DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard

Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

Date: November 4, 2013

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

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

Danielle R. Moon, J.D., M.P.A., Director, Medicare Drug & Health Plan Contract Administration Group

Subject: Readiness Checklist for Medicare Advantage and Prescription Drug Plans, 1876 Cost Plans, and PACE Organizations

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, 2014. The Contract Year (CY) 2014 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:

- Daily Cost Sharing – Effective January 1, 2014, sponsors are required to apply a daily cost sharing rate whenever certain prescriptions are dispensed by network pharmacies for less than 30 days' supply. *See Section H.VI.*
- Auto-Ship Refill Programs in Part D - New expectations for Part D Sponsors' network pharmacies to obtain patient consent to deliver a prescription, new or refill, prior to each delivery. *See Section H.VII.*

Your organization should review this checklist carefully and take the necessary measures to ensure that these key requirements are in place for contract year 2014. 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, and in a timely manner. 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 2014 Medicare Advantage Organization, Prescription Drug Plan, and 1876 Cost Plan Readiness Checklist

Table of Contents

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, including PACE organizations.

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. 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)

B. Ensure your External Point of Contact (EPOC) is notified of the changes regarding the Individuals Authorized Access to the CMS Computer Services (IACS) users. (http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/IACS/index.html?redirect=/IACS/)

NOTE: An individual's access to IACS will be partially disabled when 60 days or more lapses between system logins. (*IACS User Guide Document Version 3.0*, April 2013)

C. Ensure your organization is prepared to implement modifications to the Other Health Insurance (OHI) Notification Records to accommodate ICD-10-CM, and the Monthly MSP Information Data File which adds use of COB information in processing MSP payment reductions. (HPMS memo 7/17/2013).

III. Electronic Correspondence Reporting System (ECRS) – Medicare Advantage Organizations, Part D Sponsors

A. Prepare for the implementation of CMS' ICD-10 diagnosis coding. ICD-10 coding is required beginning with the dates of service on or after October 1, 2014.

B. Prepare for the ECRS batch file processing changes planned release in January 2014. (HPMS memo 9/3/2013)

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

A. **Part D Sponsors.** Ensure timely and accurate submission of CY 2014 pricing data for posting on the Medicare Plan Finder. Sponsors are required to submit MPF data during each regular submission window, which occurs every two weeks. Sponsors may not auto-certify their pharmacy cost files. (HPMS memo 6/14/2013)

Ensure preferred pharmacy arrangements are accurately identified in MPF pricing files. A pharmacy may only be associated with the plan's preferred network if a lower differential cost sharing applies to some tiers of formulary drugs at that pharmacy than actually applies at pharmacies in the non-preferred network. (Calendar Year 2014 Medicare Advantage and Part D Payment Policies and Final Call Letter)

The initial CY 2014 data submission period for live/public pricing data was September 9 through September 10, 2013. The data was published on www.Medicare.gov on October 1, 2013. (HPMS memos 8/7/2013 and 8/14/2013)

B. Part D Sponsors. Ensure pricing and pharmacy network data files for MPF have passed quality assurance checks for completeness and accuracy for CY 2014 data, and that only pharmacies under contract for 2014 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). Part D Sponsors are expected to perform quality assurance checks to ensure these files are complete and accurate. Incorrect data may result in suppression from the Medicare Plan Finder, and applicable compliance actions. (HPMS memo 6/14/2013)

C. New 2014 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 6/14/2013)

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

Ensure key staff registers for the CMS biweekly Part C & D User Calls at https://www.mscginc.com/registration/. Participants should call fifteen minutes before start time to ensure timely access to the call.

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. Part D sponsors must submit to CMS only prescription drug event (PDE) records containing an active and valid individual prescriber NPI. 42 CFR 423.102(c)(5)

VII. Patient Safety Analysis Website – Part D Sponsors

A. Ensure your organization accesses the monthly Patient Safety Reports via the Patient Safety Analysis Website 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. Be advised, sponsors are required to use the website to view and download the reports and should be engaged in performance monitoring. (HPMS memo 4/22/2011, 8/13/2012, 4/2/2013)

New sponsors for 2014 – your organization will receive log-on credentials directly from the Patient Safety Analysis Website contractor, and you will begin reviewing these reports in spring of 2014.

VIII. Overutilization Monitoring System – Part D Sponsors, including PACE

A. Ensure Medicare Compliance Officer authorizes users to access the Overutilization Monitoring System (OMS), available via the Patient Safety Analysis Website. At least one user from each contract must have access to Summary and Confidential Beneficiary Reports to view and respond to beneficiary-level overutilization issues.

B. Ensure the OMS quarterly reports (beginning July 31, 2013) are reviewed and acted upon and CMS receives a response within 30 days of the report. For additional information, user guides and the medication lists used to calculate the overutilization issues are available on the Patient Safety Analysis Website under *Help Documents*.

(HPMS memo 07/05/2013)

IX. 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 your organization establishes access to Acumen's PDE Analysis and PDE Reports websites as described in the May 6, 2013 HPMS memo.

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. Coverage Gap Invoice Report.

D. Practice due diligence in determining if a drug is a Part D covered drug and is currently marketed using the FDA's Comprehensive NDC Structured Product Labeling (SPL) Data Elements file (NSDE) to edit PDEs.

The presence or absence of an NDC on the NSDE and the accuracy of the listing information is NOT a coverage determination. CMS expects Part D sponsors to

reach out to manufacturers regarding missing or inaccurate information on the NSDE. (HPMS memos 05/14/2012 and 08/16/2012, 10/25/2012)

E. CMS requires that sponsors submit timely PDE records (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.

X. Encounter Data System (EDS) and Risk Adjustment Processing System (RAPS) – Medicare Advantage Organizations (MAO)

A. Be advised that Medicare Advantage Organization payment is primarily based on data submitted to CMS. In order to receive proper payment, MAOs and other entities must be certified to submit data through both the EDS and RAPS. All information relative to becoming certified to submit data, guidance regarding data submission to CMS, and other resources can be found on the Customer Service Support Center (CSSC) website, www.csscoperations.com.

Checklist items for EDS and RAPS submission are as follows:

i. Enroll to submit data through CSSC,

ii. Perform certification requirements,

iii. Subscribe to receive email updates,

iv. Be familiar with guidance contained on the CSSC website, and

v. Register to attend all User Groups.

Assistance with data submission can be obtained by csscoperations@palmettogba.com, or by calling 1-877-534-2772.

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, PACE Organizations*, Section 1876 Cost Plans and Part D Sponsors

Ensure your organization is prepared to submit HEDIS, HOS, HOS-M* and CAHPS measures to the appropriate entity by the specified due date. The HPMS memo dated 8/2/2013

provides the type of reporting required for each contract type and the deadlines for data submission.

* *The HOS-M is an abbreviated version of the HOS, which assesses the frailty of enrollees in PACE Organizations to generate information for payment adjustment.*

HPMS memos 8/2/2013 and 8/9/2013

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

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 memo 06/11/2013), HPMS email 3/7/2013, and the Plan Reporting Sites: http://www.cms.hhs.gov/HealthPlansGenInfo/16_ReportingRequirements.asp#TopOfPage and http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ReportingOversight.html

III. 2014 Essential Hospital Designation and Attestation - Medicare Advantage (MA) Regional Preferred Provider Organizations (RPPOs)

A. Medicare Advantage (MA) Regional Preferred Provider Organizations (RPPOs) must designate essential hospitals by Friday, October 4, 2013. Please indicate any additions or deletions to your 2013 approved hospital list when you submit this updated list.

B. RPPOs seeking to designate a non-contracting hospital as an essential hospital must establish a HIPAA-compliant electronic claims transmission connection with Noridian, which serves as the Medicare Administrative Contractor for CMS.

(HPMS memo 08/14/2013)

C. Contracting, Subcontractor Provisions, and Oversight

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

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 2014 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

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. (HPMS memos 07/23/2007, 09/20/2007, and 08/26/2008)

* *Offshore subcontractor* is defined as a first tier/downstream/related entity located out of the one of the fifty United States, the District of Columbia, or one of the United States Territories (American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands).

III. Changes to First Tier/Downstream/Related Party (FDR) Contracts for Key Part C and Part D Functions

If making changes to any FDR contracts and or contractors fulfilling key Part C and/or Part D functions on behalf of the sponsor/plan sponsor:

A. Notify your CMS Account Manager at least 60 days prior to the effective date of the new contract.

B. Ensure all systems involved are fully tested, have an executable implementation timeline with milestones and deliverables, and critical systems are run in parallel until assurances that any new system is fully functional.

C. Part D Sponsors – 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.

iii. Additional 4Rx information is available in Enrollment/Disenrollment, section IV.D.a

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. (*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. (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. 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.

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 30.6, 30.7, 30.10 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. Plan sponsors must include the Multi-Language Insert with the Summary of Benefits and the ANOC/EOC.

Medicare Marketing Guidelines, Sections 30.5, 30.5.1, 30.6, 30.7, 80.1, 100.1, and Appendix 3; 42 C.F.R. §§ 422.2264(e), 423.2264(e)); HPMS memos 6/28/2013.

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

A. Part D Sponsors. Ensure staff is familiar with the plans' Medication Therapy Management (MTM) program, including eligibility criteria and additional information required to be available on a dedicated Medication Therapy Management Program page linked from the Medicare drug plan website, and how to direct beneficiaries to the plans' MTM program page.

B. 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*)

C. Part D Sponsors. Ensure staff is prepared to accept Late Enrollment Penalty (LEP) telephonic attestations from beneficiaries, and able to assist beneficiaries with completing the prior creditable prescription drug coverage attestation. (*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, 2013 to February 14, 2014. Part D Sponsors must meet CMS standards. (*Medicare Marketing Guidelines, Appendix 5*)

B. Ensure pharmacy technical support is available at all times 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, Part D Sponsors, Cost Plans, and PACE Organizations

A. Be advised of the new release of the Complaints Tracking Module (CTM) Standard Operating Procedures (SOP), and the republishing of the CTM Exclusion Criteria.

In addition to announcing the revised SOP, the HPMS memo provides suggested examples of satisfactory CTM resolution notes.
(HPMS memo 6/28/2013)

B. 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)

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

D. 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 www.Medicare.gov website and the web site of the Ombudsman on the www.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)*

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 *errata* sheets are sent timely upon identification of inaccuracies 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), 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, 2013.

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.

vii. Indicate the actual mail date in HPMS within 15 days of mailing of the ANOC/EOC.

(*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. Referencing Star Ratings in Marketing Materials

A. Plans/Part D Sponsors must provide the overall Star Ratings information to beneficiaries through the CMS standardized Star Ratings information document, which must be distributed with any enrollment form and/SB.

B. Plans/Part D Sponsors must ensure that any references to Star Ratings comply with the 2014 requirements.

(Medicare Marketing Guidelines, Section 30)

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

A. Ensure your organization's website contains the general requirements (e.g. customer service number, required translated materials).

B. Ensure your organization includes all required content and documents as outlined in the *Medicare Marketing Guidelines* (e.g. rights and responsibilities, Summary of Benefits, 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 2014 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. 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 5, 2013. Be advised that enrollments received after December 7, 2013 may not be processed as AEP elections. Beneficiaries must be eligible for a valid Initial Election Period or Special Enrollment Period (SEP) for requests received after the December 7th deadline.

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

Be advised that the MADP begins on January 1 and ends on February 14 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.

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

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. Ensure your organizations sends individuals an acknowledgment notice within ten (10) calendar days of receiving a valid and complete:

i. 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*)

ii. 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*)

B. Ensure your organization requests 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*)

C. Ensure your organization sends 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. Ensure your organization processes 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*)

E. Ensure your organization processes unsolicited paper AEP enrollment requests received prior to the start of the AEP. Indication of sales agent or broker involvement in the submission of the request must be investigated for compliance with the requirements in the Medicare Marketing Guidelines. (Medicare Managed Care Manual, Chapter 2, Section 40; and Prescription Drug Benefit Manual Chapter 3, Section 40). Paper AEP requests received directly from sales agents or brokers prior to the start of the AEP must be denied.

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. Normal

processing time ends at 8:00 PM Eastern Time (ET) but occasionally the timeframe changes due to special processing. Advance notification will be given if there is a change in the normal processing timeframe. 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. *(Plan Communications User Guide*)

B. 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*)

C. **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 that enrollments rejected by CMS are processed in accordance with CMS requirements (e.g., providing beneficiary notices within ten (10) days of CMS rejection notice via daily TRR). (*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, PACE, 800-Series-Only and Medicare-Medicaid plans; Optional for SNPs, RFB and 1876 cost plans; Required for PDP and MA-PD)

A. Establish/maintain a process to download enrollment at least once every business day from the Online Enrollment Center (OEC) unless your organization is prohibited from participating in the OEC. (Online Enrollment Center (OEC) Timeline and Requirements for the 2014 Plan Year 08/23/13, *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 2014 to assist in guiding beneficiaries towards selecting higher performing plans.

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

Plans that are participating in the OEC and do not download and process enrollments from the OEC on a timely basis will lose the privilege of participating in the OEC. CMS tracks, and takes compliance action toward, delinquent plans, including placing repeat offenders on Corrective Action Plans (CAPs). (Online Enrollment Center (OEC) Timeline and Requirements for the 2014 Plan Year 08/23/13).

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 completes and submits a monthly attestation of enrollment information related to payment from CMS. Through the electronic signature of its CEO, CFO, or the COO, each organization certifies that, based on best knowledge, information, and belief, the enrollment information submitted to CMS is accurate, complete, and truthful. As a reminder, the certification for each month's data is due to CMS within 45 days of the date that the monthly payment reports are available with that month's data. (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, 08/16/2013)

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 2014 approved benefit package, including any late enrollment penalty amount.

B. Ensure Part D-IRMAA inquiries are 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 Part D plan.

C. Ensure your organization appropriately processes involuntary disenrollment transactions resulting from failure to pay Part D-IRMAA, and provides the appropriate notices to beneficiaries.

NOTE: Part D-Income Related Monthly Adjustment Amount (D-IRMAA) payments are NOT to be collected by sponsors. (*Medicare Managed Care Manual Chapter 2, Section 50.2.6,* and *Prescription Drug Benefit Manual Chapter 3, Section 50.2.6*)

D. Ensure your organization properly processes notifications from CMS of reinstatement for "good cause."

Note: 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. (*Medicare Managed Care Manual Chapter 2, Section 60.3.4,* and *Prescription Drug Benefit Manual Chapter 3, Section 60.2.4*)

G. Late Enrollment Penalty (LEP) and Creditable Coverage – Part D Sponsors

I. LEP

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

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. Explanation of Benefits – Medicare Advantage Organizations

As specified in §422.111(b)(12), implement systems and processes necessary to provide for the generation of Part C EOBs for all plan members in accordance with the timing and requirements as specified by CMS.

II. Advance Directives – Medicare Advantage Organizations

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,* and 42 C.F.R. § 422.128)

III. 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,* and 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*)

IV. Coverage Gap Discount Program (Discount Program) – Part D Sponsors

A. Ensure your organization updates electronic funds transfer (EFT) information used for the Discount Program via the online form on the TPA's web site (http://tpaadministrator.com). Any changes will be shared with manufacturers on a quarterly basis, per the EFT Calendar published on the TPA's web site. These data are collected and maintained outside of the Automated Plan Payment System (APPS).

B. Confirm receipt of manufacturer payments to the TPA, 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)

C. Part D sponsors are responsible for repaying manufacturers negative invoice amounts caused by PDE adjustments. In order to facilitate repayment the TPA will distribute a "Contract Negative Balance Report" to Part D sponsors in October, 2013 and every April thereafter. To facilitate this repayment process, the TPA will collect (EFT) information from manufacturers and deliver it securely to Part D sponsor's mailboxes approximately four weeks prior to report distribution. Part D sponsors are responsible for paying amounts due to manufacturers within 38 days of the Negative Balance Report distribution. (HPMS memo July 12, 2013)

V. 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)

VI. Daily Cost Sharing Requirements – Part D Sponsors

Beginning January 1, 2014, establish and apply a daily cost sharing rate whenever certain prescriptions (depending on the drug dispensed) are dispensed by a network pharmacy for less than a 30 days' supply in accordance with 42 CFR § 423.153(b)(4)(i). (*Calendar Year 2014 Medicare Advantage and Part D Final Call Letter*)

VII. Auto-Ship Refill Programs in Part D

A. No later than January 1, 2014, require that your organization's network retail and mail pharmacies obtain patient consent to deliver a prescription (new or refill) prior to each delivery.

NOTE: Such confirmation is unnecessary when the beneficiary personally initiates the refill or new prescription request. This policy does not affect retail refill reminder programs that require the patient to pick-up the prescription and does not apply to long-term care pharmacy dispensing and deliveries.

(*Calendar Year 2014 Medicare Advantage and Part D Final Call Letter*)

NOTE for EGWPs - EGWP sponsors interested in offering an automatic delivery program that does not feature obtaining consent prior to each delivery after January 1, 2014 must submit a request to PartDPolicy@cms.hhs.gov no later than December 18,

2013. EGWPs will need to submit the sponsor name, contract number(s), and whether the automatic delivery program will be applied to some or all of their EGWP contracts. (HPMS memo 10/28/2013)

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

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

- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both.
- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.
- 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*)

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

The QI program must meet the applicable requirements for the services that it furnishes to its MA enrollees, as specified at 42 CFR §422.152 and detailed in *Chapter 5* of the *Medicare Managed Care Manual*.

X. Improving Drug Utilization Controls in Part D

Implement 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, HPMS memo 9/6/2012, and http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html)

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 only serving U.S. Territories

A. Meet CMS requirements for accepting specific forms of BAE to establish a more favorable low income copayment 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 immediately applying any updates received via 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. 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)

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), set your organization's systems to charge the correct premium, deductible, and copayments effective January 1, 2014 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.

B. Make reasonable attempts to notify affected members to advise them of their retroactive liability for higher premiums and cost sharing when LIS status or eligibility is removed. (70.3.1 Chapter 13

(HPMS memos 11/30/2009 and 7/31/2013)

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 2014. (HPMS memo 07/31/2013)

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 6th 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 and HPMS memo 07/31/2013).

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

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 reconcile against their data systems' enrollees' LIS status. (HPMS memos 8/30/2006, 10/30/2006, 11/26/2008, 11/23/2009, and 12/09/2010)

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

Medicare Prescription Drug Manual Chapter 14 – Coordination of Benefits **and HPMS memo 03/02/2012**

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 transaction facilitator.

NOTE: The BAA requirement is applicable not only to sponsors directly reporting the TrOOP accumulators to the transaction facilitator, but also to sponsors using a processor for the automated TrOOP balance transfer process. Therefore, it is critical that each Part D sponsor has a signed agreement with the Transaction Facilitator.

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 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 creates and 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 both the record updates that would normally be included in the daily COB notification files and the full replacement COB data for all enrollees with other coverage. These combined daily update/full replacement COB files contain no special identifiers to distinguish them from the normal daily files, but they may be identifiable based on the date of receipt

and large size of the files. The full replacement files include the last 27 months of other coverage information.

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. (42 C.F.R. §423.466(b))

iii. Ensure your organization correctly identifies its members who are also an SPAP or ADAP enrollee, and send the member's SPAP/ADAP 4Rx data back to the pharmacy in the claim response so that the pharmacy may appropriately bill the SPAP or ADAP for their portion of the enrollee's cost sharing. To assist with the coordination of the SPAPs and ADAPs, NCPDP maintains a list of BIN/PCN on the NCPDP website. The COBC precludes Part D sponsors from updating SPAP and ADAP information. Only those programs may update the information with the COBC.

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

Ensure organization correctly processes Nx (N1, N2, N3) transactions received from the Part D Transaction Facilitator, which identify supplemental payments and thus impact the TrOOP accumulators, including N transactions providing information on SPAP/ADAP payments.

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

A. Ensure your organization accurately tracks, accumulates, and reports TrOOP for all enrollees.

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 15 days of notification of the problem.

IV. Direct Member Reimbursement

Ensure your organization follows the guidance specified for direct member reimbursement, which is outlined in section 50.4.3 and Table 50.4.3-1 of the *Medicare Prescription Drug Manual – Chapter 14*. This section provides guidance to ensure

consistent handling of out-of-network claims for both LIS and non-LIS eligible beneficiaries as well as paper claims for drugs accessed from network pharmacies.

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

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. (*Medicare 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. Maintain payment systems to ensure they are set up to charge beneficiaries the lesser of a drug's negotiated price or applicable copayment amount. (*Medicare Prescription Drug Benefit Manual Chapter 5*)

B. 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)

C. 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)

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

Ensure your organization is prepared to follow CMS guidance regarding pharmacy and provider access during a Federal Disaster or other Public Health Emergency Declaration. (HPMS memos 06/16/2008, 07/20/2009, 11/7/2012, 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.

III. 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 2014. (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 CY2013 to CY2014). 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 2014 formulary prior to January 1, 2014. 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 closely monitor current enrollees' rejected claims after the beginning of CY 2014.

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 total supply of 91- to 98-day, with refills provided consistent with the dispensing increment; 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. (*Medicare Prescription Drug Benefit Manual Chapter 6*)

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

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

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

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. Oversight of Entities Performing Delegated Functions

If your organization delegates 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 delegated functions and that this oversight is integrated into your overall compliance program.

NOTE: The role of Medical Director may not be a delegated function

IV. Rights of Medicare Part C & D Enrollees

A. Part D sponsors must ensure that their 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 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.

C. Ensure Medicare Part C & D enrollees are afforded all rights and protections of grievances, coverage determinations, and appeals processes. (*Prescription Drug Benefit Manual, Chapter 18 - Part D Enrollee Grievances, Coverage Determinations, and Appeals* and *Medicare Managed Care Manual, Chapter 13 – Beneficiary Grievances, Organization Determinations, and Appeals*)

(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.

i. 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.

ii. 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.

D. Prepare to implement changes to the Part C Reconsideration Dismissal Procedures

Effective January 1, 2014, in addition to being responsible for dismissing reconsideration requests when appropriate and providing timely notification of dismissals to enrollees or another party, Medicare Advantage organizations (MAOs) will also be responsible for informing enrollees and other parties about the right to request IRE review of the dismissal. MAOs will no longer automatically forward such reconsideration cases to the IRE for review. HPMS memo 09/10/2013

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 07/30/2013**

I. Familiarize your organization with the best practices and common findings from the 2012 program audits as described in the memo dated July 30, 2013 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.

H. Accountable for and oversees Medicare Parts C and D functions performed by FDRs; clear and defined processes and analysis for evaluating whether a contracted entity is a FDR; effective oversight program to ensure FDRs comply with CMS requirements and timely corrective actions.