

# MEMO

**DATE:** November 30, 2011  
**TO:** Clients and Friends  
**FROM:** John Gorman and Jean LeMasurier  
**SUBJECT:** CMS Proposed Changes to the MA and PDP Benefit Programs for CY 2013

On October 3, 2011, the Centers for Medicare and Medicaid Services (CMS) issued proposed rules that would implement new requirements and protections in the Medicare Advantage (MA) program and prescription drug benefit program (Part D). A full-text version of the proposed rules can be found online at: [http://www.ofr.gov/OFRUpload/OFRData/2011-25844\\_PI.pdf](http://www.ofr.gov/OFRUpload/OFRData/2011-25844_PI.pdf).

Following is a summary of the most significant changes included in the proposed regulations.

## **NEW REQUIREMENTS INCLUDED IN MIPPA AND THE AFFORDABLE CARE ACT (ACA)**

### **CODIFY COVERAGE GAP DISCOUNT PROGRAM REQUIREMENTS**

The proposed rule would codify previous guidance and drug manufacturer agreements that implemented the coverage gap discount program included in the ACA effective January 1, 2011. The proposed rule includes: conditions of coverage of drugs; the coverage gap discount program agreement; coverage gap discount payment processes; provision of applicable discounts on applicable drugs for applicable beneficiaries; manufacturer audit and dispute resolution processes; resolution of beneficiary disputes involving discounts; compliance monitoring and civil money penalties; and termination of the discount program agreements.

Under the proposed rule, the Part D plan sponsors will continue to provide the information necessary to apply the discount at the point-of-sale. Under the proposed rule, discounts also apply

to beneficiary-submitted paper claims. The proposed rule clarifies that enrollees in employer-sponsored group prescription drug plans may qualify as applicable beneficiaries. Applicable drugs include Part D drugs marketed under a new drug application or biologics license application even if the Part D sponsor otherwise considers the products to be generic under its benefit.

Applicable drugs covered under transition and emergency fill policies are subject to discounts. Discounts do not apply to Part D compounds. All applicable discounts paid by manufacturer would be treated as incurred costs for purposes of calculating the beneficiary's TrOOP. The proposed rule clarifies that a manufacturer includes "entities otherwise engaged in repackaging or changing the container, wrapper or labeling of any applicable drug product" to facilitate accurate assignment of the discount at final delivery or sale to the consumer.

The proposed rule provides that manufacturer audits of TPAs and CMS audits of manufacturers may be conducted no more than annually. The beneficiary dispute resolution process on the availability and amount of the discounts would follow existing Part D coverage determination appeals processes with appropriated modifications, e.g. adding the definitions to include manufacturers and using the term "affected party". The proposed rule includes the basis and process for imposing civil money penalties on manufacturers that fail to meet the provisions of the agreement and the basis and process for termination of manufacturer agreements.

## **EXPAND PART D COVERAGE TO INCLUDE BENZODIAZEPINES AND BARBITURATES**

Effective January 1, 2013, Part D will cover barbiturates used for the medical implications of epilepsy, cancer or a chronic mental health disorder and benzodiazepines provided they meet the other requirements for Part D coverage.

## **PHARMACY BENEFIT MANAGER (PBM) TRANSPARENCY REQUIREMENTS**

The proposed regulation addresses new reporting requirements included in the ACA to assure transparency. The rule addresses the reporting of PBMs to Part D Sponsors and the reporting of Part D plan sponsors to the Secretary. Under the proposed rule, the following information is reported:

- The total number of prescriptions dispensed;
- Percentage of all prescriptions provided through retail pharmacies compared to mail order pharmacies;
- Percentage of prescriptions for which a generic drug was available and dispensed by pharmacy type (e.g. independent, chain, supermarket), which was paid for by the Part D sponsor or PBM under contract;
- The aggregate amount and type of rebates, discounts, or price concessions that the PBM negotiates that are attributable to patient utilization under the plan. "Bone fide service fees" are excluded. The proposed rule includes a definition of these fees (e.g. inventory management services that are not passed through or patient education programs);
- The aggregate amount of the rebates, discounts or price concessions that are passed through to the plan sponsor;
- The aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount the PBM pays retail pharmacies and mail order pharmacies.

CMS is proposing to collect information on total number of prescriptions and PBM spread amount from current PDE and DIR reports, and requests comments on other simplified methods to implement the ACA requirements.

Failure to report or report timely will result in penalties under Section 1927 of the Social Security Act.

The reported information is confidential except that the Secretary may disclose information in a form which does not disclose the identity of a specific PBM, plan or prices charged for drugs for the following purposes: as necessary to carry out the purposes of Part D or the PBM Transparency requirements; for the review of the Comptroller General and the Director of the CBO.

## **PROVISIONS TO STRENGTHEN BENEFICIARY PROTECTIONS**

### **REQUIRE MA PLANS TO USE A UNIFORM ID CARD**

Under the proposed rule, the following information must be included on the member ID card for a PPO or PFFS: a statement that Medicare Limiting Charges may apply; an address for the plan's website; a customer service number; and the individual identification number for each enrollee.

Plans are prohibited from disclosing social security numbers or health insurance claim numbers on the member ID cards. The preamble specifies that this will allow all providers to easily recognize MA enrollees and facilitate verification of coverage and processing claims.

### **DETERMINATION OF ACTUARIALLY-EQUIVALENT CREDITABLE PRESCRIPTION DRUG COVERAGE UNDER THE RDS PROGRAM**

Under the proposed rule, the value of additional coverage in the Part D coverage gap and the manufacturer's discount will be excluded from the Retiree Drug Subsidy Program Creditable Coverage calculation. This change will update the regulation to address improvements in the Part D coverage gap enacted in the ACA and will reduce the number of beneficiaries who are subject to the late enrollment penalty.

### **ALLOW HEALTH CARE PROFESSIONALS TO REQUEST INDEPENDENT REVIEW ENTITY (IRE) RECONSIDERATIONS OF PART D COVERAGE DETERMINATIONS**

The proposed regulation will eliminate the requirement that the physician or other health professional submit a valid Appointment of Representative form with an appeals request, thus expediting the IRE decision and enhancing beneficiary access to Part D coverage. The proposed rule does not include an automatic forward to the IRE for adverse redeterminations. The prescriber must notify the beneficiary when they make an appeal request on behalf of the beneficiary and the IRE must inform the prescriber of its decision.

### **INDEPENDENT LTC CONSULTANT PHARMACISTS**

CMS is considering a proposed change to the LTC conditions of participation that would require LTC consulting pharmacists to be independent of any affiliation with LTC facilities' pharmacies, pharmaceutical manufacturers and distributors or any affiliates of these entities.

The change would require each LTC facility to employ or to obtain the services of a licensed pharmacist who is independent of the pharmacy, located in or under contract with the facility.

The independent pharmacist would provide consultation on all aspects of pharmacy services including monthly review of the drug regimen of each resident. This provision would address potential patient safety and quality of care that may result from various contractual arrangements involving LTC facilities (e.g. financial arrangements that involve payment from pharmaceutical manufacturers directly or indirectly to LTC pharmacies and consultant pharmacists). There are concerns that financial interests may encourage overprescribing or recommendations that conflict with the best interests of nursing home residents and Part D sponsor formularies and/or drug utilization management programs. Comments are sought on this proposal for a January 2013 effective date.

## **PROVISIONS TO EXCLUDE POOR PERFORMING PLANS**

### **AUTHORITY TO TERMINATE PLANS UNDER THREE STARS**

The proposed rule adds a requirement that an organization must demonstrate that it maintains satisfactory administrative and management arrangements by achieving a summary plan rating of at least three (3) stars for Part C and Part D each year. CMS would have the authority to terminate or non-renew MAOs and Part D sponsors that fail to provide services meriting at least a 3-star summary rating for three consecutive years.

Plans can achieve scores of less than three stars on individual measures. This provision would elevate a low plan rating from the current status of likely indicator to conclusive evidence of substantial non-compliance. The calculation of the three-year period would begin after issuance of a final rule expected in Spring 2012 with the effect that Contract Year 2013 plan ratings issued in September 2012 would serve as the first year of ratings.

### **AUTHORITY TO DENY APPLICATIONS FOR PAST POOR PERFORMERS**

Medicare Advantage Organizations or Part D plans with a past CMS initiated contract termination or non-renewal will have a 38-month waiting period before they can submit a new application to re-enter the program. This is one year longer than the current two-year waiting period for plans that voluntarily non-renew their contract. In implementing the 38-month provision, CMS may deny an application where a "covered person" also served as a "covered person" for the terminated or non-renewed contract (e.g. owners or member of the board of directors of terminated plans). This is consistent with the current requirement for plans that voluntarily non-renew their contract.

## **PROVISIONS TO IMPROVE PROGRAM EFFICIENCIES**

### **NEW BENEFIT FLEXIBILITY FOR FULLY-INTEGRATED DUAL ELIGIBLE SPECIAL NEEDS PLANS**

Under the proposed rule, current Full-Integrated Dual Eligible Special Needs Plans (FIDE SNPs) that have operated in the previous contract year and that meet certain CMS criteria (including, but not limited to, being a high quality plan as defined in the Call Letter beginning in CY 2013) would be afforded additional supplemental benefit flexibility beyond that allowed for MA plans. Examples of benefits that could be offered under the proposal include: personal care services in the home; non-skilled nursing activities in the home; custodial care; and in-home food delivery for vulnerable beneficiaries.

CMS would approve the proposed benefit offerings. The change is intended to allow greater integration of care for duals. Because FIDE SNPs are required to offer LTC supports and services, this flexibility is also consistent with the objective of keeping beneficiaries at risk of institutionalization in their homes and preventing health status decline. CMS is seeking comments

on the proposal, including the scope of additional benefits and ways to minimize the cost impact on beneficiaries.

### **REQUIRE MAOs TO MEET THE FFS HOSPITAL ACQUIRED INFECTIONS AND PRESENT ON ADMISSION INDICATOR POLICY**

Beginning in CY 2013, MAOs would be required to include in their contracts with hospitals that they will reduce payments for Part A hospital services for serious events that could be prevented through evidence-based guidelines in accordance with the Hospital Acquired Infections (HAI) and Present on Admission (POA) indicator policy that applies in FFS Medicare. Under this policy, IPPS hospitals do not receive a higher payment for cases when a selected condition is acquired during hospitalization that was not present on admission (currently ten conditions such as falls and surgical site infection). Rather, the case is paid as though the secondary diagnosis is not present. This policy currently applies to MA payment to non-contracting hospitals and under the rule would be extended to contracting hospitals.

The preamble recognizes that MAOs may pay contract hospitals under capitation or other methods. It indicates that MAOs will have flexibility to determine the best methodology for hospitals to report these serious conditions and events (e.g. using the HIPAA 5010 claim form that will be used for the new MA encounter data system) and to determine whether the condition was present on admission or caused during the inpatient hospital stay and paying hospitals appropriately. CMS seeks comments on issues to consider in extending the FFS policy to MAOs.

### **CLARIFYING COVERAGE OF DURABLE MEDICAL EQUIPMENT**

The proposed rule would allow MAOs to limit Durable Medical Equipment (DME) coverage to preferred products or brands subject to coverage limitations. With regard to access, the MAO must ensure that contracts with suppliers assure that enrollees have access to all preferred DME products or brands (e.g. through arrangements to special order products or brands of any preferred DME items or supplies) and that enrollees have access to all medically necessary non-preferred DME items or supplies.

The medical necessity determination process must be on an individual basis overseen by a physician medical director and subject to the MA appeal process. The MAO must establish a transition policy (similar to the Part D policy for non-formulary drugs) that allows one refill during the first 90 days and provides for repair of non-preferred DME items. MAOs would be prohibited from eliminating preferred coverage of DME items mid-year, although plans may add to preferred DME products. MAOs must use the current organization determination and appeals process for beneficiary appeals. MAOs must disclose the limitation of DME coverage and the right to appeal and obtain medical necessity determinations in the ANOC/EOC.

### **MORE FLEXIBLE AGENT/BROKER COMPENSATION RULES**

MAOs may annually select compensation rates which are at or below the fair market value (FMV) cut off annually established by CMS. This will allow payment to better reflect current economic conditions and will allow established plans to better compete with new entrants. Plans would also be required to report their intentions to use independent agents and/or brokers in the upcoming year along with the amounts they will be paid, if applicable.

### **COST SHARING TAILORED TO A TRIAL FILL OF A PRESCRIPTION DRUG**

Under the proposed rule, Part D sponsors would be required to provide all enrollees with access to a daily prorated cost-sharing rate for prescriptions dispensed by a network pharmacy for less than a 30-day supply for an initial fill of a new medication. The daily cost sharing rate is the Part D copayment divided by 30 or 31 rounded to the nearest dollar amount or the coinsurance rate

applied to the ingredient cost divided by 30 or 31. The proposal would apply to solid oral doses of drugs, except antibiotics or drugs which are dispensed in their original containers. The daily cost-sharing policy would also apply to drugs in LTC facilities and the proposal would supersede the April 2011 rule which requires 14 days or less dispensing in LTC facilities.

The proposed policy would apply to both brand name and generic drugs. This proposal would save costs and is intended to allow the enrollee to synchronize refill dates of multiple drugs. Use of the daily rate is voluntary for enrollees and prescribers. CMS seeks comments on this proposal including how to deal with nominal copays for LIS enrollees, how pharmacies can facilitate synchronization of refills and the potential for increased administrative costs and dispensing fees.

## **PROVISIONS TO CODIFY AND CLARIFY PROGRAM REQUIREMENTS**

### **SINGLE DEDUCTIBLE FOR PREFERRED PROVIDER ORGANIZATIONS**

The proposed rule would extend the single deductible that applies to Regional Preferred Provider Organizations (RPPOs) to Local Preferred Provider Organizations (LPPOs), including the provision allowing the single deductible to be applied differentially for in-network services. The rule also provides more flexibility in how the RPPO and LPPO may apply the single deductible. For example, limiting the amount to specific services or to exempting application to particular services. The rule clarifies that RPPOs and LPPOs must exclude certain Medicare covered preventive services from the single combined deductible.

### **VALID NPI ON PDE RECORDS**

The proposed rule requires Part D sponsors to submit an active and valid individual prescriber NPI on any PDE record submitted to CMS. The requirement would only impact approximately ten percent of PDE submissions that currently do not include valid NPIs and this change is not expected to be burdensome to plans or prescribers. Additionally, it is expected to facilitate the identification of fraud and abuse. The rule would also codify existing guidance that Part D sponsors may not reject pharmacy claims without NPIs at the point of sale (except in certain circumstances, e.g. suspected fraud or claim involving a foreign prescriber).

The Part D sponsor may not reject paper claims from beneficiaries due to lack of a valid prescriber NPI. CMS is requesting comments on the proposal including whether Part D should prohibit sponsors from paying claims that involve prescriptions written by foreign prescribers regardless of whether the foreign prescriber obtains an individual NPI.

The proposed rule includes additional technical changes to correct timelines and cross references and to clarify regulatory changes to ensure consistency in policy and protections across plan types, or to clarify regulatory language where there has been past confusion.

## **FOR MORE INFORMATION**

If you have specific questions regarding the content of this memo, please contact Gorman Health Group at [ghg@gormanhealthgroup.com](mailto:ghg@gormanhealthgroup.com).

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