DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR DRUG and HEALTH PLAN CHOICE

Date: September 15, 2009

To: All Medicare Advantage Organizations (MAO) and Prescription Drug Plan (PDP) Sponsors

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Subject: CY 2010 Medicare Advantage and Prescription Drug Readiness Checklist

With the Annual Enrollment Period (AEP) fast approaching, we want to remind organizations of established requirements critical to ensuring a plan's enrollees receive effective coverage in 2010. The CY 2010 Readiness Checklist (Attachment A) summarizes the 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 the necessary measures to ensure that these key requirements are in place for CY 2010 open enrollment.

Similar to previous years, CMS will expect organizations to perform their own audit of these requirements. At a later date, CMS will provide a timeline to organizations 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 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 appropriate CMS guidance, or you can contact your account manager.

Attachment A

A. Systems, Data & Connectivity

(Primary reference documents: MMA Help website, OMB Circular M07-16, FISMA, HIPAA, HPMS Memos 06/09/2006, 08/30/2006, 10/30/2006, 07/23/2007, 02/26/2008, 05/01/2008, 10/21/2008, 11/24/2008, 11/26/2008, 12/09/2008, 12/16/2008, 06/09/2009)

1. **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:**
   - Data files are not saved on public or private computers when accessing corporate e-mail through the internet.
   - Electronic systems are properly programmed for beneficiary mailings in order to prevent documents containing PII from being sent to the wrong beneficiaries.
   - PII data on all portable devices are encrypted.
   - Security measures are implemented to restrict access to PII based on an individual's need to access the data.
   - 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.
   - Weaknesses or gaps in Organization's security program are quickly remedied.
   - Staff is trained on responsibilities and consequences of failing to secure sensitive beneficiary information.
   - 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.

   (HPMS Memo: 12/16/2008)

2. **As needed, participate in MMA Help's eLearning modules on Connectivity, Enrollment Transaction Processing, and Enrollment System Reports and Data Files.**
   (http://www.cms.hhs.gov/MMAHelp/12_eLearning.asp#TopOfPage)

3. **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 MMA Help Desk website, http://www.cms.hhs.gov/MMAHelp/downloads/Data_Exchange_Preparation_Procedures_20080729.pdf)

4. **For New 2010 Organizations only:**
   Register appropriate staff for submitter and representative roles in IACS to ensure active access to CMS user interfaces, file transfer execution to CMS systems, and MMA Help Desk Announcements.
   (http://www.cms.hhs.gov/IACS/)

5. **Ensure key staff registers for:**
   - HPMS access (http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf),
   - Plan Connectivity Data (PCD) Module within CMS, and
   - Bi-weekly CMS Part C & D User Calls (http://www.mscginc.com/registration/).

6. **Update Organization's contact information in HPMS for the 2010 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.**

7. **For New 2010 Organizations only:**
   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 MMA Help website, http://www.cms.hhs.gov/mmahelp/PRG **.**

8. **For New 2010 Organizations only:**
   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.hhs.gov/MMAHelp/downloads/EPOC_Letter_Requirements.pdf . Register an 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/IACS/03_General_User_Guides_and_Resources.asp#TopOfPage.

MAO-Only Organizations → Skip to → Section C

9. **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)

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

11. **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.**

12. **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)

13. **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:**
    - Drug Data Processing System (DDPS) Cumulative Beneficiary Summary,
    - PDE Accounting Report,
    - P2P (plan to plan) files, and
    - Part D Payment Reconciliation Report.

    (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.)

14. **Ensure timely and accurate submission of CY 2010 pricing data for posting on the Drug Plan Finder.**

15. **The initial CY 2010 data submission period for live/public pricing data will be September 21 through September 22, 2009. The data will be published on, or about, October 8, 2009.**

16. **For New 2010 Part D Sponsors, or Part D Sponsors with New Financial Information Reporting (FIR) Processors not previously Certified for FIR, only:**
    - Ensure Sponsor (or its processor) completes Automated True Out-Of- Pocket Expenditures (TrOOP) Balance Transfer testing and certification.
    - The Sponsor and/or its processor must be certified by November 15, 2009 and be fully prepared to respond to TrOOP Balance Transfer (TBT) transactions for 2010 beneficiaries on January 1, 2010.

17. **For New 2010 Part D Sponsors, or Part D Sponsors with New Financial Information Reporting (FIR) Processors not previously Certified for FIR, only:**
    - Ensure Sponsor (or its processor) completes Automated True Out-Of- Pocket Expenditures (TrOOP) Balance Transfer testing and certification.
    - The Sponsor and/or its processor must be certified by November 15, 2009 and be fully prepared to respond to TrOOP Balance Transfer (TBT) transactions for 2010 beneficiaries on January 1, 2010.

    (HPMS Memo and attachment (Operational Guidance): 10/21/2008)

18. **Ensure 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)

19. **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, 2010. 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. In these situations, organizations should wait until they receive the result of the SSA determination to update their systems.**
    (HPMS: 11/24/2008)

20. **Demonstrate, or be prepared to demonstrate, the ability to the 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, https://PartD.ProgramInfo.US/LIS.**
    - 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.

- 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.
- 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.

NOTE: CMS publishes the LIS match rate for each Sponsor on the Medicare Prescription Drug Plan Finder.
(HPMS Memos: 08/30/2006 & 10/30/2006, 11/26/2008)

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

(Primary reference documents: Prescription Drug Benefit Manual Chapter 13; 2009 Call Letter; and HPMS Memos 04/06/2009, 8/4/2008, 10/16/2008, 4/6/2009, and 5/11/2009)

Be prepared to:

1. **Apply correct CY 2010 benefit parameters (such as cost-share and deductible if applicable) based on LIS status in CMS systems or Best Available Evidence, if more favorable to the beneficiary.**
   (HPMS Memo: 04/06/2009)

2. **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.**
   (HPMS Memo: 06/09/2009)

3. **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)

4. **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 SSA for the Low Income Subsidy.**
   (HPMS Memo: 08/04/2008 and 10/16/2008)

5. **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)

6. **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)

7. **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)

8. **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.**

   NOTE: The BAE documentation must match the "Type of Documentation Supporting Request" field in the Excel worksheet sent to IntegriGuard.
   (HPMS Memo: 05/11/2009.)

9. **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)

10. **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)

C. Reporting

(Primary reference documents: Prescription Drug Benefit Manual Chapter 5 and CMS website: Plan Reporting and Oversight, 2010 Call Letter, HPMS Memo: 12/15/2008)

1. **Ensure a process is in place to submit all Part D CY 2010 reporting requirements to CMS according to specified timelines.**

2. **Ensure Sponsor has 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.**

3. **Ensure a process is in place to implement reporting standards and data validation specifications for Parts C and D reporting requirements.**

4. **Sponsors making Pharmacy Benefits Manager (PBM) changes mid-year, or post-CY2010 application approval:**
   - 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.
   - Additionally, update all members' 4Rx data prior to the effective date of the PBM change to reflect the new BIN and PCN.

D. Subcontractor Provisions, Contracting, and Oversight

(Primary reference documents: 42 CFR § 423.505 (i)(3)(iv), Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), and HPMS memos 07/23/2007, 09/20/2007 and 08/26/2008)

1. **Organizations with changes to offshore contractor arrangements: Within 30 calendar days after 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)

2. **Ensure all requirements are followed according to CMS' application, contract, guidance, and other advisory materials.**
   - **Recall that the 2010 Part C & D applications/solicitations are binding for Organizations that applied using earlier application/solicitation versions.**

3. **Ensure MAO's payment to non-contracted providers is prompt and for the correct amount.**
   (42 CFR § 422.100(b) and 422.214)

4. **Ensure contracts with first tier, downstream, and related entities are updated to address Part D prompt payment requirements.**
   (MIPPA 173, 42 CFR § 423.505(b)(19), 42 CFR § 423.505(b)(21)(i-ii), and 42 CFR § 423.520)

5. **Ensure Sponsor's and applicable first tier, downstream, and related entities' systems and procedures have been updated, as appropriate, to ensure clean claims are paid to network pharmacies within 14 days after an electronic claim is received, or 30 days for any other claim. Such systems and procedures may include increasing the frequency in which:**
   - Clean claims are batched for payment,
   - The Sponsor approves the payment, and
   - The electronic transfer of funds to pharmacies occurs.

   (42 CFR § 423.520)

E. Marketing

(Primary reference documents: Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), 42 CFR § 422.111, 422.2262, 422.2264(a), 422.2268(q), 422.2272, 422.2274, 423.128, 423.2262, 423.2264(a). 423.2268(q), 423.2272, 423.2274, Prescription Drug Benefit Manual Chapter 2 (Medicare Marketing Guidelines), Medicare Managed Care Manual Chapter 3 (Medicare Marketing Guidelines), HPMS memos, 2010 Call Letter)

1. **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.**

2. **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.**

3. **Market CY 2010 benefits to Medicare beneficiaries using CMS-approved and CMS-File & Use accepted marketing materials. CY 2010 marketing may begin no earlier than October 1, 2009.**

4. **CMS Review of Medicare Advantage and Prescription Drug Websites: Organizations are required to have a website or web page dedicated to each product they offer.**

   Those requirements include, but are not limited to:
   - Sponsors must maintain Internet Web sites which 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)
   - Any marketing materials placed on websites must be displayed in minimum of 12 point Times New Roman-equivalent font.
   - Website content should use language from marketing materials that have been reviewed and approved and appropriately submitted to CMS under File & Use.
   - 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.
   - Renewing organizations are required to provide website content beginning October 1 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.

5. **Verify accuracy of 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, including, but not limited to: the Summary of Benefits (SB), Medicare Options Compare and Medicare Prescription Drug Plan Finder on http://www.medicare.gov, and the Medicare & You Handbook.
   - To ensure the consistent use of standardized plan-type terminology across all organizations, HPMS will auto-populate the plan type label at the end of each plan name beginning in CY 2010.

6. **Website Postings and Required Links: The following information must be accessible via a link on the organization's website:**
   - Summary of Benefits,
   - Enrollment Instructions,
   - Privacy Notice,
   - Evidence of Coverage,
   - LIS Premium Summary chart,
   - Information related to plan's exception and appeals process, and

   - 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, 2009),
   - Plan transition process information via a link from the Medicare Prescription Drug Finder, and
   - Provide a link regarding the Best Available Evidence Policy.

7. **E-Prescribing: Medicare Advantage Organizations should indicate in their provider directories which of their participating physicians or physician practices support e-prescribing. Additionally, Part D Sponsors' pharmacy directories should indicate which of their network pharmacies support e-prescribing.**

8. **Ensure Organization meets the requirements regarding the appointment of agents and brokers and compliance with State information requests under 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 our compensation regulations at 42 C.F.R. §422.2274 and §423.2274.

- Compensation rates for 2010 must be adjusted based on 2009 compensation rates adjusted by MA or Part D percentage rate change from the annual rate notice for that year.
- 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.
- CMS does not differentiate between agents, brokers, general agents, general agencies and distribution partners.

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.

9. **Organization follows instructions for global hard copy changes to CY 2010 Summary of Benefits (SB) made without prior approval from CMS Central Office due to programming errors in the Plan Benefit Package (PBP/SB) software.**
   - Submit SB with global hard copy changes to Regional Office reviewer following the normal marketing material review process. All other SB change requests must be submitted to the SB mailbox for Central Office review prior to submitting to the Regional Office.

10. **Outbound Education and Verification Calls to all New Enrollees. Implement a process through outbound verification calls to ensure beneficiary requesting enrollment understands the type of plan and plan rules.**

11. **For Renewing Organizations: Marketing of CY 2009 plans through mass media or direct mail marketing (except for age-in mailings) must cease once an organization begins marketing CY 2010 plans.**
    (2010 Call Letter)

12. **For Renewing Organizations: Ensure all current members of PDPs, MA plans, MA-PD plans, and Cost plans offering Part D, receive the CY 2010 annual renewal materials on time.**
    Due to current members by October 31, 2009:
    - Combined Annual Notice of Change (ANOC)/Evidence of Coverage (EOC)

- Dual Eligible SNPs that are fully integrated with the State are not required to use the standardized ANOC/EOC
- LIS Rider to the EOC to members qualified for the Federal Low-Income Subsidy,
- Abridged or comprehensive formularies

NOTE: Employer-Only series /Employer Direct/Cost Sponsors – Employer/union group ANOCs/EOCs are required to be received by beneficiaries 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

- Summary of Benefits is not required but must be available upon request.

13. Implement procedures and safeguards to ensure the CMS-approved formulary matches marketed formulary both in print and on the website.

14. Request use of, and sign applicable licensing agreement for, the Medicare Prescription Drug Benefit Program Mark in 2009, if planning to use it during CY 2010.

F. Enrollment/Disenrollment

(Primary reference documents: Medicare Managed Care Manual Chapter 2 & Prescription Drug Benefit Manual Chapter 3)

1. **Ensure an updated CY 2010 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. **Excluding MSA, Cost Plans, and 800-Series-Only; Optional for SNPs: (NOTE: 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)

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 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).

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. **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,

   - Organization reported enrollment and status information to CMS correctly,
   - Organization reviewed and reported to CMS any discrepancies between the Organization's records and CMS monthly membership reports and reply listings, and
   - Follow existing procedures for submitting requests for the correction of discrepancies to the Retroactive Adjustment Processing Contractor.

   (42 CFR § 422.504(l)(1) and 423.505(k)(2), and HPMS Memos: 03/29/2006 & 07/21/2009)

9. **Effective August 2, 2009, Reed & Associates is the new retroactive processing contractor and will be responsible for:**

   - Retroactive processing requests,
   - Monthly Certification of Monthly Enrollment and Payment Data, and
   - All other related materials.

   Organization ensures 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)

10. **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.**

G. Late Enrollment Penalty (LEP) & Creditable Coverage

(Primary reference documents: MIPPA (Sec. 114), 42 CFR § 423.780(e), Prescription Drug Benefit Manual Chapters 4 & 18, and HPMS Memos: 04/11/2008, 11/26/2008, 01/14/2009)

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, 2010, when the demonstration ends.

2. **Report changes to the number of uncovered months previously reported for both current and former (required when the change is a result of the Sponsor's completed creditable coverage period determination or a reconsideration decision from Maximus) plan members.**

   (HPMS Memo: 11/26/2008)

3. **Ensure 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: 04/11/2008)

4. **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)

5. **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.**

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

   (Prescription Drug Benefit Manual Chapter 4)

H. Coordination of Benefits (COB)

(Primary reference documents: Medicare Prescription Drug Benefit Manual Chapter 14, Medicare Secondary Payer Manual Publication #100-05, HPMS Memo: 11/24/2008)

1. **Establish/maintain systems and procedures for at least weekly COB data report/file processing.**
   - Organizations are required to not only receive COB information but also to apply it to their system(s).
   - Organizations utilize the ECRS to send COB updates to CMS. (ECRS user guide is available on the CMS website).
   - CMS receives daily COB updates from the COBC, and CMS subsequently sends the COB file to the Sponsors.

   (Medicare Prescription Drug Benefit Manual Chapter 14, Medicare Secondary Payer Manual Chapter 6) and the Plan Communication User Guide (PCUG))

2. **Follow the new coordination of benefits (COB) notification process and requests beneficiary to provide new updates of other prescription drug coverage information only when the other drug coverage information exists on the COB file.**
   - Organizations opting to implement the change from the COB survey to the COB notification process in CY2009 should incorporate this revised approach at the same time.
   - Changes in other prescription drug coverage information provided by beneficiaries must be forward to the COB contractor (COBC) via Electronic Correspondence Referral System (ECRS).

   (2010 Call Letter and update via HPMS Memo: 07/21/2009)

3. **Interpret the COB file correctly.**
   - 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.
   - The information on the COB file is collected by the COB contractor 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. The COBC also provides the mechanism for support of the tracking and calculating of beneficiaries' "true out-of-pocket" (TrOOP) expenditures under Part D.

   (2008 Regional Prescription Drug Event Data Technical Assistance Participant Guide, HPMS Memo: 11/24/2008)

I. Claims Process/Transition/Point of Sale (POS)

(Primary reference documents: Medicare Managed Care Manual Chapter 4, Medicare Prescription Drug Benefit Manual Chapters 5 & 6, HPMS Memo: 06/16/2008)

1. Pharmacy and Provider Access during a Federal Disaster or Other Public Health Emergency Declaration:

We advise MAOs, Cost Plans, and Part D Sponsors to consult the U.S. Department of Homeland Security's Federal Emergency Management Agency's (FEMA) website (see http://www.fema.gov/hazard/dproc.shtm) for information about the disaster or emergency declaration process and the distinction between types of declarations. Organizations should also consult the Department of Health and Human Services (DHHS) or Centers for Medicare & Medicaid Services (CMS) websites for any detailed guidance that may be posted.

In the event of a Presidential emergency declaration, a Presidential (major) disaster declaration, a declaration of emergency or disaster by a Governor, or an announcement of a public health emergency by the Secretary of Health and Human Services Cost & MA plans - absent an 1135 waiver by the Secretary:

- **Cost and MA plans are expected to:**
  - Allow Part A/B and supplemental Part C plan benefits to be furnished at specified non-contracted facilities (note that Part A/B benefits must, per 42 CFR § 422.204(b)(3), be furnished at Medicare-certified facilities);
  - Waive in full, or in part, requirements for authorization or pre-notification;
  - Temporarily reduce plan approved out-of-network cost sharing amounts; and
  - Waive the 30-day notification requirement to enrollees provided all the changes (such as reduction of cost sharing and waiving authorization) benefit the enrollee.
- **Part D Sponsors are expected to:**
  - Lift their "refill-too-soon" edits, when these circumstances create a disruption in access to covered Part D drugs.
  - Part D Sponsors may exercise some operational discretion as to how these edits are lifted during a disaster or emergency as long as access to Part D drugs is provided at the point-of-sale.

(HPMS memos: 06/16/2008, 07/20/2009, and Prescription Drug Benefit Manual Chapter 5)

2. Cover vaccine administration per Medicare Managed Care Manual Chapter 4 and Medicare Prescription Drug Benefit Manual Chapter 6.

3. **Ensure staff is trained on the prescription drug transition policy and any related information systems necessary to accommodate administration of the transition policy. 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, and
   - The revised Model Transition Letter. Revision includes:
     - Specific instructions as to when the model should be used,
     - Additional information to member regarding purpose and extent of the transition supply, and
     - A checklist for the Part D transition letter.

   (Prescription Drug Benefit Manual Chapter 6, HPMS Memo: 07/21/2009)

4. **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)

5. **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)

6. **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)

J. Appeals and Grievances

1. **CMS strongly recommends that all MAOs and Part D plan sponsors include complete copies of the relevant Evidence of Coverage (EOC) and/or formulary (Part D sponsors) with any case files sent to an independent review entity (IRE) for review.**
    - Each case file sent to an IRE includes a CD with complete versions of the EOC and/or formulary relevant to an enrollee's specific case.

2. **On January 12, 2009, CMS published a final rule with comment period (CMS-4131-FC) in the Federal Register entitled "Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions." Organizations must have policies and procedures in place to ensure compliance with the following regulatory changes:**
    - Under the Medicare Advantage (Part C) program, §422.578 and §422.582 have been revised to allow a physician who is providing treatment to an enrollee, upon providing notice to the enrollee, to request a standard plan reconsideration on the enrollee's behalf without having been appointed as the enrollee's representative. This change aligns our policy on standard reconsiderations with our policy on expedited reconsiderations.
    - Under the prescription drug benefit (Part D) program, §423.560 has been revised to add a definition for "other prescriber," that is, health care professionals other than physicians who have the requisite authority under State law or other applicable law to write prescriptions for Medicare beneficiaries. We have also replaced the term "physician" with the phrase "physicians and other prescribers" throughout the Subpart M regulations. The effect of these changes is that other prescribers may now perform the same functions that prescribing physicians are allowed to perform with respect to the Part D coverage determination and appeals processes. In addition, consistent with the changes to the MA regulations, §§423.580 and 423.582 have been revised to allow prescribing physicians and other prescribers, upon providing notice to the enrollee, to request a standard redetermination on the enrollee's behalf without having been appointed as the enrollee's representative.

3. **PFFS plans must update their terms and conditions using the instructions for contacting First Coast Service Options, Inc. (FCSO) as outlined in the January 2, 2009 HPMS memo.**

4. **MA organizations' questions regarding the adjudication process or individual disputes being reviewed by the IRE should be directed to FCSO.**

   Note: Enrollee appeals of organization determinations and out-of-network 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 contract with FCSO.

   (01/12/ 2009 CMS final rule (CMS-4131-FC) "Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions; 2010 Call Letter; HPMS: 01/02/2009, 06/20/2009)

K. Customer Service

(Primary reference documents: Prescription Drug Benefit Manual Chapter 2, Medicare Managed Care Manual Chapter 3, and 42 CFR § 423.128 (d)(1))

1. **Ensure call centers are able to accommodate non-English speaking/reading beneficiaries.**
   - Sponsors should have interpretation services available to answer questions non-English speaking beneficiaries may have concerning aspects of the prescription drug benefit.

2. **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 2010 operations. MAOs and Part D Sponsors must meet CMS standards.**
   - 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 Organization offers Medicare plans.
   - Beneficiary call center requirement after the first 60 days of 2010:
     - 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. **Ensure that pharmacy technical call centers will be staffed appropriately to handle increased call volume during the annual enrollment period and the first 60 days of 2010 operations. Part D Sponsors must meet CMS standards.**
   - 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.

-End of CY 2010 MA and Prescription Drug Readiness Checklist-