DEPARTMENT OF HEALTH & HUMAN SERVICES
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**CENTER FOR MEDICARE**

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

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Subject: Contract Year 2013 Medicare Advantage Organization, Prescription Drug Plan and 1876 Cost Plan 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, 2013. The Contract Year (CY) 2013 Readiness Checklist summarizes key operational requirements as established in statutes, regulations, manual chapters, Health Plan Management System (HPMS) memos, applications, and other advisory materials. In particular, CMS would like to draw your attention to the following:

- September 1st, CMS began using the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE) to edit PDEs. Part D Sponsors will use this file to make determinations of currently marketed Part D drugs marketing categories for the Coverage Gap Discount Program. *See Sections A.VIII and H.IV.*
- Timing of the 2013 Annual Enrollment Period and key dates for submitting enrollment transactions are provided in Section F.I.
- CMS updated requirements to prevent overutilization of prescribed Part D drug prevention. *See Section H.VIII.*
- Beginning January 1, 2013, Part D sponsors must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI.

Given the significance of the overall updates and changes, your organization should review this checklist carefully and take the necessary measures to ensure that these key requirements are in place for the CY 2013 AEP. Please note that the Readiness Checklist is not an exhaustive list of all Medicare Advantage (MA), Prescription Drug Plan (PDP), 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 is not/will not be in compliance, your organization must report these problems to your Account Manager 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 cooperation and remain committed to working with organizations to ensure that beneficiaries have continued access to health care services and prescription drugs during the upcoming contract year.

If you need additional information regarding requirements listed in the checklist, please refer to the appropriate CMS guidance, or contact your Account Manager.

# CY 2013 Medicare Advantage Organization, Prescription Drug Plan, and 1876 Cost Plan Readiness Checklist

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Note: Unless otherwise indicated, where a requirement applies to Medicare Advantage Organizations, it also applies to 1876 Cost Plans. References to Part D sponsors include all organization types offering Part D.

## 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 PACE and contracts only serving the U.S. Territories (e.g., U.S. Virgin Islands, Puerto Rico, etc.)**

**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. (ongoing HPMS memos)

**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. (http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/IACS/index.html?redirect=/IACS/ )

**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 CY2012.

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

**A. Part D Sponsors.** Ensure timely and accurate submission of CY 2013 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 2013 MPF submission window.

**B. Part D Sponsors.** The initial CY 2013 data submission period for live/public pricing data is September 10th through September 11th. The data will be published on Medicare.gov on or about October 1, 2012.

**C. Part D Sponsors.** Ensure pricing and pharmacy network data files for MPF have passed quality assurance checks for completeness and accuracy for CY 2013 data, and that only pharmacies under contract for 2013 are included for display. Updates and announcements to the QA process may be found on the MPF Communications website (https://partd.programinfo.us/Planfinder/default.aspx).

**D. Medicare Advantage Organizations and Part D Sponsors.** The Plan Preview Schedule for CY 2013 was as follows:

**i.** The initial preview period was from August 15, 2012 to August 16, 2012, and

**ii.** The second preview period was from September 5, 2012 to September 7, 2012.

**E. New 2013 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 6/25/2012)

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

**A.** Ensure key staff registers 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.** Beginning January 1, 2013, Part D sponsors must submit to CMS only a prescription drug event (PDE) record that contains an active and valid individual prescriber NPI. 42 CFR 423.102(c)(5)

## 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, 8/13/2012)

**C.** Sponsors are required to use the website to view and download the reports and should be engaged in performance monitoring.

**D.** New sponsors for 2013 should be prepared to begin reviewing these reports in spring of 2013, 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, 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, and

**iv.** Gap Coverage Invoice Report.

**D.** Ensure PDE records contain the changes required to close the coverage gap. (HPMS memos 7/9/2010, 7/20/2010, 9/24/2010)

**E.** Effective September 1, 2012, CMS will use the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE) to edit PDEs. Specifically, CMS will reject PDE submissions with all of the following:

**i.** Drug coverage status code of 'C',

**ii.** Date of service (DOS) on or after September 1, 2012, and

**iii.** NDC not listed on the NSDE file, or NDC listed on the NSDE file with a marketing end date prior to DOS. (HPMS memos 05/14/2012 and 08/16/2012)

**F.** 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 10/6/2011)

**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 90 days following receipt of rejected record status from CMS, and

**iii.** Submit adjustments and deletions within 90 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.

**G.** 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 10/8/2010)

**H.** Ensure your organization establishes access to Acumen's PDE Analysis and PDE Reports websites as described in the February 24, 2012 HPMS memo.

## IX. Medicare Advantage Encounter Data System (EDS) – Medicare Advantage Organizations

**A.** Complete the EDI Agreement for Encounter Data

**B.** Prepare and become Front-end Certified

**C.** Prepare and become End-to-End Certified

**D.** Be aware of EDS Submission requirements

**E.** Be familiar and remain current with EDS guidelines (www.csscoperations.com)

## X. Part C and D Plan Ratings - Medicare Advantage, Part D Sponsors, 1876 Cost, and Demonstration Organizations

**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, Section 1876 Cost Plans 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 8/3/2012)

**i.** New for 2013, the 1,000 minimum enrollment requirement for reporting HEDIS data has been eliminated (Call Letter, April 2, 2012). All HEDIS® 2013 measures must be submitted to NCQA by 11:59 p.m. EDT on June 17, 2013. Please note that late submissions will **not** be accepted. (HPMS memo 8/3/2012)

**ii.** Medicare Advantage (MA) Organizations, including Private Fee for Service (PFFS) and Medicare Savings Account (MSA) contracts, and section 1876 Cost contracts will be required to collect data on all HEDIS measures covering services provided in CY 2012 and to report the audited data to CMS through NCQA in June 2013 using the HEDIS 2013 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 8/8/2011)

**iii.** Medicare Advantage Organizations, including PFFS and MSA contracts, section 1876 Cost contracts and Part D sponsors will be required to contract for the 2013 survey administration with an approved MA and 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 1, 2012 are required to contract with CMS-approved MA & PDP CAHPS survey vendors to conduct data collection. (HPMS memos 12/2/2009, 6/25/2010 and 8/3/2012)

**iv.** Medicare Advantage Organizations, including PFFS and MSA contracts, and continuing section 1876 Cost contracts with open enrollment will also be required to contract for the 2013 survey administration with an approved HOS survey vendor to collect the HOS data on their behalf. Specifically, Medicare Advantage Organizations (MAOs) with 500 or more enrollees as of July 1, 2012 are required to contract with an approved vendor and notify NCQA of their choice no later than January 18, 2013. (See HPMS memo 8/3/2012 for details and for requirements for PACE, Cost, and SNP organizations/plans.)

**v.** Ensure your organization uses an approved 2013 MA & PDP CAHPS or HOS survey vendor. (HPMS memo 8/3/2012)

**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 memos, 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*)

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

**A.** For organizations with offshore subcontractor 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, we request that organizations 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 2013**

**A.** MAOs that offer a D-SNP must ensure they have a signed contract with their State Medicaid Agency. Ratified contracts are submitted annually to CMS. (HPMS memos 1/11/2010, 4/6/2010, 8/19/2010, 8/27/2010, 06/17/2011, 1/30/2012, and 6/19/2012, MIPPA – Section 164(1)(B)(iii)`(3)`(D), 42 CFR §422.107, *Medicare Managed Care Manual Chapter 16-B*)

Fully integrated dual eligible (FIDE) SNPs – Frailty payment requires a contract with the State that has been determined to have met all of the fully integrated criteria established in the law and regulations and the population has been found to have a frailty factor similar to PACE.

## 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 1 to February 14, which includes the AEP. MAOs and Part D Sponsors must meet CMS standards. (*Medicare Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines, Section 80.1* and *Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines, Section 80.1*)

**i.** From October 1st to February 14th. 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. Plans may use alternative technologies on Thanksgiving and Christmas. In addition, from February 15 through September 30, organizations are permitted to use alternative technologies to meet the customer service call center requirements for Saturdays, Sundays, and holidays. (HPMS memo 11/02/2011)

**ii.** From February 15th until the following marketing and 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.** 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.** Plan sponsors must make the marketing materials identified in the Medicare Marketing Guidelines sections 30.8, 30.9, 30.12 and the Part D Transition Letter available in any language that is the primary language of five percent or more of a plan sponsor's plan benefit package service area. Additionally, plan sponsors must place translated versions of these materials on the plan's website.

**C.** Beginning with the CY2013 marketing season, all plan sponsors must include the Multi-Language Insert with the Summary of Benefits and the ANOC/EOC.

*Medicare Marketing Guidelines,* Sections 30.7, 30.8, 30.9, 30.12, 80.1, 100.1, and Appendix 4; 42 C.F.R. §§ 422.2264(e), 423.2264(e)); HPMS memos 6/7/2012 and 08/17/2012.

## 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. (CTM SOP—Plan Version Section I)

**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 Managed Care Manual, Chapter 3 - Medicare Marketing Guidelines, Appendix 5* and *Medicare Prescription Drug Benefit Manual, Chapter 2 - Medicare Marketing Guidelines, Appendix 5*)

**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 CTM all 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 12/22/2011)

**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 CFR §§ 422.504 and 423.505)

## E. Marketing

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

**A.** Ensure your organization is able to provide basic services and information to individuals with disabilities, upon request.

*(Medicare Marketing Guidelines Section 30.6)*

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

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

**i.** Ensure your documents are accurate prior to mailing the ANOC/EOC.

**ii.** Ensure an *errata* is sent timely upon identification of an inaccuracy in the ANOC/EOC.

**iii.** Ensure that new enrollees with effective dates of October 1st, November 1st, or December 1st receive both an EOC for the current contract year and an ANOC/EOC for the upcoming contract year.

**iv. Medicare Advantage Organizations (excluding D-SNPs) and Part D Sponsors, and 1876 Cost Plans offering Part D -** send the upcoming ANOC/EOC, LIS Rider, and abridged or comprehensive formulary for member receipt no later than September 30, 2012.

**v. D-SNPS -** May choose to send the ANOC for member receipt by September 30th for the upcoming coverage year, and the EOC for member receipt by December 31st. In this case, the SB must be sent with the ANOC. DSNPs sending a combined ANOC/EOC must send it for member receipt by September 30th.

**vi. 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, Section 60.7)

**III. Formulary – Part D Sponsors**

**A.** Ensure your organization's CMS-approved formulary matches the marketed formulary both in print and on the website.

**B.** Ensure your organization's formulary is updated on the website when changes are made.

*(Medicare Marketing Guidelines, Section 60.5)*

**IV. Outbound Education and Verification Calls to all New Enrollees – Medicare Advantage Organizations, Part D Sponsors, and Cost Plans**

**A.** Ensure outbound enrollment and verification calls are conducted for all enrollments effectuated by agents and brokers, both independent and employed.

**B.** Ensure all outbound enrollment and verification calls have a minimum of three documented attempts to contact the beneficiary by telephone within fifteen (15)

calendar days of receipt of the application, and the first two attempts are made within the first ten (10) days.

**C.** Ensure that the enrollment verification letter is sent to the beneficiary if they have not been successfully reached following the second outbound verification call.

*(Medicare Marketing Guidelines, Section 70.8)*

**V. Websites – Medicare Advantage Organizations, Part D Sponsors, and Cost Plans**

**A.** Ensure your organization includes all required content as outlined in the Medicare Marketing Guidelines (e.g. rights and responsibilities, link to CMS appointment of representative, information on how to file a grievance/coverage determination/appeal).

*(Medicare Marketing Guidelines, Section 100)*

**VI. Agents and Brokers – Medicare Advantage Organizations, Part D Sponsors, and Cost Plans**

**A.** Ensure all agents/brokers (including those employed by the plan) that sell Medicare products are annually trained and tested on Medicare rules, regulations, and specific plan products, prior to marketing CY 2013 products.

**B.** Ensure your organization's training curricula contain the minimum information and required elements listed in the annual guidelines HPMS memo Agent Broker Training and Testing.

**C.** Ensure your organization follows all CMS rules and guidance for compensation of independent agents and brokers, when utilized for the sale of Medicare products.

**D.** Ensure your organization has processes in place for oversight of Agent/Broker marketing and sales activities.

*(Medicare Marketing Guidelines, Section 120)*

## F. Enrollment/Disenrollment and Premium Billing

**I. Timing of AEP – Medicare Advantage Organizations and Part D Sponsors**

**A.** Prepare for the current timing of the AEP, also known as the "Fall Open Enrollment" season, which 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 (e.g., employer group enrollments and enrollments made during an individual's Initial Coverage Election Period (ICEP)) for January 1st effective dates beginning October 6, 2012. (HPMS memo 09/14/2011)

**C.** Be advised that enrollments beyond December 7, 2012 are beyond the AEP. Only beneficiaries with a valid Election or Special Enrollment Period (SEP) will be processed after the December 7th deadline.

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

**A.** Be advised that the MADP begins on January 1 and ends on February 15 each year. An MA enrollee may disenroll from the coverage and go back to Original Medicare. If s/he has disenrolled from a MA plan, s/he may also enroll in a stand-alone Part D plan. (HPMS memo 09/14/2011).

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

**A.** Beneficiaries eligible for Medicare Advantage (MA), MA-Prescription Drug Plans (MA-PDs), or Prescription Drug Plan (PDPs) 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. Be advised that 5-Star plans must be prepared to accept all valid enrollment requests made using this SEP. (*Medicare Managed Care Manual Ch. 2, sec. 30.4.4; Medicare Prescription Drug Plan Benefit Manual Ch. 3, sec. 30.3.8*)

## IV. Enrollment Processes and Notices– Medicare Advantage Organizations and Part D Sponsors

**A.** Implement a process to send individuals an acknowledgment notice within ten (10) calendar days of receiving a complete and valid enrollment request from that individual, as well as a confirmation notice within ten (10) calendar days of receiving confirmation of enrollment from CMS.

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

**B.** Implement a process to send individuals an acknowledgment notice within ten (10) calendar days if you receive a valid 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 (10) calendar days of receiving the notice of disenrollment on the Transaction Reply Report (TRR). (*Medicare Managed Care Manual Chapter 2, Section 50.1.4,* and *Prescription Drug Benefit Manual Chapter 3, Section 50*)

**C.** Implement a process to send individuals a denial notice within ten (10) calendar days of receipt of an invalid enrollment or disenrollment request. (*Medicare Managed Care Manual, Chapter 2, Sections 40 and 40.2.3;* and *Prescription Drug Benefit Manual Chapter 3, Sections 40 and 40.2.3*)

**D.** Implement a process for requesting for more information from individuals within ten (10) calendar days of receipt of a valid incomplete enrollment or disenrollment request. (*Medicare Managed Care Manual, Chapter 2, Sections 40, 40.2.1, 40.2.2 and 50.4.2;* and *Prescription Drug Benefit Manual Chapter 3, Sections 40, 40.2.1, 40.2.2 and 50.4.2*)

**E.** Ensure that processes are in place for processing valid requests to cancel an enrollment or disenrollment request prior to the effective date of the original enrollment or disenrollment request. (*Medicare Managed Care Manual, Chapter 2, Sections 60.2, 60.2.1, and 60.2.2;* and *Prescription Drug Benefit Manual Chapter 3, Sections 60.1, 60.1.1, and 60.1.2*)

## 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. (*Plan Communications User Guide, Appendix C,* HPMS memo 1/29/2010)

**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. (*Medicare Managed Care Manual Chapter 2, Section 60, Chapter 19, Prescription Drug Benefit Manual Chapter 3, 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 (7) calendar days of receipt of the completed enrollment request. CMS is monitoring whether sponsors submit enrollments timely and has established a compliance threshold of 90% (not applicable to employer-only 800-series plans) submitted within seven (7) calendar days. [The lower-than-usual compliance threshold accounts for the fact that some applications may be incomplete upon receipt.] (HPMS memo 08/07/2012, *Medicare Managed Care Manual Chapter 2, Section 40.3*, and *Medicare Prescription Drug Benefit Manual Chapter 3, 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 Guide*)

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

**A.** Ensure the enrollment process allows for appropriate CMS rejection in accordance with CMS requirements (e.g., providing beneficiary notices within ten (10) days of

CMS rejection notice via daily TRR, whichever is earliest). (*Medicare Managed Care Manual Chapter 2, Section 40.4.2, Prescription Drug Benefit Manual Chapter 3, Section 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)

The Medicare Plan Finder online enrollment function will be disabled for Medicare health and prescription drug plans with low-performing plan icons for CY 2013 to assist in guiding beneficiaries towards selecting higher performing plans.

Enrollments created from data received through the OEC are considered plan generated enrollments.

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

**A.** Submit enrollments and disenrollments directly to MARx following the "current calendar month" cycle. Organizations can submit enrollments and disenrollments for the current calendar month and for the calendar month prior to the current calendar month, using the 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 has completed an attestation in HPMS for Monthly Enrollment and Payment Data for all contracts within 45 days of the date that the monthly reports are available. The attestation confirms 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) and § 423.505(k)(2), and HPMS memos 03/29/2006, 07/21/2009, 08/17/2012)

**X. Premium Billing – Medicare Advantage Organizations, Medicare Cost Plans, and Part D Sponsors**

**A.** Ensure plan sponsor is billing enrollees monthly for the correct premium amount based on CY 2013 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. Part D-IRMAA inquiries must be redirected to the appropriate agencies, Social Security Administration (SSA) for D-IRMAA calculation and Centers for Medicare & Medicaid Services (CMS) for Part D enrollment and disenrollment due to non-payment of Part D-IRMAA. Failure to pay Part D-IRMAA to CMS or RRB (as billed) will lead to disenrollment from the plan which includes the individual's Part D coverage. Be prepared to appropriately process the involuntary disenrollment transactions resulting from failure to pay Part D-IRMAA. Model notices include beneficiary communications about the disenrollment and ability to request reinstatement for Good Cause. (*Medicare Managed Care Manual Chapter 2, Section 50.2.6, Prescription Drug Benefit Manual Chapter 3, Section 50.2.6*)

**C.** Good Cause. Be advised that upon disenrollment for failure to pay the plan's premium or Part D-IRMAA, 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." Members requesting reinstatement must be referred to CMS. (*Medicare Managed Care Manual Chapter 2, Section 60.3.4, Prescription Drug Benefit Manual Chapter 3, Section 60.2.4*)

## G. Late Enrollment Penalty (LEP) and Creditable Coverage

**I. 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 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 (6) to twelve (12) months, then ensure that you disenroll beneficiaries who are absent from the plan's service area for six (6) months. (*Managed Care Manual, Chapter 4, Section 100.7,* HPMS memo 4/30/2010)

**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 02/14/2012)

**C.** Confirm receipt of manufacturer payments to the third party administrator (TPA), CSSC, within five (5) business days of payment receipt. In the event that payment is received after the confirmation of payment report is submitted the report should be updated with the new payments and resubmitted. (HPMS Memo 12/22/2010)

## IV. Formulary – Part D Sponsors

**A.** Implement processes to rely on the FDA Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE file) to help determine which NDCs represent currently marketed Part D drugs. Sponsors also should rely on this file to make marketing category determinations for the Coverage Gap Discount program. (HPMS memos 5/14/2012 and 08/16/2012)

**B.** Ensure your organization allows overrides of edits on topical ophthalmic products when appropriate to prevent unintended interruptions in drug therapy. (HPMS memo 6/2/10)

**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), addresses populations identified by CMS based on a review of current quality performance,

and conducts quality improvement projects (QIPs) that can be expected to have a favorable effect on health outcomes and enrollee satisfaction, and meets the requirements of 42 CFR §422.152(d). (Medicare Managed Care Manual, Chapter 5, Section 20.1)

**VIII. Improving Drug Utilization Controls in Part D**

**A.** Implemented processes and procedures to comply with drug utilization management (DUM) requirements of 42 C.F.R §423.153 et seq. to prevent overutilization of prescribed covered Part D drugs. (2013 Call Letter and June 29, 2012 memo)

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

**I. Best Available Evidence (BAE) Policy – Part D Sponsors, excluding PACE organizations and plan sponsors <u>only</u> 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 memo 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 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. (*Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.5*)

**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.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Best_Available_Evidence_Policy.html) containing CMS policy guidance. (*Medicare Drug Benefit Manual Chapter 13, Section 70.5* and HPMS memo 08/04/2008).

## II. Low Income Subsidy Benefit Administration – Part D Sponsors, excluding PACE organizations and plan sponsors only 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 Chapter 13*)

**B.** Be prepared to apply correct CY 2013 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. Ensure correct cost-sharing rules for full benefit dual eligible individuals enrolled in home and community-based services (HCBS) waiver programs. Such individuals have zero-dollar cost sharing, equal to the LIS level for institutionalized beneficiaries. (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. Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment. (*Medicare Prescription Drug Benefit Manual Chapter 13, Section 70.3.1* and 42 C.F.R. § 423.466 and § 423.800)

**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. (70.3.1 Chapter 13)

## III. Loss of Low Income Subsidy Data File – Part D Sponsors, excluding PACE organizations and plan sponsors only 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, 2013 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)

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

**A.** Ensure your organization follows the CMS guidance for re-determination of Part D LIS eligibility for 2013. (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 daily 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 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.*

## V. LIS Match Rate – Part D Sponsors, excluding PACE organizations and plan sponsors only 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 8/30/2006, 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.

## VI. Monthly BAE Monitoring – Part D Sponsors, excluding PACE organizations and plan sponsors only 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.

## 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.** Ensure a business associate agreement (BAA) is executed between sponsors and Relay Health, the coordination of benefits contractor (COBC). (HPMS memo 03/02/2012)

**B.** Establish/maintain systems and procedures for at least weekly COB data report/file processing. (*Medicare Prescription Drug Benefit Manual Chapter 14, Medicare Secondary Payer Manual Chapter 6*) and the *Plan Communication User Guide (PCUG)*).

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

**ii.** Organizations utilize the 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 COBC, and CMS subsequently sends the COB file to the MAOs and Part D sponsors.

**C.** Interpret the COB file correctly. (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*)

**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 03/02/2012)

**D. 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. (2010 Call Letter and update via HPMS memo 07/21/2009)

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

**ii.** Coordinate benefits with State Pharmacy Assistance Programs (SPAPs), AIDS Drug Assistance Programs (ADAPs), Indian Health Service (IHS), and other entities providing prescription drug coverage, beneficiaries, and others, paying on behalf of beneficiaries for a period not to exceed three years from the date on which the prescription for a covered Part D drug was filled. To assist with the coordination of the SPAPs and ADAPs, NCPDP maintains a list of BIN/PCN on the NCPDP website. (42 C.F.R. §423.466(b))

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

**A.** Ensure organization correctly processes Nx (N1, N2, N3) transactions received from POS, which identify supplemental payers and thus impact the TrOOP accumulators.

**B.** The COBC now precludes Part D sponsors from updating SPAP and ADAP information. Only those programs may update the information with the COBC. (HPMS memo 03/02/2012)

**III. TrOOP Balance Transfer (TBT) and Financial Information Reporting (FIR) Version 1.2– Part D Sponsors**

**A.** Ensure your FIR processor was certified by the Transaction Facilitator to process NCPDP FIR transaction standard version 1.2 including the Contract/PBP fields, by the implementation date of September 1, 2012. (HPMS memo 03/27/2012)

**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.** As of July 1, 2012, 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 03/27/2012)

**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.** 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)

**F.** 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.

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. Since summer 2011, CMS sends the Medicare MED files to plan sponsors on a monthly basis. However, this 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. (HPMS memos 06/16/2008, 07/20/2009, and *Medicare Prescription Drug Benefit Manual Chapter 5, Medicare Managed Care Manual, Chapter 4, Section 30.9*)

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.

## 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 2013. (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 CY2012 to CY2013). 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 2013 formulary prior to January 1, 2013. Sending the ANOC is not sufficient to effectuate the transition. (HPMS memo 3/25/2010, 8/27/2010)

One way to ensure a transition supply has been provided is to monitor current enrollees' rejected claims after the beginning of CY 2013

**C.** Effectuate a meaningful transition for:

**i.** New enrollees into prescription drug plans at the beginning of a contract year,

**ii.** Newly eligible Medicare beneficiaries from other coverage at the beginning of a contract year,

**iii.** Individuals who switch from one plan to another after the beginning of a contract year, and

**iv.** Enrollees residing in long-term care (LTC) facilities. Specifically, during the first 90 days of enrollment in a plan, sponsors will ensure that the transition for beneficiaries residing in LTC settings will provide for a 91- to 98-day fill consistent with the dispensing increment, with refills provided; and after the transition

period has expired, a 31-day emergency supply of non-formulary Part D drugs is available while an exception or prior authorization is requested.

**D.** Ensure the Sponsor provides access to a transition supply of medication within the first 90 days of enrollment, including for those beneficiaries whose first 90 days cross contract years (e.g., effective date of enrollment is November 1st or December 1st).

**E.** 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.

**F.** 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))

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

**H.** 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.

**I.** 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 CFR § 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 Plan 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

(42 C.F.R. § 423.128)

**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.

**B.** **(Part D and MAOs)** CMS continues to identify areas of significant non-compliance during plan audits with respect to how MAOs and Part D plan sponsors are processing initial coverage requests, plan level appeals, and grievances. CMS expects MAOs and Part D plan sponsors to have internal controls in place to detect and promptly correct potential deficiencies in operations impacting organization and coverage determinations, plan appeals, and grievances. In addition, MAOs and Part D plan sponsors are expected to solicit necessary clinical documentation from providers and prescribers to the extent this documentation is needed to properly adjudicate coverage requests and appeals.

**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.

**D.** Part D sponsors must ensure that their systems are properly transmitting codes to network pharmacies that instruct the pharmacies to provide enrollees with a notice at point of sale in certain circumstances where the prescription cannot be filled under the Part D benefit. The notice provided at point of sale explains the enrollee's right to contact the plan to request a coverage determination.

**IV. Change to Part C and Part D Qualified Independent Contractor (QIC) Filing Locations**

**A.** MAXIMUS Federal Services has consolidated its operations and is processing all Part D drug benefit and late enrollment penalty (LEP) reconsiderations in Pittsford, NY. The toll free customer service and fax numbers remain the same. As of May 24, 2012 all reconsiderations should be forwarded to the following locations:

**a.** Medicare Prescription Drug Reconsiderations should be directed to:

MAXIMUS Federal Services
3750 Monroe Ave., Suite #703
Pittsford, NY 14534-1302
Fax: (585) 425-5301
Toll free fax: (866) 825-9507
Toll free customer service: (877) 456-5302

**b.** Late Enrollment Penalty Reconsiderations should be directed to:

MAXIMUS Federal Services
3750 Monroe Ave., Suite #704
Pittsford, NY 14534-1302
Fax: (585) 869-3330
Toll free fax: (866) 589-5241
Toll free customer service: (877) 456-5302

**c.** The Part C QIC filing location is:

MAXIMUS Federal Services
Medicare Managed Care & PACE Reconsideration Project
3750 Monroe Avenue
Suite 702
Pittsford, NY 14534-1302
Phone: 585-348-3300

## M. Compliance and Fraud, Waste, and Abuse (FWA) Compliance Program – Medicare Advantage Organizations and Part D Sponsors

***Prescription Drug Benefit Manual Chapter 9 and Medicare Managed Care Manual Chapter 21;* 42 C.F.R. §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi), and HPMS memo 09/10/2012**

**I. Familiarize your organization with the best practices and common findings from the 2012 program audits as described in the memo dated September 10, 2012 to focus your internal monitoring efforts and help ensure any common findings are corrected.**

**II. 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:**

**A.** Standards of Conduct and written policies and procedures that describe compliance expectations, address FWA, implement compliance operations, provide guidance to

employees and first tier, downstream, and related entities (FDRs)on dealing with suspected, detected or reported compliance issues, identify how to communicate issues, describe investigation and resolution processes, and include a policy on non-intimidation and non-retaliation.

**B.** A governing body that is knowledgeable on the content and operations of the Medicare Compliance Program and conducts oversight of the program; a Compliance Officer and Compliance Committee that report directly to and are accountable to the Chief Executive Officer (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.

**C.** Effective training and education on the Standards of Conduct and on reporting suspected or detected noncompliance for all employees, governing body, and volunteers, to be made part of orientation for new employees, and at least annually thereafter; and FWA training for all employees, governing body, volunteers, and FDRs at orientation and at least annually thereafter.

**D.** Effective lines of communications between the Compliance Officer and employees, managers, directors, governing body, FDRs, and plan members that are accessible to all, and that allow compliance and potential fraud, waste and abuse 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 the reporting methods.

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

**F.** Implementation of an effective system for routine-monitoring, auditing and identification of risks, that includes, among other things: a baseline assessment of your organization 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, and effective monitoring activities to prevent and detect FWA.

**G.** Implementation of procedures and a system for prompt response to compliance issues as they are raised; the investigation of potential problems identified through self-evaluation and audit; the prompt and thorough correction of problems identified; procedures for the voluntary self-reporting of issues to CMS or its designee, as appropriate; and the prompt repayment of claims for drugs, items, or services prescribed or provided by excluded providers.

## N. Management and Organization Structure

**I. Medical Professional Oversight – Medicare Advantage Organizations and Part D Sponsors**

**A.** Ensure that your organization employs:

**i.** Physicians or other appropriate health care professionals with sufficient medical experience and other experience, including knowledge of the Medicare program, to review organization determinations involving medical necessity.

**ii.** A Medical Director who is responsible for ensuring the clinical accuracy of all organizational determinations and appeals involving medical necessity.

**II. Requirements for Owners and Directors – Medicare Advantage Organizations and Part D Sponsors**

**A.** Be advised of the prohibition in program participation by organizations whose owners or directors served in similar capacity with another organization that terminated its Medicare contract within the previous two years.