MEDICARE PRESCRIPTION DRUG BENEFIT

Abbreviated Application for PACE Organizations Offering Part D Coverage

March 9, 2005

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1. GENERAL INFORMATION

Background

The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D-1 through 1860 D-41 of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the Voluntary Prescription Drug Benefit Program (hereinafter referred to as "Part D").

Objectives and Structure

The new Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965 by recognizing the vital role of prescription drugs in our health care delivery system. However, PACE organizations have a longstanding history of providing statutorily required prescription drugs to all participants. Prior to Part D, prescription drugs were included as a portion of the Medicaid capitation rate. However, the MMA mandates that State Medicaid programs may no longer cover Part D drugs on behalf of dual eligible beneficiaries. PACE organizations may elect to offer a Part D plan in a similar manner as MA-PD local plans in order to account for this shift in payer source for prescription drugs.

The Medicare Prescription Drug Benefit application has been abbreviated on behalf of PACE organizations. This relates to the fact that PACE organizations are required to submit a comprehensive PACE provider application that provides CMS with the majority of the information required in the PDP application. However, all PACE organizations will be required to submit this abbreviated document to the address listed below in order to provide Part D coverage for several reasons. First, Part D is not incorporated into the PACE provider application. As a result, additional information surrounding drug claims and formularies, previously not required, will be needed. We note that this Part D application follows a review timeline separate from the PACE provider application timeline outlined in section 460.20 of the PACE regulation. In addition, Part D CMS review panelists will be tracking Part D related information requirements. Proper submission of the Medicare Prescription Drug Benefit application will assure that appropriate CMS review panelists receive all necessary information.

NOTE: CMS reserves the right to amend or cancel this solicitation at any time. CMS also reserves the right to revise the Medicare Prescription Drug Benefit program implementation schedule, including the solicitation and bidding process timelines.

Summary of PACE Organization's Roles and Responsibilities

Each PACE Organization should have the ability to:

- Submit a formulary each year for CMS approval (as applicable).

- Submit a Part D bid each year for CMS approval.

- Administer the Part D benefit.

- Provide all statutorily required prescription drug services as outlined in the PACE statute and regulation.

- Operate quality assurance, drug utilization review, and medication therapy management programs in accordance with existing PACE requirements.

- Protect the privacy of beneficiaries and beneficiary-specific health information.

- Develop and/or maintain systems to support enrollment, provide claims-based data to CMS, accept CMS payment, and support e-prescribing.

- Provide necessary data to CMS to support payment, oversight, and quality improvement activities and otherwise cooperate with CMS oversight responsibilities.

- Ensure the integrity of the Medicare Trust Fund by eliminating fraud, abuse, and waste within its organization.

Payment to PACE Organizations

CMS will provide payment to PACE Organizations in the form of advance monthly payments (consisting of the plan's standardized bid, risk adjusted for health status, minus the beneficiary monthly premium), estimated reinsurance subsidies (applicable to dual eligible enrollees), and estimated low-income subsidies. After the end of the payment year, CMS will reconcile the correct amounts of low-income subsidies and reinsurance (applicable to dual eligible enrollees) amounts against the amount paid as a part of the prospective monthly payments. Risk sharing amounts (if applicable) will be determined after all other reconciliations have been completed. We note that this payment methodology is based on the February 18, 2005 45-Day Notice. This payment structure is subject to change based on public comments submitted on the 45-Day Notice. The final PACE payment methodology will be released in the Announcement of CY 2006 Medicare Payment Rates on April 4, 2005.

Payments will be wired to the organization's account on the first business day of each month (or the last business day of the prior month if the first day of the month is not a business day). The monthly payment will include those premiums CMS is paying on behalf of low-income individuals. However, a separate CMS payment will be made to the organization on approximately the 7^{th} or 8^{th} of each month that will include premiums that the SSA or other agencies are deducting from beneficiary Social Security payments. Estimated monthly reinsurance subsidies (applicable to dual eligible enrollees), and low-income subsidies will also be included.

Monthly beneficiary-level payment reports will be available detailing the components of each payment. PACE Organization-level reports summarizing the monthly payment and any applicable adjustments will also be provided. PACE Organizations will download these reports via their MDCN connectivity.

Test versions of these reports will be provided in late summer of 2005. Specific testing instructions will be provided at a later date.

2. INSTRUCTIONS

Technical Support

CMS will conduct weekly technical support calls for Applicants from January 19, 2005 through June 2005, followed by bi-weekly calls. CMS operational experts (e.g. enrollment, information systems, marketing, bidding, formulary design, and coordination of benefits) will be available to discuss and answer questions on the agenda items for each meeting. Registration for the technical support calls can be found at www.aspenxnet.com/partd/usergroups. Although these calls are not specifically geared to PACE organizations, some of the basic information presented may be useful to PACE providers.

In addition, PACE organizations may contact their team lead with specific Part D questions. If you have not yet been assigned a CMS team lead, you may contact Brenda Hudson at bhudson@cms.hhs.gov

Health Plan Management System (HPMS) Data Entry

The HPMS data being requested includes, but may not be limited to the following:

Provide the trade name for your organization, if different than the legal entity name
Website address for applicant's organization
Provide information for the individual(s) in your organization who would be the primary contact for this Part D application as well as for any additional personnel that will be accessing the HPMS system. Include Name, Mailing Address, Phone Number, Fax, and Email for each of these individuals.
Provide information on members of your organization's Pharmacy and Therapeutics (P&T) Committee (only applicable to those organizations electing to function under a formulary): • Full Name of Members • Practice/Expertise (Physician, Pharmacist) • Expertise with Elderly or Disabled? • Is member free of conflict of interest with: - Part D sponsor? - Part D plan? - Pharmaceutical manufacturers?

Instructions and Format of Qualifications

Format To assure that each CMS review panelist receives the application in the manner intended by the applicant, Applicants should deliver a total of four (4) hard copies of the written application and supporting documentation.

- All hard copies should be in separate 3-ring binders. Tab indexing should be used to identify all of the major sections of the application. Page size should be 8 ½ by 11 inches and the pages should be numbered. Font size should be 12 point.

- One application should be clearly marked, "Original" and contain all original signed certifications requested in the application.

- Additionally, the Applicant must submit the written application and supporting documentation electronically using (CDs). This will support the review of the application by different CMS components. The Applicant must submit 4 sets of CDs identified below. Each set should be inserted inside of each hard copy application being submitted.

CONTENTS ON CD
Entire Application and Supporting Documentation – including Appendices, and Attachments (*Do Not Include Pharmacy Lists*)
All required forms, tables, appendices and attachments

- All responses should be completed in Microsoft Word (in a version that is compatible with Office 2003). Attachments (such as existing contracts) can be submitted in Microsoft Word (in a version that is compatible with Windows 2003) or as a PDF file. Pharmacy lists should be created in Microsoft Excel (in a version that is compatible with Office 2003).

- The CD must be clearly labeled with the information in the table below:

Applicant's Organization Name
CMS Identification Number
Section and/or Subsection Name

- Failure to submit an application consistent with these instructions may delay its review by CMS and could result in receipt of an intent to deny.

- Applications must be sent to:

Centers for Medicare & Medicaid Services (CMS)
Marietta Mack
Attn: Part D **PACE** Application
Mail Stop: S2-04-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

- Applications mailed through carriers that do not have CMS Security Clearance could be delayed due to clearance processing. Carriers with CMS Security Clearance include Federal Express and Airborne Express.

Summary Instruction for Part D Bids

Each PACE applicant must submit to CMS two Part D bids; 1 for dual eligible enrollees and 1 for Medicare-only enrollees. Applicants that meet one or more of the definitive criteria for formularies described later in this document will be required to submit their formularies to HPMS on or before April 18, 2005.

Format of Part D Bids

Bid Submission Due June 6, 2005

Pursuant to 423.505(k)(4), the CEO, CFO, or a delegee with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information and belief) that the information in the bid submission is accurate, complete, and truthful, and fully conforms to the requirements in section 423.265 of the regulations (except section 423.265(b), the applicability of which is discussed below). In addition, the pricing component of the bid must be certified by a qualified actuary.

PACE Organizations that are not operational by June 6, 2005 will receive an automatic waiver of the June 6, 2005 bid submission deadline. However, these organizations will be required to submit bids and receive CMS approval of the Part D bid prior to providing Part D benefits in 2006. To the extent PACE organizations with program agreements effective prior to June 6, 2005 anticipate the inability to meet the bid submission deadline; they may request a waiver of this date. The CMS will issue a standardized bid deadline waiver request form via the PACE listserve that interested organizations may complete and forward to CMS.

3. GENERAL APPLICATION REQUIREMENTS

Note: Nothing in this application is intended to supersede the regulations at 42 CFR Part 423 or Part 460. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and PACE Organizations are required to comply with all applicable requirements of the regulations in Part 423 or Part 460 of 42 CFR.

Business Integrity

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	Yes	No
1. Applicant and its affiliated companies, subsidiaries or subcontractors, subcontractor staff, any member		

of its board of directors, and any key management or executive staff agree that they are bound by 45 CFR Part 76 and attest that they are not excluded by the Department of Health and Human Services Office of the Inspector General or by the General Services Administration.		

List any past or pending, if known, investigations, legal actions, or matters subject to arbitration brought involving the Applicant (and Applicant's parent firm if applicable) and its subcontractors, including any key management or executive staff, or any major shareholders (5% or more), by a government agency (state or federal) over the past three years on matters relating to payments from governmental entities, both federal and state, for healthcare and/or prescription drug services. Provide a brief explanation of each action, including the following:

1) Legal names of the parties;
2) Circumstances;
3) Status (pending or closed);
4) If closed, provide the details concerning resolution and any monetary payments; and
5) Settlement agreements or corporate integrity agreements

Compliance Plan

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A Part D CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	Yes	No
1. Applicant attests that they will have a compliance plan that consists of procedures for effective monitoring and auditing. §423.504(b)(4)(vi)(F)		
2. Applicant attests that they will have a compliance plan that consists of procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as a Part D plan sponsor. §423.504(b)(4)(vi)(/G)		
3. Applicant attests that they will have a compliance plan that consists of a comprehensive fraud and abuse plan to detect, correct, and prevent fraud, waste, and abuse. This fraud and abuse plan should include procedures to voluntarily self-report potential fraud or misconduct related to the Part D program to the appropriate government authorities. §423.504(b)(4)(vi)(/H)		

Electronic Prescription Program

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO THE FOLLOWING QUALIFICATION TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO THE FOLLOWING QUALIFICATION BY PLACING A CHECKMARK IN THE RELEVANT COLUMN.	YES	NO
1. Once electronic prescribing standards are published and in effect, the Applicant agrees to have an electronic prescription program that supports electronic prescribing with pharmacies as well as physicians.		

Reporting Requirements

Although the table below reflects a general overview of the data reporting requirements, CMS will issue a separate sub-regulatory guidance outlining the specific PACE requirements for submitting prescription drug event data.

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN:	YES	NO
CLAIMS DATA		
1. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing collection of data in either an NCPDP or X12 format. Data to be collected will encompass quantity, type, and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).		
2. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing submission of prescription drug claims information for Medicare enrollees for every Part D drug prescription in the format required by CMS, using batch submission processes. Data to be submitted will encompass quantity, type and costs of pharmaceutical prescriptions filled for enrollees. The plan must link this information to Medicare beneficiary identification numbers (HIC#s).		
3. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing submission of data to CMS via the Medicare Data Communications Network (MDCN).		
4. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing performance of data edit and quality control procedures to ensure accurate and complete prescription drug data.		
5. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing correction of all data errors identified by CMS.		
6. The Applicant or the Applicant's representative, such as a third party administrator (TPA), has data management processes and data systems capable of accomplishing collection of data for dates of service within the coverage period with a 3-month closeout window for the submission of remaining unreported claims data.		
7. Applicant will send and receive claims data for third party payers from the CMS contractor that will serve as the clearinghouse for all Part D beneficiary outpatient drug claims.		
REBATE DATA		
8. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the provision of documentation, as specified by CMS, to support the accuracy and completeness of data. Documentation will be provided to CMS in response to an audit-based request.		
9. The Applicant will report rebate dollars on a quarterly basis at the manufacturer/brand name level (unique strength and package size not required) in the manner specified by CMS.		
10. The Applicant or the Applicant's representative has accounting systems capable of accomplishing the production of financial reports to support rebate accounting. The rebate accounting must allow for step-down cost reporting in which rebates received at the aggregate level may be apportioned down to the level of plan enrollees.		

Data Exchange Between PACE Organizations and CMS

Complete the table below:

APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. ATTEST 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT	YES	NO

COLUMN:		
HPMS		
1. Applicant will use HPMS to communicate with CMS in support of the Part D application process, formulary submission process, bid submission process, ongoing operations of the Part D program, and reporting and oversight activities. PACE Organizations are required to secure access to HPMS in order to carry out these functions.		
2. Applicant will establish access to HPMS.		
ENROLLMENT & PAYMENT		
3. Applicant will establish connectivity to CMS via the AT&T Medicare Data Communications Network (MDCN).		
4. Applicant will submit test enrollment and disenrollment transmissions.		
5. Applicant will obtain CMS User ID and Password.		
6. Applicant will submit enrollment, disenrollment and change transactions to communicate membership information to CMS each month.		
7. Applicant will reconcile plan data to CMS enrollment/payment reports within 45 days of availability.		
8. Applicant will submit enrollment/payment attestation forms within 45 days of CMS report availability.		

4. APPLICABILITY OF FORMULARY REQUIREMENTS

Definition of a Formulary for Submission Purposes

For purposes of formulary submission and review, the following paragraphs describe the definition of a formulary.

1. Cost sharing tiers

Any coverage list that utilizes more than one cost sharing tier with differential co-pay or coinsurance, is considered a formulary.

2. Prior authorization

Any coverage list that contains one or more drugs that must undergo prior authorization before dispensing is considered a formulary. If in the normal course of clinical practice, the prescribing physician uses FDA-approved indications and use criteria to determine appropriateness of therapy, this is not considered prior authorization.

3. Step therapy

Any coverage list that contains one or more drugs that are part of a step therapy management program is considered a formulary. This includes any program that requires a certain drug to be used first, before a different drug can be dispensed. Step therapy can apply to certain drug classes or among brand and generic drug combinations.

4. Quantity limitations

Any coverage list that contains one or more drugs with quantity limits is considered a formulary. Quantity limits are often used in cases where FDA-approved prescribing instructions state that only a certain number of doses should be used in a certain time period. Common examples include erectile dysfunction drugs and antimigraine drugs.

5. Steerage

Any coverage list that contains one or more drugs that are considered preferred or drugs that are steered towards is considered a formulary. Common prescribing patterns are not considered steerage as long as there are no adverse consequences to physicians or patients if a particular drug is not chosen.

If a plan meets any of the five criteria referenced above, then their coverage list is considered a formulary and needs to be submitted to CMS for review and approval.

All PACE Organizations must complete the form below:

Formulary Form 1:

INDICATE IF THE APPLICANT ANTICIPATES SUBMITTING A FORMULARY *Note: CMS is using this information to understand how many formularies it may need to review beginning April 18, 2005.*
Check Yes or No ☐ Yes ☐ No

Only those applicants that have checked yes in the previous table will be required to adhere to formulary requirements specified in section 423.120(b) and complete the remainder of this chapter including submission of the following information to CMS:

Pharmacy and Therapeutics (P&T) Committee

Complete the form below

Formulary Form 2:

PROVIDE THE NAMES OF THE MEMBERS OF YOUR ORGANIZATION'S P&T COMMITTEE. INDICATE WHICH MEMBERS ARE PRACTICING PHYSICIANS, OR PRACTICING PHARMACISTS, FURTHER INDICATE WHICH MEMBERS ARE EXPERTS IN THE CARE OF THE ELDERLY OR DISABLED, AND FREE OF ANY CONFLICT OF INTEREST WITH YOUR ORGANIZATION AND PHARMACEUTICAL MANUFACTURERS. (APPLICANTS SHOULD MARK THE INFORMATION AS PROPRIETARY.) ADD ADDITIONAL ROWS AS NECESSARY

	Practice/Expertise *Mark an 'X' in Appropriate Column*			**Free of Any Conflict of Interest** *Type Yes or No*	
Full Name of Member	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With Your Organization?	With Pharmaceutical Manufacturers?

Complete the table below:

Formulary Table 1:

REPLY 'YES' OR 'NO' TO EACH OF THE FOLLOWING QUALIFICATIONS BY PLACING A CHECKMARK IN THE RELEVANT COLUMN. IF APPLICANT INDICATED THAT THEY ARE PROVIDING A FORMULARY, THEN THE APPLICANT MUST ATTEST 'YES' TO EACH OF THE FOLLOWING QUALIFICATIONS TO BE APPROVED FOR A PART D CONTRACT. IF APPLICANT INDICATED THAT IT IS NOT PROVIDING A FORMULARY AND REPLIES NO TO ANY OF THE ATTESTATIONS BELOW, THIS WILL NOT DISQUALIFY THE APPLICANT FROM A CONTRACT	YES	NO
1. Applicant will develop and use a P&T committee to develop and review the formulary and to ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market.		
2. Applicant's P&T committee will first look at medications that are clinically effective. When two or more drugs have the same therapeutic advantages in terms of safety and efficacy, the committee may review economic factors that achieve appropriate, safe, and cost-effective drug therapy.		
3. Applicant will assure that the P&T committee uses appropriate scientific and economic considerations to consider utilization management activities that affect access to drugs, such as access to non-formulary drugs, prior authorization, step therapy, generic substitution, and therapeutic interchange protocols.		
4. Applicant will adhere to P&T guidelines that will, from time to time, be promulgated with regard to such subject areas as membership, conflict of interest, meeting schedule, meeting minutes, therapeutic classes, drug review and inclusion, formulary management, utilization management and review, formulary exceptions, and educational programs for providers.		
5. Applicant's P&T committee will make a reasonable effort to review within 90 days, and will make a decision on each new chemical entity, and new FDA clinical indicators, within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.		
6. Applicant's P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.		
7. The majority of the membership of the Applicant's P&T committee shall be practicing physicians and/or practicing pharmacists.		
8. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are free of conflict with respect to the Applicant organization and pharmaceutical manufacturers.		
9. The membership of the Applicant's P&T committee will include at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons.		
10. Applicant's P&T committee will recommend protocols and procedures for the timely use of and access to both formulary and non-formulary drug products.		

Quality Assurance and Patient Safety

Describe below the transition process your organization will use to address coverage of new enrollees' prescribed Part D drugs that are not on the plan's formulary.

Complete the form below:

Formulary Form 3:

PROVIDE THE CONTACT INFORMATION FOR INDIVIDUAL RESPONSIBLE FOR QUALITY ASSURANCE AND PATIENT SAFETY PROGRAMS	
Name of Individual:	Title of Individual:
Company Name:	
Full Address: *(Street, City, State, Zip):*	
Telephone Number:	Email Address:

5. CERTIFICATION

I, the undersigned, certify to the following:

1) I have read the contents of the completed application and the information contained herein is true, correct, and complete. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.

2) I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes that may jeopardize my ability to meet the qualifications stated in this application prior to such change or within 30 days of the effective date of such change. I understand that such a change may result in termination of the approval.

3) I agree that if my organization meets the minimum qualifications and is Medicare-approved, and my organization enters into a Part D contract with CMS, I will abide by the requirements contained in this Application and provide all required PACE services in accordance with sections 1894 and 1934 of the Act.

4) I agree that CMS may inspect any and all information necessary including inspecting of the premises of the Applicant's organization or plan to ensure compliance with stated Federal requirements including specific provisions for which I have attested. I further agree to immediately notify CMS if despite these attestations I become aware of circumstances which preclude full compliance by January 1, 2006 with the requirement stated here in this application as well as in Part 423 of 42 CFR of the regulation.

5) I understand that in accordance with 18 U.S.C. § 1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.

6) I further certify that I am an authorized representative, officer, chief executive officer, or general partner of the business organization that is applying for qualification to enter into a Part D contract with CMS.

_____	_____
Authorized Representative Name (printed)	Title
_____	_____
Authorized Representative Signature	Date (MM/DD/YYYY)

6. PART D WAIVERS

CMS is authorized to grant waivers of Part D program requirements where such a requirement conflicts with or duplicates a PACE requirement, or where granting such a waiver would improve the PACE Organization's coordination of PACE and Part D benefits. The following waivers are in draft format and subject to OMB review.

Summary of Medicare Part D Regulatory Requirements Waived for PACE Organizations

Part D Regulation	Regulatory Requirement(s) Description	Basis and Rationale for Waiver
423.44	Involuntary disenrollment	Duplicates PACE requirements for involuntary disenrollment in section 460.164 of the PACE regulation.
423.48	Information about Part D	Waiver will promote coordination of benefits between Part D and PACE.
423.50	Approval of marketing materials and enrollment forms	Duplicates PACE requirements in section 460.82 of the PACE regulation.
423.104(g)(1)	Access to negotiated prices	Waiver will promote coordination of benefits between Part D and PACE.
423.112	Establishment of PDP service areas	Conflicts with PACE requirements in section 460.22 of the PACE regulation.
423.120(a)	Access to covered Part D drugs	Waiver will promote coordination of benefits between Part D and PACE requirements in 42 CFR Part 460.
423.120(c)	Use of standardized technology	Waiver will promote coordination of benefits between Part D and PACE requirements in 42 CFR Part 460.
423.124	Out-of-network access to covered Part D drugs at out-of-network pharmacies	Duplicates PACE requirements in section 460.100 of the PACE regulation. Conflicts with PACE requirements in section 460.90(a) of the PACE regulation.
423.128	Dissemination of Part D plan information	Duplicates PACE requirements in section 460.112(b) of the PACE regulation.

Part D Regulation	**Regulatory Requirement(s) Description**	**Basis and Rationale for Waiver**
423.132	Public disclosure of pharmaceutical prices for equivalent drugs	Waiver will promote coordination of benefits between Part D and PACE.
423.136	Privacy, confidentiality, and accuracy of enrollee records	Duplicates PACE requirements in sections 460.200(d) and 460.200(e) of the PACE regulation.
423.153(a)-423.153(d)	Drug utilization management, quality assurance, and medication therapy management programs (MTMPs)	Duplicates PACE requirements in sections 460.102(d), 460.106 and 460.134 of the PACE regulation.
423.156	Consumer satisfaction surveys	Duplicates PACE requirements in section 460.134(a)(2) of the PACE regulation.
423.162	Quality Improvement organization activities	Duplicates PACE requirements in Subpart H of the PACE regulation, and waiver will promote coordination of benefits between Part D and PACE.
423.265(b) ***Note: Automatic waiver applies to new or potential organizations that are not operational by the June deadline. Those organizations with effective program agreements must submit a Part D waiver request in the event they are unable to meet the June deadline.***	Part D bid submission deadline	Waiver will promote coordination of benefits between Part D and PACE.
423.401(a)(1)	Licensure	Conflicts with PACE requirements in sections 460.12(b) and 460.32(a)(2) of the PACE regulation.
423.420	Solvency standards for non-licensed entities	Conflicts with PACE requirements in section 460.80 of the PACE regulation.

Part D Regulation	**Regulatory Requirement(s) Description**	**Basis and Rationale for Waiver**
423.462	Medicare secondary payer procedures	Conflicts with PACE requirements in section 460.180(d) of the PACE regulation.
423.464(c)	Coordination of benefits and user fees	Waiver will promote coordination of benefits between Part D and PACE.
423.464(f)(2) and 423.464(f)(4)	Coordination with other prescription drug coverage	Waiver will promote coordination of benefits between Part D and PACE.
423.502(b)(1)(i-ii)	Documentation of State licensure or Federal waiver	Conflicts with PACE requirements in sections 460.12(b) and 460.32(a)(2) of the PACE regulation.
423.504(b)(2-3), 423.504(b)(4)(i-v) and (vi)(A-E), and 423.504(b)(5)-(d) ***Note: Organizations are required to abide by 423.504(b)(4)(vi)(F-H)***	Conditions necessary to contract as a Part D plan sponsor	Conflicts with PACE requirements in sections 460.12(b), 460.32, 460.60-68, and 460.80 of the PACE regulation.
423.504(e)	Severability of contracts	Conflicts with PACE requirements in sections 460.30-34 of the PACE regulation.
423.505(a-c) and 423.505(e-i) ***Note: Organizations are required to abide by 423.505(d and j)***	Contract provisions	Duplicates PACE requirements in Part 460 of the PACE regulation.
423.505(k)(6) ***Note: Organizations are required to abide by 423.505(k)(1-5)***	Certification for purposes of price compare	Waiver will promote coordination of benefits between Part D and PACE.
423.506-423.514	Contracting terms	Conflicts with or duplicates PACE requirements in sections 460.32, 460.34, 460.50, 460.52, 460.54 and Subpart L of the PACE regulation.

Part D Regulation	**Regulatory Requirement(s) Description**	**Basis and Rationale for Waiver**
423.551-423.552	Change of ownership or leasing of facilities during term of contract	Duplicates PACE requirements in section 460.60(d)(4) of the PACE regulation.
423.560-423.638	Grievances, coverage determinations, and appeals	Conflicts with or duplicates PACE requirements in sections 460.120, 460.122 and 460.124 of the PACE regulation, and the waiver will promote coordination of benefits between Part D and PACE.
N/A	A PDP sponsor is required to be a nongovernmental entity	Conflicts with sections 1894(a)(3) and 1934(a)(3) of the PACE statute.

We note that any differences between Part D and PACE will be taken into consideration for a separate proposed PACE rule to implement all Part D provisions. However, in recognition that PACE organizations will be adhering to a Part D timeline, we recognize the importance of identifying Part D waivers applicable to PACE organizations.

Applicant Requests for Additional Waivers:

CMS may grant additional waivers upon a PACE Organization's request, provided that the waivers may be justified as duplicative of or conflicting with PACE requirements, or improving the coordination of PACE and Part D benefits. Any waiver granted by CMS will apply to all similarly situated PACE Organizations.

PACE Organizations that identify the need for additional Part D waivers must submit a separate Part D waiver request package that includes:

1. The Part D regulation reference;
2. The appropriate waiver criteria (e.g. duplicative, conflicts, improves benefit coordination);
3. A discussion of how the requested waiver meets at least one of the three waiver criteria.

These requests should be submitted to the following address:

Centers for Medicare and Medicaid Services (CMS)
Brenda Hudson
Attn: Part D PACE Waiver Request
Mail Stop: C5-05-27
7500 Security Boulevard
Baltimore, MD 21244-1850

In addition, the PACE Organization should also send a copy to:

Centers for Medicare and Medicaid Services (CMS)
Marietta Mack
Attn: Part D PACE Waiver Request
Mail Stop: S2-04-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Finally, the PACE Organization should also copy their State Administering Agency on the request as well as their CMS PACE Team Lead.

CMS will notify Applicants whether their requests were approved upon completing a comprehensive review of the request in a similar manner as PACE BIPA 903 waivers are evaluated in accordance with sections 460.26(b) and 460.28 of the PACE regulation.

7. APPENDICES

APPENDIX I

APPENDIX V

HIPAA Security Attestation Statement

(Date)

_____ (MA-PDP, PDP etc.) attests that, as of the initial enrollment date, appropriate administrative, technical and physical safeguards will be in place to protect the privacy of protected health information in accordance with 45 CFR §164.530(c), and that we will meet the standards, requirements and implementation specifications as set forth in 45 CFR part 164, subpart C, the HIPAA Security Rule, prior to beginning enrollment of beneficiaries.

_____

(Signature of Chief Information Officer)

APPENDIX II

CERTIFICATION OF MONTHLY ENROLLMENT AND PAYMENT DATA RELATING TO CMS PAYMENT TO A PACE Organization

Pursuant to the contract(s) between the Centers for Medicare and Medicaid Services (CMS), and _____ *(name of PACE Organization)* hereafter referred to as the "Prescription Drug Plan" governing the operation of the following PACE Organization _____ *(plan identification number)*, the PACE Organization hereby requests payment under the contract, and in doing so, makes the following certifications concerning CMS payments to the PACE Organization. The PACE Organization acknowledges that the information described below directly affects the calculation of CMS payments to the PACE Organization and that misrepresentations to CMS about the accuracy of such information may result in Federal civil action and/or criminal prosecution. This certification shall not be considered a waiver of the PACE Organization's right to seek payment adjustments from CMS based on information or data that does not become available until after the date the PACE Organization submits this certification.

1. The PACE Organization has reported to CMS for applications received in the month of_____
(month and year) all new enrollments, disenrollments, and changes in service area with respect to the above-stated PACE Organization. Based on best knowledge, information, and belief, all information submitted to CMS in this report is accurate, complete, and truthful.

2. The PACE Organization has reviewed the CMS monthly membership report and reply listing for the month of _____ *(month and year)* for the above-stated PACE Organization and has submitted requests to the IntegriGuard, under separate cover, for retroactive adjustments to correct payment data when the PACE Organization has more accurate information. This may include enrollment status and State and County Code related to specific beneficiary. For those portions of the monthly membership report and the reply listing to which the PACE Organization raises no objection, the PACE Organization, through the certifying CEO/CFO, will be deemed to have attested, based on best knowledge, information, and belief, to their accuracy, completeness, and truthfulness.

NAME: _____
TITLE: _____
On behalf of: _____ *(PACE Organization)*

NOTE: The person signing this form must be the CEO, CFO, or an individual delegated the authority to sign on behalf of on of the CEO or CFO and who reports to the CEO or CFO. Otherwise the certification will be considered invalid, per CFR 423.505(k).