enrollment growth means an increase of more than 30% for a single contract. This increase can be intended (e.g., increased marketing efforts) or unintended (e.g., as a result of other plans leaving your service area) or as a result of receiving auto-enrollees. CMS requests that your organization briefly describe the steps your organization has taken to ensure that your systems, staff, and processes are capable of handling the increased number of enrollees. Please conduct a risk assessment of the areas likely affected by the significant enrollment increase and describe back-up processes in place in the event there are problems with enrollment and benefit delivery systems and processes. Submit this information to the DrugBenefitImpl@cms.hhs.gov mailbox **by Friday, October 8, 2010.** Additionally, CMS recommends that you also inform your State Department of Insurance of your significant enrollment growth prior to the start of the contract year.

9. Online Enrollment Center

a. Medicare Advantage Organizations and Part D Sponsors (Excluding MSA, Cost Plans, and 800-Series-Only; Optional for SNPs) Required for PDP and MA-PD. Establish/maintain a process to download enrollment on at least a daily basis from the Online Enrollment Center (OEC) unless your organization is prohibited from participating in the OEC. (2010 Call Letter)

10. Retroactive Enrollments

a. Medicare Advantage Organizations and Part D Sponsors. Reed & Associates is the current retroactive processing contractor. Organizations need to ensure systems and processes are in place to ensure retro enrollments and disenrollment referrals to Reed & Associates are made appropriately and are timely. (HPMS memo 07/21/2009, additional information available at **www.reedassociates.org**)

J. Late Enrollment Penalty (LEP) and Creditable Coverage

1. Revised Manual Chapter

a. Part D Sponsors. Ensure your organization has reviewed the revised chapter of the **Medicare Prescription Drug Benefit Manual, Chapter 4 - Creditable Coverage Period Determinations and the Late Enrollment Penalty**, and implemented new policies and clarifications therein, some of which are listed below: (HPMS memo 1/7/2010)

   i. Clarified the process for making a creditable coverage period determination.
   ii. Provided information regarding reporting creditable coverage information for former plan members.
   iii. Included attestation forms for reporting creditable coverage.

2. Late Enrollment Penalty

a. Part D Sponsors. 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 LIS 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 was effective January 1, 2010, when the demonstration ended. (Prescription Drug Benefit Manual Chapter 4)

3. Creditable Coverage

a. Part D Sponsors. Report adjustments to the number of uncovered months previously reported for a current or former member (required when there is an adjustment to uncovered months [zero or greater] previously reported, e.g., when the Sponsor completes a creditable coverage period determination or receives a reconsideration decision from Maximus necessitating an adjustment) plan members. (Prescription Drug Benefit Manual Chapter 4)

b. Part D Sponsors. Ensure that Part D Sponsors perform the required follow-up of a beneficiary's attestation of creditable coverage in all cases where an initial attestation form was mailed. Part D Sponsors can use the model Late Enrollment Penalty (LEP) Attestation "final" notice or other means, such as the telephone, to remind enrollees of the need to submit a timely attestation if they have prior creditable prescription drug coverage. (Prescription Drug Benefit Manual Chapter 4)

c. Part D Sponsors. Ensure procedures are in place to accept and retain creditable coverage information from all employer and union groups, as well as State Pharmaceutical Assistance Programs (SPAPs), which attest to their members' creditable coverage history. (Prescription Drug Benefit Manual Chapter 4)

d. Part D Sponsors. 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. All Part D Sponsors are required to mail the attestation form. This telephonic option is only available after plan has mailed the attestation form to the member. (Prescription Drug Benefit Manual Chapter 4)

K. Marketing

1. Revised Manual Chapters

a. Medicare Advantage Organizations and Part D Sponsors. Ensure your organization has reviewed the following revised chapters: **Medicare Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines,** and **Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines**, and implemented new policies and clarifications therein, some of which are listed below: (HPMS memo 6/4/2010, and clarifications in HPMS memo 8/17/2010)

i. Guidance related to use of Federal funds (section 160) and allowable use of beneficiary information obtained from CMS (section 170).
ii. Clarified guidance related to requirements for plan sponsors with non-English speaking or special needs populations (section 30.7).
iii. Clarified guidance for plan mailing statements and requirements for use of plan name and logo on every mailing (section 50.2).
iv. Clarified that door hangings are considered unsolicited contacts (section 70.4).
v. Clarified guidance regarding use of Medigap data (section 30.4).
vi. Clarified guidance related to agent/broker compensation and charge backs (section 120).

2. Agents and Brokers

a. Medicare Advantage Organizations and Part D Sponsors. Ensure your organization meets the requirements regarding the appointment of agents and brokers and is in compliance with State information requests under Medicare Improvements for Patients and Providers Act (MIPPA), including agent and broker compensation limits, plan reporting of terminated agents, and training and testing requirements. Organizations are reminded that while the use of independent agents and brokers is optional, if they choose to use them, they must follow CMS compensation regulations at 42 C.F.R. § 422.2274 and § 423.2274.

i. Ensure your organization has appropriately adjusted compensation rates for CY 2011. (HPMS memo 5/14/2010 and Medicare Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines, section 120.5.7, and Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines, section 120.5.7)
ii. Ensure plan sponsors adhere to the CY2011 compensation rates for enrollments and submit compensation data and enrollment information through the Health Plan Management System (HPMS). Compensation must be paid in accordance with the structure of the plan in which the

enrollment occurred so long as the agent is in good standing and the member is still enrolled. (HPMS memo 7/12/2010)

iii. Ensure your organization complies with CMS' guidelines for agent and broker testing for CY 2011. (HPMS memo 7/29/2010)

iv. CMS does not differentiate between agents, brokers, general agents, general agencies and distribution partners.

v. Plans are further reminded that independent brokers and agents must follow all of CMS' regulations and guidance, and plans are responsible for ensuring compliance on the part of the brokers and agents with whom they have arrangements.

3. Formulary

a. Part D Sponsors. Implement procedures and safeguards to ensure the CMS-approved formulary matches marketed formulary both in print and on the website. (42 C.F.R. § 423.120(b)(5) and § 423.128(a)-(e))

b. Part D Sponsors. Ensure that your organization checks HPMS to verify that your formulary is approved prior to the beginning of marketing on October 1, 2010, because only approved formularies can be marketed. (HPMS memo 7/30/2010)

4. Medicare Marketing Material Review and Usage

a. Medicare Advantage Organizations and Part D Sponsors. Ensure all marketing materials include all necessary information and undergo thorough quality control review prior to submission for CMS review. Sponsors are accountable for the accuracy and completeness of their marketing materials. (42 C.F.R. § 422.2262, § 422.2264, § 423.2262, and § 423.2264)

b. Medicare Advantage Organizations and Part D Sponsors. File & Use Certification. 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. Organizations may request a manual review of no more than 10 percent of materials that qualify for File & Use. (42 C.F.R. § 422.2262(b) and § 423.2262(b))

5. Medicare Prescription Drug Benefit Mark

a. Part D Sponsors. Organizations should sign the applicable licensing agreement for the Medicare Prescription Drug Benefit Program Mark in 2011 in the HPMS Electronic Contracting module. (Medicare Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines, and Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines, 150.3)

6. Model Marketing Materials

a. Medicare Advantage Organizations and Part D Sponsors. Ensure appropriate use of CY2011 marketing model materials, including the following:
   i. Models in Medicare Managed Care Manual, Chapter 2 Medicare Enrollment and Disenrollment and Medicare and in the Prescription Drug Benefit Manual, Chapter 2 Medicare Enrollment and Disenrollment.
   ii. Models in the Medicare Managed Care Manual, Chapter 13 - Medicare Managed Care Beneficiary Grievances, Organization Determinations, and Appeals applicable to Medicare Advantage plans and Medicare Prescription Drug Benefit Manual, Chapter 18 Part D Enrollee Grievances, Coverage Determinations and Appeals.
   iii. Model Part D Prescription Transfer Letter (previously titled Model Part D Mail-Order Pharmacy Letter), (HPMS memo 1/22/2010)
   iv. Standardized Annual Notice of Change (ANOC) and Evidence of Change (EOC) Templates, (HPMS memo 5/27/2010, and corrections in HPMS memo 8/11/2010)
   v. Model Part D Abridged Formulary, (HPMS memo 5/27/2010)
   vi. Model Part D Comprehensive Formulary, (HPMS memo 5/27/2010)
   vii. Excluded Provider Directory, (HPMS memo 5/27/2010)
   viii. Pharmacy Directory, (HPMS memo 5/27/2010)
   ix. Prescription Transfer Letter, (HPMS memo 5/27/2010)
   x. Transition Letter, (HPMS memo 5/27/2010)
   xi. Low Income Subsidy (LIS) Rider, (HPMS memo 5/27/2010)
   xii. CY2011 Model Explanation of Benefits (EOB), and (HPMS memo 6/11/2010)
   xiii. Part C Provider Directory. (HPMS memo 5/27/10)

7. Outbound Education and Verification Calls to all New Enrollees

a. Medicare Advantage Organizations and Part D Sponsors. Implement a process through outbound verification calls to ensure beneficiaries requesting enrollment understand the type of plan they are enrolling into and plan rules. (42 C.F.R. § 422.2272 (b) and § 423.2272 (b))

8. Plan Name Verification

a. Medicare Advantage Organizations and Part D Sponsors. Ensure your organization has verified the accuracy of your Plan Name in HPMS. MAOs and PDP Sponsors enter and maintain their plan names in HPMS. The plan name is used by internal CMS systems and in standardized marketing tools and models, including, but not limited to: the Summary of Benefits (SB), Annual Notice of Change/Evidence of Coverage (ANOC/EOC), Medicare Options Compare and

Medicare Prescription Drug Plan Finder on http://www.medicare.gov, and the Medicare & You Handbook.

9. Summary of Benefits Changes

a. Medicare Advantage Organizations and Part D Sponsors. Ensure the Organization follows instructions for submitting the Summary of Benefits (SB) hard copy change request to the Health Plan Management System (HPMS). Ensure the Organization also follows instructions for global hard copy changes to CY 2011 SBs that are a result of programming errors in the Plan Benefit Package (PBP/SB) software. (Medicare Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines, and Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines, Appendix 1 – Summary of Benefits)
    i. Ensure the SB is submitted with global hard copy changes to Regional Office reviewer following the normal marketing material review process.
    ii. Ensure the SB hard copy change request is submitted via HPMS for CO review and approval.

10. Timing for CY 2010 and CY 2011 Marketing Materials

a. Medicare Advantage Organizations and Part D Sponsors. For renewing organizations, marketing of CY 2010 plans through mass media or direct mail marketing (except for age-in mailings) must cease once an organization begins marketing CY 2011 plans. Plans must include information in CY 2010 marketing and enrollment materials to inform potential enrollees about the possibility of plan (benefit) changes beginning January 1, 2011. (2010 Call Letter)

b. Medicare Advantage Organizations and Part D Sponsors. For renewing organizations, ensure all current members of PDPs, MA plans, and MA-PD plans offering Part D, receive the CY 2011 annual renewal materials on time and conduct a quality check for accuracy and assurance that materials are received by the dates specified by CMS. The following materials are due to current members by October 31, 2010: (42 C.F.R. § 422.111, § 423.128, § 422.2264, and §423.2264)
    i. Combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC).
    ii. LIS Rider to the EOC to members qualified for the Federal Low-Income Subsidy.
    iii. Abridged or comprehensive formularies.
    iv. Summary of Benefits is not required but must be available upon request for renewing members;
    v. Dual Eligible SNPs that are fully integrated with the State are not required to use the standardized ANOC/EOC. The ANOC and SB are due to current members by October 31, 2010. Members must receive the EOC, LIS riders and abridged or comprehensive formularies by December 31,

2010. Current members enrolled in employer/union group plans must receive the ANOC/EOC no later than 15 days before the beginning of the Annual Election Coordinated Period (ACEP) which is based on the employer/union sponsor's open enrollment period; and (refer to § 20.3.2.1 of Chapter 9 of the Medicare Managed Care Manual and § 20.3.2.1.2 of Chapter 12 of the Prescription Drug Benefit Manual)

vi. Plan sponsors must follow the instructions on meeting the requirement for entering the actual mail date in the HPMS User Guide-Marketing Module section.

11. Websites

a. Medicare Advantage Organizations and Part D Sponsors. Organizations are required to have a website or web page dedicated to each product they offer. Those requirements include, but are not limited to: (42 C.F.R. § 422.2264(a) and § 423.2264(a))
   i. Sponsors must maintain Internet websites that are compliant with web-based technology and information standards for people with disabilities as specified in Section 508 of the Rehabilitation Act; (www.section508.gov);
   ii. Any marketing materials placed on websites must be displayed in minimum of 12 point Times New Roman-equivalent font;
   iii. Website content should use language from marketing materials that have been reviewed and approved or appropriately submitted to CMS under File & Use;
   iv. Websites must be submitted via HPMS under a 45-day review. Organizations will be required to attest that the website is compliant with the Medicare Marketing Guidelines; and
   v. Renewing organizations are required to provide website content beginning October 1, 2010 for the next contract year. Organizations must maintain current contract year content on their website at least until December 31 with each year's content in a separate and distinct area of the organization's website for ease of beneficiary navigation.

b. Medicare Advantage Organizations and Part D Sponsors. The following information must be accessible via a link on the organization's website: (42 C.F.R. § 422.111 (b)(8), § 422.2264 (a), § 423.128 (b), and § 423.2264 (a))
   i. Summary of Benefits.
   ii. Enrollment Instructions and Forms.
   iii. Privacy Notice.
   iv. Evidence of Coverage.
   v. LIS Premium Summary chart.
   vi. Information related to plan's exception and appeals process.

vii. Part D Sponsors only.
    1. Utilization management applied to formulary drugs, including quantity limit amount, quantity limit days supply, prior authorization criteria and step therapy criteria must be displayed by November 15, 2010.
    2. Plan transition process information via a link from the Medicare Prescription Drug Finder must be displayed.
    3. Provide a link regarding the Best Available Evidence Policy.

L. Operational Changes

IMMEDIATE ACTION ITEM

1. **Inform CMS of Significant Operational Changes for CY2011**

    a. Medicare Advantage Organizations and Part D Sponsors. **Notify CMS if your organization will make any significant changes in your organization's operations or policy that could affect beneficiary access, benefit delivery, and/or payments.** A significant change would include: change in pharmacy benefit manager (PBM), change in subcontractors, substantial programming changes or redesigns, data platform changes, wholesale process changes, and/or major shifts in responsibility within your organizational structure or operations. CMS requests that your organization briefly describe the change(s); conduct a risk assessment of the areas likely affected by the significant change(s); and describe back up processes in place in the event there are problems regarding the change(s). Submit this information to the DrugBenefitImpl@cms.hhs.gov mailbox **by Friday, October 8, 2010**.

M. Reporting

1. Financial Reporting

a. Medicare Advantage Organizations and Part D Sponsors. Ensure your organization is prepared to submit financial statements to the HPMS Fiscal Soundness module. (HPMS memo 3/29/2010 and 2010 Part C and Part D Reporting Requirements)
   i. Part D Sponsors should be prepared to submit quarterly financial statements to the HPMS fiscal soundness module.
   ii. Medicare Advantage Organizations should be prepared to submit annual financial statements unless CMS specifically requested to report quarterly by CMS.
   iii. Required data elements to be entered into HPMS in 2011, as currency fields:
      1. Total assets as of the end of the reporting period.
      2. Total liabilities as of the end of the reporting period.
      3. Cash from operations as of the end of the reporting period.
      4. Net income as of the end of the reporting period.

2. Healthcare Effectiveness and Data Information Set (HEDIS), Health Outcomes Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS)

a. Medicare Advantage Organizations and Part D Sponsors. Ensure your organization is prepared to submit HEDIS, HOS, and CAHPS measures to the appropriate entity by the specified due date. (HPMS memo 12/2/2009)
   i. New for 2011, Medicare Advantage (MA) Private Fee for Service (PFFS) and Medicare Savings Account (MSA) contracts will be required to collect data on all of the administrative HEDIS measures covering services provided in CY 2010 and report the audited data to CMS through NCQA in June 2011 following the HEDIS 2011 Technical Specifications. The following year PFFS and MSA contracts will be required to collect data on all HEDIS measures and report the audited data to CMS following the HEDIS 2012 Technical Specifications. (HPMS memo 12/2/2009)
   ii. New for 2011, Medicare Advantage Organizations, including PFFS and MSA contracts, and Part D contracts will be required to contract for the 2011 survey administration with an approved MA and Prescription Drug Plan (PDP) CAHPS Survey Vendor to collect the CAHPS data on their behalf. Specifically, MA and Part D Sponsors with 600 or more enrollees as of July 2010 are required to contract with CMS approved Medicare CAHPS survey vendors to conduct data collection. (HPMS memos 12/2/2009 and 6/25/2010)

3. Part C and Part D Reporting Requirements

a. Medicare Advantage Organizations. Ensure your organization is prepared to collect data on all Part C reporting requirements, conduct appropriate data validation, and submit data to CMS according to the requirements, deadlines, and technical specifications. (HPMS memos 12/23/09, 2/24/2010, and 5/10/2010, HPMS Plan Reporting Site: http://www.cms.hhs.gov/HealthPlansGenInfo/16_ReportingRequirements.asp#TopOfPage)

b. Part D Sponsors. Ensure your organization is prepared to collect data on all Part D reporting requirements, conduct appropriate data validation, and submit data to CMS according to the requirements, deadlines, and technical specifications. (HPMS memos 12/23/2009, 12/24/2009, and 5/10/2010)

c. Medicare Advantage Organizations and Part D Sponsors. Ensure sponsors have users designated for Acumen's Part C/D Plan Reporting website where feedback on sponsors' reporting requirements data, such as overdue and outlier notices, will be provided. The website is: https://cpc.programinfo.us/CDReporting.

d. Medicare Advantage Organizations. Ensure your organization is prepared to report fully favorable decisions made as a result of a request for an organization determination and fully favorable decisions made as a result of a request for a reconsideration. (HPMS memo 8/4/2010)

4. Pharmacy Benefit Manager Change

a. Part D Sponsors. If making Pharmacy Benefits Manager (PBM) changes mid-year, or post-CY2011 application approval:
   i. Ensure all steps have been followed per the Medicare Prescription Drug Manual Chapter 5, Section 50, if making changes to the PBM contracted to maintain your organization's pharmacy networks;
   ii. Update all members' 4Rx data prior to the effective date of the PBM change to reflect the new BIN and PCN; and
   iii. Inform your CMS Account Manager of the PBM change.

N. Systems, Data & Connectivity

1. **Financial Information Reporting (FIR) Processors**

    a. For New 2010 Part D Sponsors, or Part D Sponsors with New Financial Information Reporting (FIR) Processors not previously Certified for FIR, only (HPMS memo 10/21/2008):
        i. Ensure Sponsor (or its processor) completes Automated True Out-Of-Pocket Expenditures (TrOOP) Balance Transfer testing and certification.
        ii. The Sponsor and/or its processor must be certified by November 15, 2010 and be fully prepared to respond to TrOOP Balance Transfer (TBT) transactions for 2011 beneficiaries on January 1, 2011.

2. **Health Plan Management System (HPMS) Connectivity**

    a. Medicare Advantage Organizations and Part D Sponsors. Ensure key staff register for HPMS access: http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf.

    b. Medicare Advantage Organizations and Part D Sponsors. Ensure key staff register for the Plan Connectivity Data (PCD) Module within HPMS by emailing hpms_access@cms.hhs.gov.

    c. Medicare Advantage Organizations and Part D Sponsors. Update organization's contact information in HPMS for the 2011 contract year and keep all contracts' contact data current. Changes to any HPMS contacts should be made immediately upon the effective date of the responsibility transfer.

3. **Low Income Subsidy (LIS) Match Rate Website**

    a. Part D Sponsors. Identify or validate up to five authorized users for the Acumen LIS Match Rate Website: https://PartD.ProgramInfo.US/User_Security. (HPMS memo 11/26/2008)

4. **MARx**

    a. Medicare Advantage Organizations and Part D Sponsors. Review and implement guidance regarding software improvements to the enrollment and payment systems for Medicare Advantage and Prescription Drug (MA-PD) programs. (HPMS memo 1/12/2010)
        i. Medicare Advantage Organizations and Part D Sponsors. Ensure your organization meets the Plan Data due date for submitting transactions as indicated in the Plan Communications User Guide by 8:00 PM Eastern

Daylight Time (EDT). Retro-file submittal is due by noon on the Wednesday before the Plan Data Due date. (HPMS memo 1/29/2010)

ii. Medicare Advantage Organizations and Part D Sponsors. Plan sponsors can submit enrollments for January 1st effective dates after the Plan Data Due date in October. (HPMS memo 2/24/2010)

iii. Medicare Advantage Organizations and Part D Sponsors. Ensure your External Point of Contact (EPOC) is notified of the changes regarding the Individuals Authorized Access to the CMS Computer Services (IACS) users, some of which are listed below. (HPMS memo 5/21/2010)
    1. IACS will require a date of birth (DoB) from new users at registration and from current users missing a DoB in their profile. (HPMS memo 5/21/2010)
    2. IACS users who have been inactive for at least 180 days since the last login will be partially disabled. (HPMS memo 5/21/2010)

iv. Part D Sponsors. Ensure your organization is prepared to process the Coverage Gap Discount (CGD) payment. (HPMS memo 7/2/2010)

5. Medicare Plan Finder Data

a. New 2011 Part D Sponsors. Ensure your organization has access to the Medicare Plan Finder (MPF) Communications website and has authorized new users. (https://PartD.ProgramInfo.us/User_Security) (HPMS memo 7/23/2010)

b. Part D Sponsors. Ensure pricing and pharmacy network data files for Medicare Plan Finder have been through quality assurance checks for completeness and accuracy for CY2011 data. Known exceptions granted for CY2010 pricing and pharmacy data will be removed. (HPMS memo 6/30/2010)

c. Part D Sponsors. Ensure timely and accurate submission of CY 2011 pricing data for posting on the Drug Plan Finder.

d. Part D Sponsors. The initial CY 2011 data submission period for live/public pricing data will be September 20 through September 21, 2010. The data will be published on or about October 7, 2010.

6. National Provider Identifier Requirements

a. Part D Sponsors. Ensure network pharmacies send and are able to accept claim (billing) transactions with the pharmacy's National Provider Identifier (NPI), and a prescriber ID in all cases (which must be the prescriber's NPI whenever known; when not available, another non-NPI identifier such as a DEA number or State License number is used- as permitted under state law) in the transaction. (OMB Circular M07-16, FISMA, HIPAA, HPMS memos 06/09/2006, 07/23/2007, and 05/01/2008)

b. Part D Sponsors. Sponsors need to ensure the validity of the prescriber identifiers (i.e., NPI, DEA number, unique provider identification number (UPIN), or state license number) used for covered transactions. (HPMS memo 8/13/2010)

7. Office of Information Services Testing Requirements

a. Medicare Advantage Organizations and Part D Sponsors. Fulfill all testing requirements established by the CMS Office of Information Services. Specific information about testing is provided in the Data Exchange Preparation Procedures (DEPP) document, which is accessible from the MAPD Help Desk website: http://www.cms.gov/MAPDHelpDesk/PRG/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS056665&intNumPerPage=10

8. Patient Safety Analysis Website

a. Part D Sponsors. Ensure your organization has access to the Patient Safety Analysis website to download reports to update NDC lists. (HPMS memo 7/16/2010)

9. Prescription Drug Event (PDE) Requirements

a. Part D Sponsors. Ensure organization meets Prescription Drug Event (PDE) testing and certification requirements outlined at http://csscoperations.com/ (follow link, "Enroll to Submit PDE"). After completing certification, Sponsors must submit PDEs at least monthly.

b. Part D Sponsors. Ensure systems and processes are in place to research, correct, and resubmit PDE rejections per CMS guidelines. Ensure organization is current with PDE reject codes and subcategories. The list of affected NDCs is available at http://csscoperations.com. (HPMS memos 02/26/2008, 12/09/2008)

c. Part D Sponsors. 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 organization's internal records correspond. Monthly reports include:
   i. Drug Data Processing System (DDPS) Cumulative Beneficiary Summary.
   ii. PDE Accounting Report.
   iii. P2P (Plan to Plan) files.
   iv. Part D Payment Reconciliation Report.

d. Part D Sponsors. Ensure PDE records contain the changes required to close the coverage gap. (HMPS memos 7/9/2010 and 7/20/2010)

e. Part D Sponsors. CMS asks that sponsors submit PDE records as soon as possible after the date of service. (HPMS memo/email 7/23/2010)

f. Part D Sponsors. CMS strongly recommends that organizations contracting with third parties for PDE submission and reporting also receive copies of monthly reports directly from CSSC Operations in addition to receiving the reports from the third party.

10. Protection of Beneficiary Information

a. Medicare Advantage Organizations and Part D Sponsors. Ensure effective security of all beneficiary information, whether in paper or electronic format. Measures to protect the security and privacy of personally identifiable information (PII) that should be taken by organizations include, but are not limited to, ensuring that: (HPMS memo 12/16/2008)
    i. Data files are not saved on public or private computers when accessing corporate e-mail through the internet;
    ii. Electronic systems are properly programmed for beneficiary mailings in order to prevent documents containing PII from being sent to the wrong beneficiaries;
    iii. PII data on all portable devices are encrypted;
    iv. Security measures are implemented to restrict access to PII based on an individual's need to access the data;
    v. An internal risk assessment is performed, or an industry-recognized security expert is engaged, to conduct a risk assessment of the organization to identify and address security vulnerabilities;
    vi. Weaknesses or gaps in Organization's security program are quickly remedied;
    vii. Staff is trained on responsibilities and consequences of failing to secure sensitive beneficiary information; and
    viii. Compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Security and Privacy rules is documented, and Organization keeps current in response to environmental or operational changes affecting the security of the electronic protected health information.

11. Registrations and Connectivity for New 2011 Organizations Only

a. Register appropriate staff for submitter and representative roles in Individuals Authorized Access to CMS Computer Services (IACS) to ensure active access to

CMS user interfaces, file transfer execution to CMS systems, and MAPD Help Desk Announcements. (http://www.cms.hhs.gov/IACS/)

b. Establish connectivity (Gentran, Connect:Direct, or Third Party Vendor) with CMS systems for purpose of electronic file transfers. Connectivity methods (Gentran, Connect:Direct, or Third Party Vendor), setup instructions and forms are available in the Plan Reference Guide for CMS Part C/D Systems section of the MAPD Help website, http://www.cms.gov/mapdhelpdesk .

c. Submit an External Point of Contact (EPOC) Designation Letter to CMS using the instructions provided in the memo available on the website: http://www.cms.gov/MAPDHelpDesk/downloads/EPOC_Letter_Requirements_Final.pdf

d. Register an EPOC in IACS per the User Guide available from the MAPD Help website: http://www.cms.hhs.gov/IACS/03_General_User_Guides_and_Resources.asp#TopOfPage.

12. Risk Adjustment Data Validation (RADV)

a. Medicare Advantage Organizations. Consistent with regulations regarding access to facilities and records used in the determination of amounts payable under an MA contract, organizations need to be prepared to provide CMS and/or its contractors access to facilities and records (including medical records) that are to be used for RADV purposes. CMS reminds organizations of their obligation to ensure that there is specific language in contracts with providers and suppliers that reminds them of their obligation to cooperate in the provision of such records. (2011 Call Letter, HPMS memo 4/5/2010)

13. User Group Calls

a. Ensure key staff register for CMS' bi-weekly CMS Part C & D User Calls: (http://www.mscginc.com/registration/).