REQUESTS FOR ADDITIONAL WAIVERS OF REQUIREMENTS FROM SPONSORS OF 2006 EMPLOYER/UNION-ONLY GROUP PLANS (JANUARY 25, 2006)

Background

The Medicare Modernization Act (MMA) provides employers and unions with a number of options for providing Medicare prescription drug coverage ("Part D") to their Medicare-eligible active employees and retirees. Under the MMA, those options include making special arrangements with Medicare Advantage (MA) Organizations and Section 1876 Cost Plans to purchase customized benefits, including drug benefits, for their active employees and retirees; purchasing customized benefits from sponsors of prescription drug-only plans (PDPs); and contracting directly with CMS to themselves sponsor a Medicare plan. Under Sections 1857(i) and 1860D-22(b) of the Social Security Act (SSA), CMS may waive or modify requirements for these arrangements that "hinder the design of, the offering of, or the enrollment in" these employer or union-sponsored group Part D plans.

CMS may exercise its statutory waiver authority for two basic types of entities: (1) MA Organizations, PDP Sponsors and Section 1876 Cost Plan Sponsors[1] that offer or administer employer/union-only sponsored group waiver plans (hereinafter referred to as "EGWPs"); and (2) employers/unions that directly contract with CMS to themselves offer an employer/union-sponsored group plans (hereinafter referred to as "Direct Contract EGWPs"). For 2006, CMS issued guidance waiving or modifying a number of Part D requirements for these entities. CMS waiver guidance is located at: http://www.cms.hhs.gov/EmpGrpWaivers.

In addition to these existing waivers, 42 CFR 423.458(c) allows any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan to request, in writing, a waiver or modification of additional requirements under Part D that hinder the design of, the offering of, or the enrollment in, such plans. Waivers or modifications approved by CMS apply to any similarly situated entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan that meets the conditions of the waiver or modification.[2]

During the 2006 solicitation for applications process, CMS notified Part D applicants that it would allow entities applying to offer EGWPs or Direct Contract EGWPs to request that CMS waive and/or modify additional requirements beyond those already waived/modified in CMS guidance. Applicants were instructed to submit these requests for additional waivers with their application materials (2006 Part D Application Instructions for Employer/Union Sponsored Retiree Group Plans (as revised April 19, 2005).

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[1] Section 1876 Cost Plan Sponsors may only offer Part D coverage as an optional supplemental benefit. CMS' employer group waiver authority applies only to Part D, *not* to Parts A or B of the Cost Plan.

[2] Similarly, 42 CFR 422.106(d) allows sponsors of MA plans (including MA-PD plans) to submit requests to waive or modify additional Part C or Part D requirements.

CMS has completed its review and consideration of the requests received for additional waivers/modifications of requirements. Many of the waivers and/or modifications requested have already been granted pursuant to CMS guidance and are available on the above-referenced employer group waiver website. Below are the CMS final determinations on the requests for waivers/modifications received from 2006 Direct Contract EGWPs and PDPs, MA Organizations and Cost Plans that offer EGWPs.

Please direct any questions concerning these determinations to Brenda Tranchida, Deputy Director, Employer Policy and Operations Group, at (410) 786-2001 or via email at: Brenda.Tranchida@cms.hhs.gov or Jim Mayhew, Director, Division of Policy, Employer Policy and Operations Group, at (410) 786-9244 or via email at: James.Mayhew@cms.hhs.gov.

Approved Waiver Requests

WAIVER OF SERVICE AREA RESTRICTIONS FOR LOCAL NON-NETWORK PRIVATE FEE-FOR-SERVICE (PFFS) MA-ONLY AND MA-PD PLANS:

42 CFR 422.2

Two MA Organizations requested a waiver to allow local Private Fee-for-Service (PFFS) MA-only and MA-PD non-network plans to extend coverage to retirees residing outside the state where the employer is headquartered, regardless of where retirees live. The requestors justified the request by stating a waiver is needed to avoid disruption of coverage for those retirees and to offer a single national solution for employers with large numbers of retirees living outside of the state where the local PFFS plan is sold. Also, the requestors stated that provider access is not an issue with these kinds of Medicare Advantage plans and the waiver would meet the needs of national employers who would like to offer Medicare eligible retirees a managed care plan in conjunction with the retiree drug subsidy.

CMS granted a waiver of the service area requirements to allow employer/union-only group non-network PFFS plans to extend coverage beyond the normal service area to all retirees of a particular employer or union group, regardless of where they reside in the nation. This waiver applies when the most substantial portion of the employer's employees (or in the case of a union, participants) reside in a state where the PFFS plan is a provider of non-group MA coverage. This waiver only applies to non-network PFFS MA-only and PFFS MA-PD plans providing non-network MA coverage and Part D coverage (which requires networks). *See* CMS June 23, 2005 employer group waiver guidance.

WAIVER OF SERVICE AREA RESTRICTIONS FOR REGIONAL MA-PDs (RPPOs):

Section 1858 of the Social Security Act, 42 CFR 422.2

A MA Organization requested a waiver to allow Regional MA-PDs to extend coverage to retirees residing outside the region. The requestor stated a waiver of service area restrictions is needed to avoid disruption of coverage for those retirees.

CMS granted a waiver of the service area requirements to allow employer/union-only RPPOs to extend coverage beyond the normal service area to all retirees of a particular employer or union group, regardless of where they reside in the nation. This waiver applies when the most substantial portion of the employer's employees (or in the case of a union, participants) reside in a MA region where the RPPO plan is a provider of non-group MA coverage. While nationwide coverage will be available for any employer/union groups meeting the waiver requirements, RPPO coverage will only be available in the plan's RPPO non-group MA region(s). In all other areas throughout the country, the MA Organization may use Local Health Maintenance Organization Point of Service (HMOPOS) or non-network Private Fee-For-Service plan options to cover employer/union group members. *See* CMS June 23, 2005 employer group waiver guidance.

WAIVER/MODIFICATION OF EXPLANATION OF BENEFITS (EOB) REPORTING REQUIREMENTS:

Sections 1860D-4(a)(4) and 1806(a) of the Social Security Act, 42 CFR 423.128(e)

A MA Organization requested a modification of the requirement to provide beneficiaries with a monthly Explanation of Benefits (EOB) for certain large not-for-profit employers/unions to allow the EOB to be provided on a quarterly or annual basis and/or to provide call center support capabilities for inquiries coupled with point of sale receipts where available (many large chain pharmacies and mail order pharmacies currently provide members with receipt at point of sale that includes relevant EOB information). The requestor stated the monthly requirement will lead to substantial additional administrative costs (including mailing and corresponding unnecessary customer inquiry costs), which could further erode the financial ability of these entities to continue to provide prescription drug coverage to retirees and would be better invested in a point of sale capability to provide this information. Alternatively, the MA Organization requested CMS consider granting a similar waiver to these entities for a limited transition period.

A PDP Sponsor requested a waiver to suppress the entire EOB, or alternatively, the TrOOP balance on an EOB, for enrollees with employer sponsored, full wrap around Part D coverage ("first dollar coverage" and no TrOOP expenditures result) as the information may be confusing to these enrollees and may lead to the need for increased customer support volume.

A Direct Contract EGWP requested a similar waiver/modification of the requirement to provide monthly EOBs on the basis that such requirements will be costly and that the entities currently provide adequate EOB information on each claim at the point of sale and whenever an adverse claim decision is made. The requestor asked to provide information via the internet and/or via a toll-free customer number, when a beneficiary is within $100 of TrOOP limit and also upon request.

CMS granted a waiver of EOB requirements to Direct Contract EGWPs, and MA Organizations, PDPs or Cost Plans offering EGWPs in certain limited circumstances. In accordance with this waiver guidance, the disclosure requirements set forth in 42 CFR 423.128 (which include explanation of benefits) will not apply when the employer/union is subject to alternative disclosure requirements (e.g., the Employee Retirement Income Security Act of 1974 ("ERISA")) and fully complies with such alternative requirements. *See* Beneficiary/Marketing Communication waiver contained in the CMS March 9, 2005 Part D Employer Group Waiver Guidance. The Part D EOB requirements will continue to apply to all EGWPs and Direct Contract EGWPs that do not meet the conditions of this waiver.

WAIVER TO ALLOW FOR SINGLE IDENTIFICATION (ID) CARD BY MERGING HOSPITAL/MEDICAL SUPPLEMENTAL ID CARD WITH THE PART D ID CARD ISSUED TO THE BENEFICIARY:

Medicare Marketing Guidelines, published: August 1, 2005; revised: November 1, 2005, 42 CFR 423.120(c)

A PDP Sponsor requested a modification of the CMS Medicare Marketing Guidelines to extend the current flexibility available to MA-PDs to use a single ID card for hospital/medical and drug benefits to standalone PDPs offering EGWPs. The PDP Sponsor requested that CMS allow for the merger on one group ID card private Medicare supplemental ID benefit information with the Part D ID benefit information. If the waiver is not granted, the requestor stated that PDP enrollees in group plans would need to carry 3 cards (one for PDP coverage, one for Medicare, and one for supplemental coverage).

CMS granted a waiver to allow Direct Contract EGWPs and PDPs that offer employer/union-only group waiver plans (EGWPs) to merge their existing member identification (ID) cards in order to provide enrollees with one combination member ID card (for medical/hospital supplemental and PDP drug benefits). *See* Medicare Marketing Guidelines (published: August 15, 2005, revised: November 1, 2005).

WAIVER OF THE REQUIREMENT OF POSTING THE EVIDENCE OF COVERAGE (EOC) AND SUMMARY OF BENEFITS (SB) ON THE PLAN'S WEBSITE:

42 CFR 423.128(d)(2), 42 CFR 422.111(f)(12)

A MA Organization requested a waiver of the requirement contained in 42 CFR 422.111(f)(12) to post on its website the Evidence of Coverage (EOC) and Summary of Benefits (SB) for employer group waiver plans offered. The MA Organization justified the request by stating that the requirement would render this information public to any online user, employers are reluctant to reveal their benefit plans to other employers because of concerns about competition, and the requirement may create enrollee confusion when attempting to locate specific plan information among other employer plan information on the MA Organization's website.

For MA Organizations that offer employer/union-only group waiver plans, CMS has waived the requirement contained in 42 CFR 422.111(f)(12) to post specific information on the organization's website. CMS also has waived the Part D requirement contained in 42 CFR 423.128(d)(2) for PDPs and Cost Plan Sponsors to provide certain information through an internet website for employer group waiver plans offered.

WAIVER OF REQUIREMENT TO POST PLAN INFORMATION ON MEDICARE WEBSITE:

42 CFR 423.48

A PDP Sponsor requested a waiver so that employer/union-only group waiver plans would not be required to post plan information on the Medicare.gov website and/or provide information to the public about these plans on 1-800-MEDICARE. The requestor stated that this requirement would confuse non-group Medicare beneficiaries who will not have access to the plan.

Prior to the MMA, this waiver was previously granted to MA Organizations. *See* 2005 Medicare Managed Care Manual, Chapter 150.1.3. CMS has extended the waiver of this requirement to Part D EGWPs offered by MA Organizations, PDP Sponsors and Cost Plan Sponsors and Direct Contract EGWPs.

WAIVER OF REVIEW AND APPROVAL OF MARKETING/OUTREACH MATERIALS:

42 CFR 423.50, 42 CFR 422.80

A PDP Sponsor requested a waiver to allow employer sponsored plans to follow a "file and use" protocol for marketing materials that are distributed solely to employer groups. The requestor stated that employer/union-only group waiver plans are not "marketing" their plans (rather they are explaining how their program works) and these entities should

be allowed to continue to create and customize these outreach materials to meet the unique needs of their retirees.

CMS waived the review and approval of marketing materials contained in 42 CFR 423.50 and 42 CFR 422.80. *See* Medicare Marketing Guidelines (published: August 15, 2005, revised: November 1, 2005).

WAIVER OF MEDICARE APPEALS AND COVERAGE DETERMINATIONS:

Sections 1860D-4(f), (g) and (h) of the Social Security Act, 42 CFR, Subpart M (Grievances, Coverage Determinations and Appeals)

A PDP Sponsor requested a waiver to allow employer/union sponsored plans to follow ERISA requirements for appeals and coverage determinations. The requestor stated that absent a waiver of Medicare appeals rules, two separate, often conflicting sets of rules would have to be followed. The requestor stated that in its March 9, 2005 waiver guidance, CMS exempted employer/union sponsored enhanced plans from complying with a broad array of regulatory issues where the employer or union was subject to ERISA or other applicable state and federal regulatory requirements and that the same waiver should apply here to exempt employer plans from the Medicare appeals and coverage determinations and allow them to follow the ERISA requirements.

A Direct Contract EGWP requested that CMS waive the Medicare grievance and appeals requirements when the entity complies with the ERISA appeals and grievance procedures. The Direct Contract EGWP stated that the ERISA regulations provide adequate protections and the employer should not be required to administer an additional grievance and appeal system.

CMS has granted a limited waiver for certain Direct Contract EGWPs. More specifically, CMS has waived the Medicare appeals and coverage determination requirements for Direct Contract EGWPs subject to ERISA. These plans may use the ERISA claims and appeals rules for adverse benefit determinations and appeals in lieu of the Medicare rules, as long as:
(1) the plan sponsor offers a level of independent review similar to the requirement contained in 42 CFR 423.600; and (2) the plan sponsor provides beneficiaries with the right to request:

- An exception for a non-formulary Part D drug as required under 42 CFR 423.578(b);
- A tiering exception as required under 42 CFR 423.578(a);
- An exception to cost utilization tools as required under 42 CFR 423.578(b)(1)(iii); and
- Corresponding appeals of each of these adverse determinations.

Disapproved Waiver Requests

The requests to waive/modify additional requirements set forth below were disapproved for one or more of the following reasons: the requirement did not hinder the design of, the offering of, or the enrollment in employer-sponsored group prescription drug plans; certain beneficiary protections outweighed any alleged hindrance presented by the requirement; and/or the operational complexities associated with the implementation of the waiver could not be overcome.

WAIVER OF ANY WILLING PHARMACY REQUIREMENT FOR MAIL ORDER PHARMACIES:

Section 1860D-4(b)(1)(A) of the Social Security Act, 42 CFR 423.120(a)(8)(i)

A PDP Sponsor and a MA Organization requested a waiver to allow employer/union sponsored plans to contract with only one mail order provider. The requestors alleged that allowing employers to continue to contract with one mail order provider (as they do today) will minimize member confusion and allows employers that typically also offer a benefit to their active employees to contract with only one mail order provider.

WAIVER OF LEVEL PLAYING FIELD BETWEEN RETAIL NETWORK AND MAIL-ORDER PHARMACIES:

Section 1860D-4(b)(1)(D) of the Social Security Act, 42 CFR 423.120(a)(10)

A PDP Sponsor requested a waiver to allow employer/union-sponsored plans to continue to differentiate between the days supply that may be dispensed at retail pharmacies (e.g., 30 days), and the quantity that may be dispensed through mail service pharmacies (typically 90 days). The requestor stated that existing employer benefit programs traditionally encourage mail order usage for maintenance drugs through various cost share incentives in order to better control the overall costs of prescription drugs and for manufacturer pricing concessions to be maximized, thereby increasing the savings to the employer, who will still be covering a large portion of the share of drugs in these plans.

WAIVER OF PERFORMANCE STANDARDS FOR MAIL ORDER PHARMACIES:

Requirement contained in 2006 PDP Solicitation for Applications, Section 3.17, A3 and A4 (same requirements contained in MA-PD, section 3.13 and Cost Plan application, section 3.14)

A PDP Sponsor requested waiver of performance standards in order to base mail order pharmacy turnaround times on a percentage or average complete within a set period of time based on negotiations between the employer and the PDP, rather than the current CMS “turnaround time” performance standard. Under the current performance standard, 100% of all non-protocol prescriptions must be dispensed within 3 business days and

100% of all prescriptions must be dispensed within 5 business days. The requestor argued in support of the waiver: the application requirements are inconsistent with commercial "best practice" standards and standards adopted by other government agencies such as OPM; the current standards cannot be consistently achieved without engaging in poor pharmacy practice and allow for no exceptional circumstances that may arise; and it is more in keeping with commercial practices and other government programs to require that a certain percentage of all scripts falling into these categories be fulfilled within the current 3 and 5 day periods based on negotiations between employer and PDP.

MODIFICATION OF THE REQUIREMENT THAT THE APPLICANT OBTAIN WRITTEN AGREEMENTS FROM EMPLOYER/UNION GROUP SPONSORS REQUIRING THESE SPONSORS TO OFFSET PREMIUM AMOUNTS COLLECTED FROM LOW-INCOME ELIGIBLE EMPLOYEES/RETIREES BY THE AMOUNT OF ANY APPLICABLE LOW-INCOME PREMIUM SUBSIDY:

Section 1860D-14 of the Social Security Act, 42 CFR 423.771 *et seq (*Subpart P - Premiums and Cost-Sharing Subsidies for Low-Income Individuals)

A MA Organization requested a waiver from the requirement that the plan always act as the intermediary for the pass through of the low-income subsidy to eligible retirees. The MA Organization requests that it be permitted the option to send a check directly to the low-income premium subsidy member for the full subsidy amount or to require employer/union group sponsors to offset premium amounts that they collect from employees/retirees by the amount of the low-income subsidy. The MA Organization justified its request by stating that requiring employers/unions to offset premium amounts collected with the low-income premium subsidy might violate collective bargaining agreement or summary plan descriptions which may require uniform contributions or violate the privacy of these individuals.

MODIFICATION OF FORMULARY REQUIREMENTS TO EXCLUDE CERTAIN CLASSES OF "LIFESTYLE" DRUGS:

Section 1860D-4(b)(3)(C) of the Social Security Act, 42 CFR 423.120(b)(2), 42 CFR 423.265(c)

A MA Organization requested waiver of the requirement to provide a uniform benefit package and premium for certain groups that have moral, religious or other issues. More specifically, the MA Organization requested the flexibility to allow an employer group to restrict coverage of certain prescription drugs (i.e. erectile dysfunction medications and contraceptives) when the group has moral, religious, or other issues with the drugs covered on the plan's Part D formulary.

WAIVER OF SERVICE AREA RESTRICTIONS FOR LOCAL MA-PDs:

42 CFR 422.2

Several MA Organizations requested waivers to allow Local MA-PDs to extend coverage to retirees residing outside the state (e.g., retirees who currently receive drug coverage through national networks of pharmacies, retirees who live in "contiguous" counties bordering a state). The organizations requested a number of variations to allow for the coverage of retirees outside the service area (e.g., a waiver of state licensing requirements for retiree only coverage to allow coverage outside of the service area, a waiver of the requirement to offer non-group coverage in the state, allow out of state retirees to receive services from non-contracted providers and the plan to pay these non-contracted providers for benefits). One requestor stated that the waiver allows employers to reduce costs and administrative burden by using one organization to provide coverage to both active and retired workers, and thereby providing incentives to employers to continue to offer coverage to retirees.

MODIFICATION OF PDP SERVICE AREA WAIVER "NEXUS TEST":

April 6, 2005 Part D Waiver Guidance for Employer/Union Retiree Coverage, 42 CFR 423.112(a)

A PDP Sponsor requested modification of the PDP service area "nexus" test in the CMS April 6, 2005 Part D waiver guidance to include an additional option which would allow the test to be met based on where the majority of "retirees" (vs. "employees") reside. The requestor alleged that the modification would insure access for retirees of companies that may have relocated to another area or have large numbers of employees in larger states while the majority of retirees reside elsewhere. The requestor also stated that because many employers no longer offer retiree benefits or offer limited retiree benefits to employees, it is more appropriate for the PDP to be required to serve the region where the majority of current retirees reside.

WAIVER TO ALLOW A BENEFICIARY TO ENROLL IN A MA-ONLY PLAN ALONG WITH A STANDALONE PDP:

Section 1860D-1(a)(1)(B)(ii) of the Social Security Act, 42 CFR 423.30(b)

A PDP Sponsor requested waiver of the rule that a Medicare beneficiary may not enroll in a MA plan and also a standalone PDP. The requestor stated that allowing employers/unions the choice of utilizing both options prevents disruption and loss of enrollment in coordinated care programs while allowing employers/unions to continue to offer a single national drug benefit. The requestor also stated the existing rule limits a retiree's choice and also limits benefit designs by forcing employers/unions to purchase MA and Part D coverage from the same vendor.