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

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To: All Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) Sponsors, 1876 Cost Plans, and PACE organizations as applicable

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Subject: Contract Year (CY) 2012 Medicare Advantage and Part D Readiness Checklist

With the Annual Enrollment Period (AEP) fast approaching, the Centers for Medicare & Medicaid Services (CMS) is reminding organizations of the requirements critical to ensuring a plan's enrollees receive effective coverage beginning January 1, 2012. The Contract Year (CY) 2012 Readiness Checklist summarizes key operational requirements as established in statutes, regulations, manual chapters, Health Plan Management System (HPMS) memos, applications, and other advisory materials. Given the significance of these updates and changes, your organization should review this checklist carefully and take the necessary measures to ensure that these key requirements are in place. The Readiness Checklist is not an exhaustive list of all MA, Part D, and 1876 Cost Plan requirements.

Similar to previous years, CMS expects your organization to perform your own audit of these requirements. At a later date, CMS will provide a timeline to report these results to us through a secure information collection website. Should you identify areas where your organization needs assistance or are not/will not be in compliance, your organization must report these problems to your Account Managers directly in writing. Please do not wait for the formal Readiness Checklist response request.

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 contact your account manager.

CY 2012 Medicare Advantage and Part D Readiness Checklist

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Note: Unless otherwise indicated, where a requirement states it applies to Medicare Advantage Organizations, this includes 1876 Cost Plans. References to Part D sponsors include all organization types offering Part D. PACE organizations are responsible for determining which requirements are applicable.

A. Systems, Data, & Connectivity

I. Health Plan Management System (HPMS) Connectivity – Medicare Advantage Organizations and Part D Sponsors

A. Ensure key staff members register for HPMS access: http://www.cms.hhs.gov/InformationSecurity/Downloads/EUAaccessform.pdf.

B. Ensure key staff members register for the Plan Connectivity Data (PCD) Module within HPMS by emailing hpms_access@cms.hhs.gov.

C. Update organization's contact information in HPMS, ensuring all information is current. Changes to any HPMS contacts should be made immediately upon the effective date of the responsibility transfer.

II. Low Income Subsidy (LIS) Match Rate Website – Part D Sponsors, excluding contracts exclusively serving the U.S. Territories

A. To establish or maintain existing authorization to the LIS Match Rate Website, follow the instructions in the HPMS memo released 12/09/2010, Attachment A: User Authorization Instructions. https://PartD.ProgramInfo.US/User_Security

B. Identify up to five authorized users for the CMS contractor's (Acumen, LLC) LIS Match Rate and BAE Monitoring Web sites.

(See section Best Available Evidence (BAE) and Low Income Subsidy (LIS))

III. MARx – Medicare Advantage Organizations and Part D Sponsors

A. 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.** 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.
  - **a.** IACS requires a date of birth (DoB) from new users at registration and from current users missing a DoB in their profile.
  - **b.** An individual's access to IACS will be partially disabled when 180 days or more lapses between system logins. (HPMS memo 5/21/2010)

B. Ensure your organization is prepared to implement and carry out the End of Year (EOY) systems processing activities necessary for the transition to CY 2012.

IV. Medicare Plan Finder Data (MPF) – Applicable organization types noted below

A. New 2012 Medicare Advantage and Part D Sponsors. Ensure your organization has access to the MPF Communications website and has authorized new users. Updates and announcements relating to the quality assurance (QA) process are posted on the MPF Communication website. (https://PartD.ProgramInfo.us/User_Security) (HPMS memo 7/14/2011)

B. Medicare Advantage Organizations and Part D Sponsors. The Plan Preview Schedule for CY 2012 was as follows:

- **i.** The initial preview period was from August 31, 2011 to September 2, 2011, and
- **ii.** The second preview period is from September 13, 2011 to September 18, 2011. (HPMS memo 08/18/2011 and HPMS email 09/15/2011)

C. Part D Sponsors. The initial CY 2012 data submission period for live/public pricing data was September 12th through September 13th, 2011. The data will be published on Medicare.gov on or about October 1, 2011.

D. Part D Sponsors. Ensure pricing and pharmacy network data files for MPF have passed quality assurance checks for completeness and accuracy for CY 2012 data, and that only pharmacies under contract for 2012 are included for display. Updates and announcements to the QA process may be found on the MPF website.

E. Part D Sponsors. Ensure timely and accurate submission of CY 2012 pricing data for posting on the Drug Plan Finder. Sponsors are required to submit MPF data every two weeks. Auto-certification of pricing data has been discontinued as of the initial CY 2012 MPF submission window.

V. User Group Calls – Medicare Advantage Organizations and Part D Sponsors

A. Ensure key staff register for the CMS biweekly Part C & D User Calls at http://www.mscginc.com/registration.

B. Participants should call fifteen minutes before start time to alleviate hold times.

VI. National Provider Identifier (NPI) Requirements – Part D Sponsors

A. Be advised, CMS guidance specifies that the NPI is intended to uniquely identify a health care provider in standard transactions, such as health care claims. The Health Insurance Portability and Accountability Act (HIPAA) required covered entities to use NPIs in standard transactions by May 23, 2008. This guidance is in a FAQ available on the CMS Web site at: http://questions.cms.hhs.gov/app/answers/detail/a_id/2623/session/L3NpZC9jeUQydDE3aw%3D%3D.

B. Be advised, although HIPAA requires pharmacies to use the NPI on HIPAA covered transactions, CMS recognizes that pharmacies cannot always obtain the prescriber NPI at the time of dispensing. Therefore, to ensure Part D enrollees do not experience

service interruptions, CMS guidance permits Part D sponsors to accept valid alternative prescriber identifiers, such as DEA registration numbers or state license numbers. (HPMS memo 08/13/2010)

VII. Patient Safety Analysis Website – Part D Sponsors

A. Existing Part D sponsors should ensure they have access to monthly Patient Safety Reports via the Patient Safety Analysis Website (https://PartD.ProgramInfo.US/PatientSafety) to compare their performance to overall averages and monitor their progress in improving Part D patient safety measures over time. These actionable reports include contract-level patient safety reports for expanded analyses and information and detailed beneficiary-claim level and outlier reports.

B. Sponsors may also view an 'at-a-glance' Rate Summary website feature and Performance Graphs. For additional information, *User Guides* and the NDC level medication lists used to calculate the measures are available on the Patient Safety Analysis Website under *Help Documents*. (HPMS memo 04/22/2011)

C. New sponsors for 2012 should be prepared to begin reviewing these reports in spring of 2012, after receiving log-in credentials directly from the Patient Safety Analysis Website contractor.

VIII. Prescription Drug Event (PDE) Requirements – Part D Sponsors

A. Ensure your 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 once monthly.

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

C. Ensure procedures are in place for analysis of recurring 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. CMS reports include:

- **i.** Drug Data Processing System (DDPS) Cumulative Beneficiary Summary,
- **ii.** PDE Accounting Report,
- **iii.** P2P (Plan to Plan) files,
- **iv.** Accumulator Comparison Report, and
- **v.** Gap Coverage Invoice Report.

D. Ensure PDE records contain the changes required to close the coverage gap. (HPMS memos 07/09/2010, 07/20/2010, and 09/24/2010)

E. CMS requires that sponsors submit timely PDE records. The submission schedule below will help ensure that CMS receives substantially complete data within 30 days following the close of the benefit year. (HPMS memo 05/16/2011)

- **i.** Submit original PDEs within 30 days following Date Claim Received or Date of Service (whichever is later),
- **ii.** Resolve rejected records and re-submit within 45 days following receipt of rejected record status from CMS, and
- **iii.** Submit adjustments and deletions within 45 days following discovery of issue requiring change.

CMS expects sponsors to promptly resolve rejected PDE records and take corrective action to prevent a recurrence of the issue.

F. CMS strongly encourages plans to take steps to improve their PDE submissions. Sponsors should take an active and consistent approach to the resolution of PDE errors that lead to PDE rejections and inaccuracies in plan-reported financial data used in the Part D payment reconciliation process. (HPMS memo 10/08/2010)

G. Ensure your organization establishes access to Acumen's PDE Analysis and PDE Reports websites as described in the March 4, 2011 HPMS memo.

IX. Financial Information Reporting (FIR) Processors – Part D Sponsors

A. Ensure your organization's FIR processor was certified by the Transaction Facilitator (formerly the TrOOP Facilitator) to process FIR transactions including the Contract/PBP fields. The Transaction Facilitator began piloting the new version of the FIR transactions in September 2011. (HPMS memo 06/16/2011)

(See section Coordination of Benefits and Automatic TrOOP Balance Transfer)

X. Medicare Advantage Encounter Data System (EDS) – Medicare Advantage Organizations

A. Prepare for the January 2012 implementation of the Medicare Advantage Encounter Data System by successfully completing end-to-end testing and certification. The schedule of testing and certification follows:

- **i.** The Front-End Industry testing of the EDS will run from September 6 until October 4, 2011,
- **ii.** The Encounter Data Processing System (EDPS) test case preparation and education will occur from October 5 until October 28, 2011, and
- **iii.** The Encounter Data System Institutional and Professional Processing and Pricing Sub-System End-to-End Testing/certification is scheduled to run from October 31 until November 30, 2011. (HPMS memo 07/08/2011)

XI. Part C and D Plan Ratings - Medicare Advantage Organizations and Part D Sponsors

A. CMS strongly encourages your organization to preview measure data and star ratings for accuracy in data sources, calculations, and star assignments, and review associated technical notes and presentations related to Plan Ratings.

B. Notify CMS of any issues or questions following your organization's review per plan preview schedules.

B. Reporting

I. Healthcare Effectiveness and Data and Information Set (HEDIS), Health Outcomes Survey (HOS), and Consumer Assessment of Healthcare Providers and Systems (CAHPS) – Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization is prepared to submit HEDIS, HOS, and CAHPS measures to the appropriate entity by the specified due date. (HPMS memo 08/08/2011)

i. New for 2012, all HEDIS® 2012 measures must be submitted to NCQA by 11:59 p.m. EDT on **June 15, 2012**. Please note that late submissions will **not** be accepted. If an organization (contract/plan) submits HEDIS® data after June 15, 2012, they will automatically receive a rating of one star for the required HEDIS® measures for the data that are updated on Medicare Plan Finder. MA ratings affect MA quality bonus payments. (HPMS memo 07/01/2011)

ii. Medicare Advantage (MA) Private Fee for Service (PFFS) and Medicare Savings Account (MSA) contracts will be required to collect data on all HEDIS measures covering services provided in CY 2011 and to report the audited data to CMS through NCQA in June 2012 using the HEDIS 2012 Technical Specifications. When a required measure allows the hybrid method to be used for data collection, plans may choose that method. If a required measure offers only the hybrid method for data collection, plans must use that method (e.g., *Controlling High Blood Pressure*). (HPMS memo 08/08/2011)

iii. Medicare Advantage Organizations, including PFFS and MSA contracts, and Part D sponsors will be required to contract for the 2012 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 2011 are required to contract with CMS-approved Medicare CAHPS survey vendors to conduct data collection. (HPMS memos 12/02/2009 and 06/25/2010)

iv. Ensure your organization uses one of the approved 2012 CAHPS survey vendors. (HPMS memo 09/03/2010)

II. Part C and Part D Reporting Requirements – Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization is prepared to collect data on all Part C and Part D (as applicable) reporting requirements, conduct appropriate data validation, and submit data to CMS according to the requirements, deadlines, and technical specifications. (HPMS Plan Reporting Site: http://www.cms.hhs.gov/HealthPlansGenInfo/16_ReportingRequirements.asp#TopOfPage and https://www.cms.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp)

III. Pharmacy Benefit Manager (PBM) Change – Part D Sponsors

A. If making Pharmacy Benefit Manager (PBM) changes:

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. Notify your CMS Account Manager at least 60 days prior to the effective date of the new contract or the date the new PBM would begin providing services to beneficiaries, whichever is earlier.

(See additional 4Rx information in Enrollment/Disenrollment, section IV.D.a)

C. Contracting, Subcontractor Provisions, and Oversight

I. Contracting Requirements – Medicare Advantage Organizations and Part D Sponsors

A. Ensure all contracts for Medicare services meet all the requirements according to CMS' application, contract, guidance, regulations, and other advisory materials. Also, recall that the requirements included in the 2012 Part C & D applications/solicitations are binding for organizations that applied using earlier application/solicitation versions. (*Annual Contract with CMS*)

B. Record Retention and Confidentiality: All plan sponsors must abide by CMS rules and regulations regarding record retention by retaining documents (i.e. books, records and documents etc.) for a period of ten years. The retained documents should be sufficient to include all policy and operational procedures conducted during the course of the effective period of the CMS contract with the plan sponsor. During the period of record retention, plan sponsors must abide by all confidentiality requirements. (*Managed Care Manual, Chapter 4, Section 10.8, 42 C.F.R.* §§ 422.504(d), 423.504(d))

II. Offshore Subcontracting – Medicare Advantage Organizations and Part D Sponsors

A. 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)

III. State Medicaid Agency Contracts – Medicare Advantage Organizations offering dual eligible Special Needs Plans (D-SNPs) in CY 2012

A. MAOs that offered new or expanded D-SNPs in CY 2010 or 2011, or for CY 2012 are offering a new or expanded D-SNP, must ensure they have a signed contract with their State Medicaid Agency. Ratified contracts were due no later than August 26, 2011 and will be effective on January 1, 2012. (HPMS memos 01/11/2010, 04/06/2010, 08/19/2010, and 08/27/2010, 06/17/2011, *Medicare Managed Care Manual Chapter 16-B*)

D. Customer Service

I. Customer Service Call Centers – Medicare Advantage Organizations and Part D Sponsors

A. Ensure that toll-free beneficiary call centers will be staffed appropriately to handle increased call volume from October 15 to February 14, which includes the AEP. MAOs and Part D Sponsors must meet CMS standards. (*Medicare Marketing Guidelines, Section 80.1*)

i. From October 15, 2011 to February 14, 2012. Beneficiary call center requirement: 8:00 AM to 8:00 PM seven days a week in all regions where the organization offers Medicare plans except for Thanksgiving and Christmas. Organizations are permitted to use alternative technologies to meet the customer service call center requirements for Saturdays, Sundays, and holidays. (HPMS memo 11/04/2010)

ii. From February 15, 2012 until the following annual enrollment period. Beneficiary call center requirement: 8:00 AM to 8:00 PM in all regions, Monday through Friday.

II. Limited English Speaking Beneficiaries – Medicare Advantage Organizations and Part D Sponsors

A. Non-English Speaking Populations: All plan sponsors' call centers must have interpreter services available to call center personnel to answer questions from non-English speaking beneficiaries. This requirement is in place regardless of the percentage of non-English speaking beneficiaries in a service area.

B. Beginning with marketing materials for the 2012 AEP, plan sponsors must make the marketing materials noted in the June 10, 2011 HPMS memorandum and the Part D

Transition Letter available in any language that is the primary language of more than five percent of a plan sponsor's plan benefit package service area.

(NOTE: the member ID card is excluded from this requirement).

Additionally, plan sponsors must place translated versions of these materials on the plan's website. (*Medicare Marketing Guidelines, Section 30.8*, 42 C.F.R. §§ 422.2264(e), 423.2264(e))

III. Customer Service Staff Knowledge – Applicable organization types noted below

A. Medicare Advantage Organizations and Part D Sponsors. Ensure staff advises 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.

B. Part D Sponsors. Ensure staff is familiar with the plans' Medication Therapy Management (MTM) program, including eligibility criteria, as applicable.

C. Part D Sponsors. Ensure staff is 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)

D. 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. (*Medicare Prescription Drug Benefit Manual, Chapter 4*)

IV. Pharmacy Technical Help Desk Call Centers – Part D Sponsors

A. Ensure that pharmacy technical help desk call centers will be staffed appropriately to handle increased call volume from October 15, 2011 to February 14, 2012. Part D Sponsors must meet CMS standards. (*Medicare Marketing Guidelines, Section 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, including Thanksgiving and Christmas.

V. Complaints Tracking Module – Medicare Advantage Organizations and Part D Sponsors

A. Plan sponsors should be prepared to resolve at least 95% of Complaints Tracking Module (CTM) complaints designated as "immediate need" within two calendar days, complaints designated as "urgent" within seven days, and resolve at least 95% of all 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 days to resolve. (HPMS memo 12/28/2009)

B. Plan sponsors should be advised that complaint rates are part of star ratings.

C. Effective January 1, 2012 all plan sponsors must prominently display the CMS developed complaint form on their websites and have a direct link to the Medicare.gov website and the web site of the Ombudsman on the Medicare.gov website. (See 42 C.F.R. §§ 422.504, 423.505)

E. Marketing

I. Agents and Brokers – Medicare Advantage Organizations and Part D Sponsors

A. Ensure all agents/brokers (including those employed by the plan) receive annual training and testing on Medicare rules, regulations, and specific plan products of all brokers and agents selling Medicare products, prior to marketing CY 2012 products. Agents/brokers must receive a passing score of 85% on the test. (*Medicare Marketing Guidelines, Section 120.3*)

B. Ensure plan sponsors' training curricula contain the minimum information and required elements listed in the guidelines attached to HPMS memo 08/01/2011.

C. Ensure plan sponsors follow all CMS rules and guidance for compensation of independent agents and brokers, when utilized for the sale of Medicare products. (*Medicare Marketing Guidelines, Section 120.5*)

II. Anti-Discrimination – Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization does not discriminate based on race, ethnicity, national origin, religion, gender, age, mental or physical disability, health status, claims experience, medical history, genetic information, evidence of insurability, or geographic location within the service area. (*Medicare Marketing Guidelines, Section 30.7*, 42 C.F.R. §§ 422.110, 422.2268(c), 423.2268(c))

B. Ensure your organization does not engage in practices such as target marketing to beneficiaries from higher income areas. (*Medicare Marketing Guidelines, Section 30.7*)

C. For beneficiaries with visual or hearing impairments: Upon beneficiary request, make sure information about their benefits is accessible and appropriate for Medicare beneficiaries who have disabilities. (*Medicare Marketing Guidelines, Section 30.9 and Medicare Managed Care Manual, Chapter 4, Section 10.6,* 42 C.F.R. §§ 422.2264(a)(4), 423.2264(a)(3))

III. Medicare Marketing Material Review and Usage – Medicare Advantage Organizations and Part D Sponsors

A. File & Use: Plan sponsors have the ability to utilize the File & Use program. To do so, plans sponsors must submit the File & Use certification to the respective CMS Account Manager. Materials that qualify under the File & Use process can be distributed five calendar days after submission to CMS, but no earlier than any date established by CMS for use of specific document/materials. (*Medicare Marketing Guidelines, Section 90.6* 42 CFR §§ 422.2262(b), 423.2262(b))

The following materials are qualified for the File & Use process when used without modification and the plan sponsor has submitted a File & Use certification to CMS:

- **i.** Provider directory (including combined provider directory and pharmacy directory),
- **ii.** Standardized combined ANOC/EOC,
- **iii.** Pharmacy directories,
- **iv.** Abridged and comprehensive formularies,
- **v.** Certain CMS enrollment/disenrollment letters, and
- **vi.** Certain claims, grievance, organization/coverage determinations, and appeals model letters. (*Medicare Marketing Guidelines, Section 90.6.1*)

IV. Translated marketing materials— Medicare Advantage Organizations and Part D Sponsors

A. Translate marketing materials, as specified in section 30.8 of the Medicare Marketing Guidelines, into any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area. The methodology for calculating the five percent of PBP enrollees is available in the HPMS memo dated 06/15/2011.

To alleviate some of the burden and to provide consistency among translated materials, CMS provides specific translated model marketing materials as identified in HPMS memos dated 07/15/2011, 08/05/2011, 08/23/2011, and 08/31/2011.

V. Medicare Prescription Drug Benefit Mark – Part D Sponsors

A. If intending to use the Medicare Prescription Drug Benefit Program Mark, obtain proper authorization from CMS via a written communication. This communication will include a licensing agreement which must be signed by the organization's CEO/CFO in order to use the Medicare Prescription Drug Benefit Program Mark prior to execution of the Part D contract. PDP and MA-PD entities may use the mark on submission of marketing materials consistent with the Medicare Marketing Guidelines. (*Medicare Marketing Guidelines, Section 150.1*)

VI. Post-Enrollment Marketing Materials – Applicable organization types noted below

A. Annual Notice of Change (ANOC)/Evidence of Coverage (EOC)

i. Medicare Advantage Organizations and Part D Sponsors, and 1876 Cost Plans offering Part D. Organizations must send the upcoming ANOC/EOC, LIS Rider, and abridged or comprehensive formulary for member receipt no later than September 30, 2011.

ii. Medicare Advantage Organizations and Part D Sponsors, excluding D-SNPs, 1876 Cost Plans not offering Part D, and EGHPs. Ensure that new enrollees with effective dates of November 1st or December 1st receive both an EOC for the current contract year and an ANOC/EOC for the upcoming contract year. (*Medicare Marketing Guidelines, Section 60.7*)

iii. Fully Integrated D-SNPS. ANOC and EOC may be separated, but ensure the ANOC is sent for member receipt by September 30th for the upcoming coverage year, and the EOC is sent for member receipt by December 31st.

iv. 1876 Cost Plans not offering Part D benefits. Ensure the combined ANOC/EOC is sent to enrollees by December 1st of each year. (*Medicare Marketing Guidelines)*

B. Summary of Benefits (SB) Changes – Medicare Advantage Organizations and Part D Sponsors.

i. If necessary, ensure your organization follows instructions for submitting the SB hard copy change request in HPMS. Because the Summary of Benefits is a standardized document, any deviation from this language, outside of an approved hard copy change or global hard copy change, will result in CMS disapproval of the material. CMS will allow an organization to make changes to hard copy SBs on a very limited basis. (*Medicare Marketing Guidelines, Appendix 1*)

VII. Formulary – Part D Sponsors

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

B. Ensure that your organization checks HPMS to verify that your formulary is approved prior to the beginning of marketing on October 1, 2011. Only approved formularies can be marketed. (HPMS memo 07/05/2011)

VIII. Outbound Education and Verification Calls to all New Enrollees – Medicare Advantage Organizations and Part D Sponsors

A. All sponsors are required to conduct outbound enrollment and verification calls for enrollments effectuated by agents and broker, both independent and employed, to ensure individuals requesting enrollment understand the plan rules.

B. Be prepared to make a minimum of three attempts, all documented, to contact the applicant by telephone within fifteen calendar days of receiving the enrollment request. If the enrollment application is received incomplete, we expect plan sponsors to concurrently conduct the outbound verification calls while obtaining completed information for the application. Plan sponsors that are unable to successfully complete the outbound verification on the first attempt should send the applicant an enrollment verification letter. (42 C.F.R. §§ 422.2272(b), 423.2272(b))

C. For AEP enrollment requests, the script and the enrollment verification letter will inform beneficiaries that they must notify the plan sponsor of their intent to cancel the processing of their enrollment within seven calendar days from the date of the letter or call, or by December 7, whichever is later. (*Medicare Marketing Guidelines, Section 70.6*)

IX. Websites – Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization has a website or web page dedicated to each product you offer. Those requirements include, but are not limited to:

- **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, 2011 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. Ensure the following information is accessible via a link on the plan sponsor's website:

- **i.** Summary of Benefits,
- **ii.** Enrollment instructions and forms,
- **iii.** Evidence Of Coverage,
- **iv.** LIS Premium Summary Table,
- **v.** Privacy notices (privacy notices are subject to enforcement by the Office for Civil Rights),

vi. Exception and appeals process and forms, and

vii. Applicable non-English materials.

viii. Part D Sponsors only. Including, but not limited to:

- **a.** Number of pharmacies in network and how the plan meets access requirements,
- **b.** Description of out of network coverage,
- **c.** Current formulary drug listing,
- **d.** Drug utilization management information that is easy to understand, clearly marked, and easy to find,
- **e.** Transition process information,
- **f.** Quality assurance policies and procedures, including MTM, and drug and/or utilization management, as applicable, and
- **g.** Provide a link regarding the Best Available Evidence (BAE) Policy, and Low-Income Subsidy (LIS) premium summary table.

(*Medicare Marketing Guidelines*, *Section 100,* 42 C.F.R. §§ 422.2264, 422.111 (g) (2), 423.2264, 423.128(b) (7), 423.2264(a), 422.2272(b), 423.2272(b))

F. Enrollment/Disenrollment and Premium Billing

I. Change in AEP – Medicare Advantage Organizations and Part D Sponsors

A. Prepare for the new timing of the AEP, also known as the "Fall Open Enrollment" season, which now begins on October 15th and ends on December 7th of every year. An enrollment/disenrollment election type "AEP" cannot be used after the end of the AEP.

B. Be ready to submit certain enrollments for January 1st effective dates beginning October 8, 2011. (HPMS memo 09/14/2011)

C. Be advised that enrollments beyond December 7th, 2011 are beyond the AEP. Only beneficiaries with a valid Election or Special Enrollment Period (SEP) will be processed after the December 7th deadline.

II. Annual Medicare Advantage Disenrollment Period (MADP) – Medicare Advantage Organizations and Part D Sponsors

A. Be advised that between January 1 and February 14 MA enrollees may disenroll from any Medicare Advantage plan and return to Original Medicare. This triggers a coordinating Part D SEP, which allows enrollment into a PDP at any time during the MADP. (*Final MA and PDP Enrollment and Disenrollment Guidance Update for CY 2012- August 19, 2011 Section 30*).

III. SEP for Enrollment into a 5-Star Plan – Medicare Advantage Organizations and Part D Sponsors

A. Prepare for the new SEP whereby beneficiaries eligible for Medicare Advantage (MA), MA-PD, or Prescription Drug Plan (PDPs) plans may enroll in 5-star plans during the year in which that plan has the 5-star rating, provided the beneficiary is otherwise eligible for that plan. An individual may only use this SEP one time between December 8 of the year prior to the year the plan sponsor has been granted a 5-star overall rating, and November 30th of the year in which the sponsor has been granted a 5-star overall rating. (*Final MA and PDP Enrollment and Disenrollment Guidance Update for CY 2012-August 19, 2011*)

IV. Enrollment Acknowledgement and Confirmation Notices – Medicare Advantage Organizations and Part D Sponsors

A. Implement a process to send individuals an acknowledgment notice within ten calendar days of receiving an enrollment request from that individual, as well as a confirmation notice within ten calendar days of receiving confirmation of enrollment from CMS.

[Plan sponsors may also use a combination acknowledgement that accomplishes both purposes within seven calendar days of confirmation from CMS. (*Final MA and PDP Enrollment and Disenrollment Guidance Update for CY 2012-August 19, 2011, Section 40.4*)]

B. Implement a process to send individuals an acknowledgment notice within ten calendar days if you receive the disenrollment request directly from the individual. If an organization only learns of a disenrollment from CMS (e.g., as a result of enrollment with another organization), the organization must send a notice confirming disenrollment within ten calendar days of receiving the notice of disenrollment on the Transaction Reply Report (TRR). (*Final MA and PDP Enrollment and Disenrollment Guidance Update for CY 2012-August 19, 2011, Section 50*)

V. Enrollment Processing – Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization meets the Plan Data due date each month for submitting transactions as indicated in the Plan Communications User Guide by 8:00 PM Eastern Time (ET). Retro-file submittal is due by noon on the Wednesday before the Plan Data Due date. (HPMS memo 01/29/2010)

B. 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. (*Final MA and PDP Enrollment and Disenrollment Guidance Update for CY 2012-August 19, 2011, Section 60,* and the *Plan Communications User Guide*)

C. Ensure your organization has processes in place to submit plan generated enrollments to CMS within seven 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% (not applicable to employer-only 800-series plans) submitted within seven calendar days. [The lower-than-usual compliance threshold accounts for the fact that some applications may be incomplete upon receipt.] (HPMS memo 07/15/2010, *Medicare Marketing Guidelines, Section 40.3*)

D. Part D Sponsors only. 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))

Of note, due to the MARx redesign, plan sponsors may now enter more than one 4Rx entry allowing current and future 4Rx information. The data will be differentiated by the effective date of each 4Rx entry. (*Plan Communication User Guide*)

VI. Enrollment Rejections – Medicare Advantage Organizations and Part D Sponsors

A. 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 ten days of receipt of enrollment request or CMS rejection notice via daily TRR, whichever is earliest). (*Medicare Marketing Guidelines, Section 40.2.3 and 40.4.2*)

VII. Online Enrollment Center – Medicare Advantage Organizations and Part D Sponsors (Excluding MSA and 800-Series-Only; Optional for SNPs and 1876 cost plans; Required for PDP and MA-PD)

A. 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* and HPMS memo 08/08/2011)

VIII. Retroactive Enrollments – Medicare Advantage Organizations and Part D Sponsors

A. Please note that the timeframe for submitting enrollments and disenrollments directly to MARx has changed to the "current calendar month" cycle. Please review the MARx Redesign & Modernization handbooks for additional information. Organizations can submit enrollments and disenrollments for the current calendar month and for the calendar month prior to the current calendar month, using the User Interface (UI) or in batch submissions. Enrollment into, or disenrollment from, EGHP plans may be submitted via the UI or in batch for the current calendar month minus three months.

B. Organizations need to ensure systems and processes are in place to support the submission of retroactive enrollment and disenrollment corrections that cannot be accomplished within the Current Calendar Month cycle to the retroactive processing contractor (Reed & Associates). These requests must be made appropriately and timely. For more information, please visit www.reedassociates.org.

IX. Certification of Monthly Enrollment and Payment Data– Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization is prepared to 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 Processing Contractor. (42 C.F.R. §§ 422.504(l)(1), 423.505(k)(2), and HPMS memos 03/29/2006, and 07/21/2009)

X. Premium Billing – Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization is billing enrollees monthly for the correct premium amount based on the CY 2012 approved benefit package, including any late enrollment penalty amount.

B. Part D-Income Related Monthly Adjustment Amount (D-IRMAA) payments are NOT to be collected by sponsors. D-IRMAA inquiries about the calculation must be directed to the Social Security Administration. Failure to pay D-IRMAA to SSA will lead to disenrollment. Be prepared to process the involuntary disenrollment transactions resulting from failure to pay D-IRMAA. Model notices include beneficiary communications about where to make D-IRMAA payments.

C. Good Cause. Be advised that upon disenrollment for failure to pay the plan's premium or D-IRMAA premium amount, CMS will make all decisions about reinstating beneficiaries on the basis of 'Good Cause'. Reinstatement criteria are narrowly defined. Organizations must be prepared to properly process notifications from CMS of reinstatement for "good cause." (*Final MA and PDP Enrollment and Disenrollment Guidance Update for CY 2012-August 19, 2011*)

G. Late Enrollment Penalty (LEP) and Creditable Coverage

I. Late Enrollment Penalty (LEP) – Part D Sponsors

A. Ensure that beneficiaries receiving LIS are not subject to a LEP.

B. Ensure timely processing of LEP changes, refunds due to error, or LIS redetermination. Changes are reported in the Monthly Premium Withhold Report Data File, LIS-LEP report, and TRR. Plan sponsors need to review the reports for changes and effectuate timely. (*Medicare Prescription Drug Benefit Manual, Chapter 4*)

II. Creditable Coverage – Part D Sponsors

A. Report adjustments to the number of uncovered months previously reported for a current or former member. This is 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 necessitating an adjustment.

B. Ensure that your organization performs 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 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.

C. 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.

D. 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 the plan has mailed the attestation form to the member. (*Medicare Prescription Drug Benefit Manual*, *Chapter 4*)

H. Benefits Administration & Beneficiary Protections

I. Advance Directives – Medicare Advantage Organizations

A. 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. (*Managed Care Manual, Chapter 4, Section 70,* 42 C.F.R. § 422.128)

II. Benefits – Medicare Advantage Organizations

A. 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 ensure that you disenroll beneficiaries who are absent from the plan's service area for six months. (*Managed Care Manual, Chapter 4, Section 100.7***,** HPMS memo 04/30/2010)

B. Regional Preferred Provider Organizations. Ensure your organization always pays non-contracted providers at least the Original Medicare payment rate in those portions of your service area where you are meeting access requirements by non-network means. (*Managed Care Manual, Chapter 4, Section 10.2*)

III. Coverage Gap Discount – Part D Sponsors

A. Be advised, CMS shares Part D Sponsors' electronic funds transfer (EFT) information currently on file in the Automated Plan Payment System (APPS) with manufacturers making payments per the Coverage Gap Discount Program (CGDP) Agreement.

B. Be advised, Part D Sponsors may request to receive CGDP payments from manufacturers into a bank account other than the existing APPS banking account via email to the CGDP third party administrator (csscoperations@palmettogba.com) and submitting a signed EFT Information Form, available at www.csscoperations.com. (HPMS memo 02/08/2011)

C. Confirm receipt of manufacturer payments to the third party administrator (TPA), CSSC, within five business days of payment receipt. (HPMS memo 12/22/2010)

IV. Formulary – Part D Sponsors

A. Implement processes to rely on the 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 10/22/2010 and 12/09/2010)

B. Ensure your organization allows overrides of edits on topical ophthalmic products when appropriate to prevent unintended interruptions in drug therapy. (HPMS memo 06/02/10)

C. Ensure that the POS claims adjudication is consistent with the HPMS-approved formulary and that no unauthorized utilization management (UM) edits are in place (HPMS memo 10/22/2010)

V. Definition of Dispensing Fee – Part D Sponsors

A. Be advised that CMS has updated the definition of *dispensing fee* to be costs that are incurred at the POS and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed, and include only pharmacy costs associated with dispensing the drug to a Part D enrollee. (42 C.F.R. § 423.100 (1)-(2))

VI. Pharmacy & Therapeutics (P&T) Committee – Part D Sponsors

A. Ensure your organization's P&T committee members come from various clinical specialties that adequately represent the needs of sponsors' enrollees.

i. A majority of the P&T committee members must be practicing physicians, practicing pharmacists, or both.

ii. At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.

iii. At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the Part D sponsor and pharmaceutical manufacturers.

(*Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.1*)

VII. Quality Improvement (QI) Programs – Medicare Advantage Organizations

A. The QI program must meet the applicable requirements for the services that it furnishes to its MA enrollees. MAOs must initiate a chronic care improvement program (CCIP) that meets the requirements of 42 CFR §422.152(c), and addresses populations identified by CMS based on a review of current quality performance. MAOs must also conduct quality improvement projects (QIPs) that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meet the requirements of 42 CFR §422.152(d). (*Medicare Managed Care Manual, Chapter 5, Section 20.1*)

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

I. Home and Community-Based Services (HCBS) Waiver Programs – Part D Sponsors, excluding plan sponsors exclusively serving U.S. Territories

A. Prepare to implement the new cost-sharing rules for full benefit dual eligible individuals enrolled in home and community-based services (HCBS) waiver programs, whereby effective January 1, 2012 such individuals have zero-dollar cost sharing, equal to the LIS level for institutionalized beneficiaries.

B. Ensure your organization is prepared to accept the new Best Available Evidence (BAE) documentation related to HCBS individuals. (*Medicare Prescription Drug Benefit Manual, Chapter 13*)

II. Best Available Evidence (BAE) Policy – Part D Sponsors, excluding PACE organizations and plan sponsors exclusively serving U.S. Territories

A. Meet CMS requirements for accepting specific forms of BAE to establish a more favorable low income subsidy status of a full benefit dual eligible beneficiary and beneficiaries who applied to the SSA for the LIS. (HPMS memos 08/04/2008 and 10/16/2008)

B. Meet the CMS requirements for accepting specific forms of BAE to establish a beneficiary is institutionalized or enrolled in a home and community-based waiver program and qualifies for zero cost-sharing.

C. 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.

D. 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.

E. 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*.

F. 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).

III. Monthly BAE Monitoring – Part D Sponsors, excluding PACE organizations and plan sponsors exclusively serving U.S. Territories

A. Be prepared to respond to Acumen's request for BAE documentation and response forms for sampled beneficiaries for whom the sponsor has a more favorable LIS level for at least four months. The requests and sponsors' responses are exchanged via the BAE secure website. CMS monitors sponsors' data submission timeliness and accuracy for this project.

In addition to the BAE monitoring of sampled beneficiaries, CMS monitors beneficiary complaints to ensure BAE policy is being applied when appropriate.

IV. Low Income Subsidy Benefit Administration – Part D Sponsors, excluding PACE organizations and plan sponsors exclusively serving U.S. Territories

A. Ensure your organization applies the correct CMS LIS levels to enrollees by referring to the daily TRR to establish the correct premium, cost sharing, and deductible levels with the correct effective dates for prior, current, and prospective enrollees. (*Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.1)*

B. Be prepared to apply correct CY 2012 benefit parameters (such as cost-share and deductible if applicable) based on LIS status in CMS systems or BAE, if more favorable to the beneficiary. (HPMS memo 04/06/2009)

C. 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. The timeframe for processing these reimbursements is described in *Section K.V.A., Retroactive Claims Adjustments, Underpayment Refunds, and Overpayment Recoveries*.

D. Make reasonable attempts to notify affected members to advise them of their retroactive liability for higher premiums and cost sharing when LIS is removed. (*Medicare Prescription Drug Manual, Chapter 13, Section 70.3.1*)

V. Loss of Low Income Subsidy Data File – Part D Sponsors, excluding PACE organizations and plan sponsors exclusively serving U.S. Territories

A. In response to the Loss of Subsidy Data File (released in December of each year), prepare to set your organization's systems to charge the correct premium, deductible, and copayments effective January 1, 2012 as well as send 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)

VI. Low Income Subsidy Deeming – Part D Sponsors, excluding PACE organizations and plan sponsors exclusively serving U.S. Territories

A. Ensure your organization follows the CMS guidance for re-determination of Part D LIS eligibility for 2012. (HPMS memo 07/26/2011)

Beginning in July 2011, CMS runs its re-deeming process daily and communicates the re-deemed records with Part D sponsors via the TRR. Beneficiaries who have been re-deemed are identified with the transaction reply code (TRC) 121.

B. Take appropriate actions in response to files concerning deeming from CMS: Twice a year, in September and December, CMS issues Loss of Subsidy files related to Part D sponsors' LIS members. The September file identifies the beneficiaries receiving the CMS "undeemed" letter, and is to be used by sponsors for outreach to those individuals. The December file is the definitive file of those losing LIS status, and sponsors must use that file to update their systems and send affected beneficiaries the LIS termination notice. Additional information is available in the *Plan Communication User Guide (PCUG) Section E18, Loss of Subsidy Data File* (http://www.cms.hhs.gov/MMAHelp).

C. Ensure procedures are in place to submit corrections to beneficiaries' LIS deemed status to the CMS contractor, Reed & Associates, following the instructions in the *Medicare Prescription Drug Manual, Chapter 13, Section 70.5.6.*

VII. LIS Match Rate – Part D Sponsors, excluding PACE organizations and plan sponsors exclusively serving U.S. Territories

A. Ensure your organization maintains accurate LIS information, which is vital to ensuring all low-income beneficiaries are charged the correct premiums and co-payments for their prescription drugs. Part D sponsors must be able to process the LIS History (LISHIST) files received from CMS, and upload the LIS contract file data to the Acumen

LIS match rate website. (HPMS memos 08/30/2006, 10/30/2006, 11/26/2008, 11/23/2009, and 12/09/2010)

B. Unless presented with BAE of a more beneficiary-favorable LIS level, sponsors are required to match their LIS data files to the CMS data files.

C. Submit monthly LIS data files to the CMS contractor, Acumen, via the LIS match rate website (https://PartD.ProgramInfo.US/LIS) for the purpose of analyzing the consistency of the two files.

D. Review the Acumen, LLC reports and resolve all discrepancies identified in those reports. Sponsors must achieve a greater than 95% match rate between their files and those of CMS.

J. Coordination of Benefits (COB) and Automatic TrOOP Balance Transfer

I. Coordination of Benefits (COB) Data Report/File Processing – Medicare Advantage Organizations and Part D Sponsors

A. Establish/maintain systems and procedures for at least weekly COB data report/file processing.

i. Organizations are required to not only receive COB information but also to apply it to their system(s).

ii. Organizations utilize the Electronic Correspondence Referral System (ECRS) (https://www.cob.cms.hhs.gov/ECRS) to send COB updates to CMS (ECRS user guide is available on the CMS website at https://www.cms.gov/manuals/downloads/msp105c05_att1.pdf).

iii. CMS receives daily COB updates from the COB contractor (COBC), and CMS subsequently sends the COB file to the MAOs and Part D sponsors.

(*Medicare Prescription Drug Benefit Manual, Chapter 14, Medicare Secondary Payer Manual, Chapter 6*)

B. Interpret the COB file correctly.

i. 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.

ii. 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.

iii. CMS annually issues full replacement COB files to all Part D plan sponsors, based on sponsors' enrollees as of the date the full replacement file is processed. These files will include the last 27 months of other coverage information. (HPMS memo 03/09/2011)

(*2008 Regional Prescription Drug Event Data Technical Assistance Participant Guide*, HPMS memo 11/24/2008, *Medicare Secondary Payer Manual, Chapter 6, Managed Care Manual, Chapter 4, Section 130*)

C. Part D Sponsors Only. Follow the 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.

i. Forward credible changes to other prescription drug coverage information reported by beneficiaries to the COBC via ECRS.

ii. Coordinate benefits with SPAPs, AIDS Drug Assistance Programs (ADAPs), Indian Health Service (IHS), and 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))

(*2010 Call Letter*, HPMS memo 07/21/2009)

II. Information Reporting Transactions (Nx or N) – Part D Sponsors

A. Ensure your organization correctly processes Nx (N1, N2, N3) transactions received from POS, which identify supplemental payers and thus impact the TrOOP accumulators. (*Medicare Prescription Drug Manual, Chapter 14, Appendix A)*

III. TrOOP Balance Transfer (TBT) and Financial Information Reporting (FIR) – Part D Sponsors

A. Ensure your organization's FIR processor is certified by the Transaction Facilitator to process the new version of FIR transactions, which include the Contract/PBP fields, by the implementation date of July 1, 2012.

i. The Transaction Facilitator began piloting the new version of the FIR transactions in September 2011. Certification test cases are currently available to FIR processors on the MedifacD website at https://medifacd.relayhealth.com/Payer/FIR_Testing.html . See heading, "Certification Test Cases Description – Version 1.2." (HPMS memo 06/16/2011)

B. Ensure your organization promptly addresses TBT problems identified through the exceptions reports. Sponsors must successfully resolve identified problems with enrollee automated TBT Transactions within 30 days of notification of the problem. (HPMS memo 11/02/2009)

IV. Medicare Advantage Maximum Out-of-Pocket – Medicare Advantage Organizations

A. Ensure correct calculation and tracking of out of pocket costs for all Medicare-covered benefits. CMS requires that all Medicare Advantage plans have a maximum out of pocket (MOOP) cap. (*Managed Care Manual, Chapter 4, Section 50.1, 2012 Call Letter,* HPMS memos 04/16/2010 and 04/20/2010)

K. Claims Processing and Transition Process

I. Point of Sale (POS) Claims Processing – Part D Sponsors

A. Ensure pharmacies can clearly determine that claims are for Part D covered drugs, and secondary payers can properly coordinate benefits on Part D claims, by utilizing unique routing identifiers (BIN or BIN/PCN combination) and beneficiary identifiers for the Part D program. The unique routing identifier must uniquely identify the Part D line of business and correspond to a payer sheet applicable solely to Part D processing. (HPMS memo 11/12/2010)

B. Ensure pharmacies process prescription claims for Part D drugs under Part D, unless the beneficiary explicitly states that the claim is not to be processed as such. (42 C.F.R. §423.120(c)(2))

C. Maintain 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*)

D. Maintain claims systems to ensure non-LIS beneficiaries receive Coverage Gap Discounts at the point of sale by calculating in real time the Gap Discount amount, and the patient and plan cost-sharing amounts. The sponsor is responsible for returning the patient and plan cost-sharing amounts to the pharmacy. (HPMS memo 12/22/2010)

E. Ensure your organization appropriately adjudicates Louisiana pharmacy claims. Sponsors need to take steps to ensure that no sales taxes are paid on any Part D Louisiana pharmacy claims when adjudicating and paying such claims. (HPMS memo 09/01/2010)

F. Be advised, Part B covers all dialysis-related drugs furnished to renal dialysis for end stage renal disease (ESRD) patients, including the Part D drugs, except oral-only ESRD drugs and biologicals. (HPMS memo 02/17/2011)

G. Be advised, Part A pays for all drugs used primarily for pain relief and symptom control related to the hospice patient's terminal illness, including POS claims. To facilitate enrollees' access to hospice medications, when submitted as a Part D drug, sponsors should process all the claims to pay at POS, and follow up subsequently to determine the responsible payer.

H. Ensure your organization has a system for transmitting codes to network pharmacies so that the network pharmacy is notified to provide an enrollee with a written notice at the point-of sale explaining how the enrollee can request a coverage determination if the prescription can't be filled. *See also* Grievances, Coverage Determinations, and Appeals section.

II. Excluded Provider Claims – Medicare Advantage Organizations and Part D Sponsors

A. Use the Medicare Exclusion Database (MED) to assist your organization in identifying excluded individuals or entities. Beginning late summer 2011, CMS sends the Medicare MED files to plan sponsors each month. However, it is not intended to replace processes and procedures that all plan sponsors are responsible for developing to ensure compliance with statutory and regulatory requirements prohibiting payments for items or services furnished by an excluded provider. (HPMS memo 06/29/2011)

B. Ensure correct implementation of exclusion information and no delay in access to care due to errors in claims processing or editing systems. To correct inappropriate exclusion denials, sponsors should follow the five steps provided in the *Excluded Providers* HPMS memo dated 06/29/2011.

C. Be advised, the CTM is now a vehicle for receiving and handling complaints about inappropriate exclusion edits.

III. Federal Disaster or Public Health Emergency Declarations – Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization is prepared to follow CMS guidance regarding pharmacy and provider access during a Federal Disaster or other Public Health Emergency Declaration.

We advise 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. Sponsors should also consult the Department of Health and Human Services (DHHS) or CMS websites for any detailed guidance that may be posted.

(HPMS memos 06/16/2008 and 07/20/2009, *Medicare Prescription Drug Benefit Manual Chapter 5, Medicare Managed Care Manual, Chapter 4, Section 30.9*)

IV. Transition Process – Part D Sponsors

A. 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 2012. (HPMS memo 3/25/2010)

B. Implement a transition process for current enrollees who will experience negative changes as a result of revisions to their plan's formulary across contract years (i.e., from

CY 2011 to CY 2012). 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 CY 2012 formulary prior to January 1, 2012. Sending the ANOC is not sufficient to effectuate the transition. (HPMS memos 03/25/2010 and 08/27/2010)

C. 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.

D. Ensure that reasonable efforts are made to notify prescribers of enrollees who receive a transition notice after adjudication of a temporary fill. (42 C.F.R. § 423.120(b)(3)(v), HPMS memo 12/20/2010)

E. 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.

F. 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. 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.

H. 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*)

V. Retroactive Claims Adjustments, Underpayment Refunds, and Overpayment Recoveries – Part D Sponsors

A. After receiving information that necessitates a retroactive claims adjustment, process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding the claims adjustment. (42 C.F.R. § 423.466(a))

L. Grievances, Coverage Determinations, and Appeals

I. Requirement to Employ a Medical Director – Medicare Advantage Organizations and Part D Plan Sponsors

A. Your organization must employ a medical director who is responsible for the clinical accuracy of all initial coverage decisions (organization or coverage determinations) and appeals (reconsiderations or redeterminations) that involve medical necessity. The medical director must be a physician with a current and unrestricted license to practice medicine in a State, Territory, Commonwealth of the United States, or the District of Columbia. (42 C.F.R. §§ 422.562, 423.562)

II. Requirement Related to Who Must Review Initial Coverage Decisions – Medicare Advantage Organizations and Part D Sponsors

A. Ensure your organization has adequate staff to satisfy the requirement that a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, review the initial coverage decision (organization or coverage determination) if your organization expects to issue a partially or fully adverse decision based on medical necessity. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States, or the District of Columbia. (42 C.F.R. §§ 422.566, 423.566)

III. Grievances, Coverage Determinations, and Appeals – Part D Sponsors

A. Ensure your organization provides immediate access to the coverage determination and redetermination processes via a toll-free telephone number and website and provides access to model forms for making coverage and appeal requests. (42 C.F.R. § 423.128)

B. CMS expects your organization to have internal controls in place to detect and promptly correct potential deficiencies in operations impacting coverage determinations, redeterminations and grievances.

C. If your organization contracts with a pharmacy benefits manager (PBM) to perform functions related to coverage determinations, appeals or grievances, your organization remains responsible for ensuring compliance with all CMS requirements. Therefore, you must be able to demonstrate that you are routinely monitoring and overseeing the PBM's delegated functions and that this oversight is integrated into your overall compliance program.

M. Compliance and Fraud, Waste, and Abuse (FWA)

I. Compliance Program – Medicare Advantage Organizations and Part D Sponsors

A. Adopt and implement an effective Compliance Program that includes all of the requirements stated at 42 C.F.R. §§ 422.503(b)(4)(vi), 423.504(b)(4)(vi). Those requirements include, but are not limited to:

i. Standards of Conduct and written policies and procedures that are reviewed and approved by the governing body and that describe compliance expectations, address FWA, implement compliance operations, provide guidance to employees and first tier, downstream, and related entities, identify how to communicate issues, describe investigation and resolution processes, and include a policy on non-intimidation and non-retaliation.

ii. A governing body that is knowledgeable on the content and operations of the Medicare Compliance Program and that meets at least quarterly to conduct oversight of the program; a Compliance Officer and Compliance Committee that report directly to and are accountable to the CEO or other senior management; a Compliance Officer that has express authority to meet with the governing body at his/her discretion; and a Compliance Officer that is an employee of the sponsor, or its parent or affiliate.

iii. Effective training and education on the structure and operation of the Medicare Compliance Program for all employees, board members, consultants, volunteers, and first tier, downstream, and related entities upon hire and at least annually thereafter; and specialized training and education on issues posing Medicare compliance risks depending upon the individual's job function.

iv. Effective lines of communications between the Compliance Officer and employees, managers, directors, first tier, downstream, and related entities, and plan members that are accessible to all, and that allow issues to be reported, including at least one method of anonymous reporting; and prominent publication to employees, board members, first tier, downstream, and related entities, and plan members of methods of reporting.

v. Implementation of well-publicized and accessible disciplinary standards that: identify non-compliant and unethical behavior and FWA; include expectations for reporting non-compliance and FWA; assist in the resolution of issues; and that are timely, consistently, and effectively enforced.

vi. Implementation of an effective system for routine monitoring and identification of risks, that includes, among other things: a risk assessment of your organization and those of your first tier, downstream, and related entities for Medicare program noncompliance and FWA risks; internal monitoring and audits to evaluate sponsor's and first tier, downstream, and related entities' compliance with Medicare Parts C and D requirements; and monthly screening of employees, board

members, consultants, volunteers, and FDRs against the OIG and GSA exclusion lists to identify persons and entities excluded from participation in federal health care programs.

vii. Implementation of procedures and a system for prompt response to detected issues and offenses including, among others: the investigation of potential problems identified through self-evaluation and audit; the prompt and thorough correction of problems identified; the self-reporting of issues to MEDICS, as appropriate; and the prompt repayment of claims for drugs, items, or services prescribed or provided by excluded providers.

N. Management and Organization Structure

II. Two Year Prohibition on Program Participation after a Non-Renewal, Termination, or Mutual Termination – Medicare Advantage Organizations and Part D Sponsors

A. Be advised of the new prohibition in program participation for two years following a non-renewal, termination, or mutual termination of organizations whose owners or directors served in a similar capacity with another organization that terminated its Medicare contract within the previous two years. This is in addition to the long-standing two year prohibition of program participation for organizations that non-renewed, terminated, or mutually terminated their own MA or Part D contracts. (42 C.F.R §§ 422.508, 423.508, 422.506, 423.508, 422.512, 423.510)