COMPETITIVE ACQUISITION PROGRAM (CAP) FOR MEDICARE PART B DRUGS <u>CAP PHYSICIAN ELECTION AGREEMENT</u> (UNDER SECTION 1847B OF THE SOCIAL SECURITY ACT)

<u>A participating CAP physician's participation in the CAP may be suspended or terminated by CMS</u> for the remainder of the election period if the participating CAP physician fails to comply with this

<u>agreement</u> and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland-21244-1850. with applicable regulations.

Please type or print all information	
 Participating CAP Physician's Legal Business Name- as reported to the IRS 	2. Correspondence Information (Mailing address and telephone number where the participating CAP physician(s) from Block 1 can be contacted directly)
3. Participating CAP Physician 's or Supplier's- Identification Number or NPI (when effective)	4a. Election/Renewal Information (Check One) New CAP Election
	<u>— Renewing election; same approved CAP vendor</u>
5. Unique Provider ID or NPI (when effective)	—Renewing Election; changing approved CAP vendor —Terminating CAP Election
	4b. Check this box if changes to the physician list on page 6- are being made
6. Select one approved CAP vendor:	

I. Meaning of Election_

For the purposes of the CAP, the term physician includes all practitioners that that meet the definition of physician under §1861(r) of the Social Security Act. If a physician

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group practice using a group billing number elects to participate in the CAP, all physicians in the group elect to participate in the CAP when billing under the group billing number. A physician or other authorized official for the practice may complete this form. Each member of a practice is not required to complete a separate form.

If your practice submits claims to more than one carrier, fully complete and submit a separate election form to each carrier that processes claims for your practice._

For purposes of this agreement, election to participate in the CAP means that the participating CAP physician will obtain <u>all CAP drugs and biologicals in selected categories from one approved</u> <u>CAP vendor in the participating CAP physician's competitive acquisition area for one year (six-</u> <u>months for 2006). or a length specified by CMS.</u> The participating CAP physician will select the categories of drugs and biologicals and the approved CAP vendor at the time of election or when renewing the election. -For 20062009, there is one drug category and one geographic area._

II. Term and Termination of Agreement_

The CAP will begin in 2006. In 2006, the election period will occur For 2009 and in the Spring and the term of election will run from July 1 to December 31, 2006. In subsequent years, the election period will occur prior to the start of the calendar year, and the term of election will run from January 1 to December 31. **Election must be renewed on an annual basis.** The participating CAP physician may select an approved CAP vendor outside the annual election process or opt out of the CAP for the remainder of the annual election period when the approved CAP vendor ceases to participate in the CAP, the participating CAP physician relocates to another competitive area, the physician leaves a group practice participating in the CAP, or in other exigent circumstances as defined by CMS as described in 42 CFR §414.908(a)(2). A participating CAP physician may withdraw from the CAP upon notification of CMS and the approved CAP vendor if the approved CAP vendor refuses to ship CAP drugs intended for administration to a beneficiary [(under the physician's care]) when the conditions of <u>42 CFR</u> §414.914(hj) are met.

Physicians that are new to Medicare may elect to participate within 90 days of their provider number activation. In such cases, the agreement shall continue through December 31 of the calendar year.

A participating CAP physician's participation in the CAP may be suspended or terminated by CMS for the remainder of the election period if the participating CAP physician fails to comply with this agreement.

III. Prescription Order, Claim Submission and Collection of Payments

Drugs in the relevant CAP category will be supplied directly to the participating CAP physician by the approved CAP vendor. CAP prescription orders may be initiated by a telephone call, but must be confirmed in writing as stated in 42 CFR §-414.908(a)(3)(iii). The approved CAP vendor will file claims for drugs supplied to the participating CAP physician under this agreement. -The approved CAP vendor is responsible for collecting the coinsurance and deductible amounts from Medicare beneficiaries to whom the product is administered after drug administration is verified. Payment for the drug and the coinsurance amount will be calculated from the quantity of the drug that is administered._

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The participating CAP physician agrees to make good faith efforts to minimize the unused portion of CAP drugs in how he or she schedules patients and how he or she orders, accepts, stores, and uses the drugs._

Participating CAP physicians will submit claims with required documentation for drug administration services to their local-carrier/Medicare Administration Contractor (MAC) within 1430 calendar days of the administration of the CAP drug. Participating CAP physicians will furnish the approved CAP vendor with the beneficiary's supplemental insurance information, as well as the other information contained in 42 CFR §-414.908-(a)-(3)-(v) at the time a CAP drug order is placed with the approved CAP vendor. _ Claims for drug administration services must also include the appropriate CAP modifier and the CAP prescription order number.

IV. Agreement to File Claims and Pursue Appeals

Submit Records Upon Request

Participating CAP physicians agree to file claims for drug administration services with the localcarrier/MAC within 1430 calendar days of the date of drug administration. -Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims. In order to appeal a denied CAP claim, participating CAP physicians agree to follow the Medicare Part B administrative appeals process found at 42 CFR §-405.801 et seq.801 and following, and to submit all required documentation (such as medical records and a certification) necessary to support payment. Participating CAP physicians understand the importance of adherence to thetechnical and substantive aspects of these requirements inasmuch as the approved CAP vendor's drug claim ispaid only upon payment of the participating CAP physician's administration claim. Participating CAP physiciansfurther understand that CMS may suspend or terminate this agreement if the participating CAP physician's fails to submit claims that include all required documentation necessary to support payment,and/or if the participating CAP physician fails to appeal denied claims with supporting documentation.-Participating CAP physicians agree that the decision made pursuant to the CMS reconsideration process presented at 42 CFR §414.916 constitutes a final decision that is fully binding on the physician and not subject to further appeal.

The participating CAP physician must reasonably cooperate with the approved CAP vendor if the vendor chooses to appeal the <u>local carrier'scarrier/MAC's</u> denial. Reasonable cooperation may include providing the approved CAP vendor with access to or copies of medical records, as appropriate and written statements._

As of April 1, 2007, the MIEA-TRHCA requires the establishment of a post-payment review process for claims submitted for CAP which assures that Medicare payments for CAP drug administration are made only if the drug has been administered to a beneficiary. This process is separate from the medical review conducted by carriers/MACs. A small sample of CAP claims is selected for post payment review. These claims are examined in order to verify that the CAP drugs were administered and were medically necessary. A participating CAP physician agrees to provide medical records or other documentation upon request for any claim that is identified for review.

V. Medical Review_

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Participating CAP physicians agree that the physician's local Medicare carrier will adjudicate CAP drug administration claims by checking that the participating CAP physician has elected to participate in the CAP, is billing for appropriate drugs from the selected approved CAP vendor, and that the claim is compliant with all local coverage determinations (LCDs)._

VI. Drug Ordering, Replacement and "Furnish as Written" Drugs_

The participating CAP physician agrees to order drugs from the approved CAP vendor by using HCPCS code and HCPCS units. The participating CAP physician also agrees to accept the NDCs shipped by the approved CAP vendor during the term of this agreement, and to accept approved changes to the approved CAP vendor's CAP drug list, unless the conditions described below are met. _

Drug replacement may be necessary in situations where a participating CAP physician uses a drug from his or her own office inventory to serve a Medicare beneficiary in need of the drug on short notice. - Participating CAP physicians agree that a claim for the administration of a drug that is being replaced or restocked through the CAP must be coded with the <u>J2-J2modifier</u>– Competitive Acquisition Program, (CAP) restocking of emergency drugs after emergency administration-modifier. By including the modifier, the participating CAP physician certifies the following:

- (1) The drugs were required immediately;
- (2) The participating CAP physician could not have anticipated the need for the drugs;
- (3) The approved CAP vendor could not have delivered the drugs in a timely manner;
- (4) The drugs were administered in an emergency situation;_
- (5) The participating CAP physician is maintaining documentation to validate the information in 1–_4; and_
- (6) -The participating CAP physician will provide this documentation to the local carrier/MAC upon request. -

There may be instances where medical necessity requires that a specific formulation of a drug be supplied to the patient. -In cases where the approved CAP vendor has been contracted to supply that specific formulation as defined by the product's NDC number, and the specified product is medically necessary, the participating CAP physician may order the drug from the approved CAP vendor by specifying the NDC. In cases where the approved CAP vendor has not been contracted to supply a product for the beneficiary, the physician may purchase the drug and bill Medicare for it using the ASP methodology. -The participating CAP physician agrees that a claim for "furnish as written" drugs will be paid only if the claim is coded with the designated "furnish as written" J3_modifier and passes the medical review process. -By including the modifier, the participating CAP physician certifies:_

- (1) -A specific drug was medically necessary;_
- (2) -The selected approved CAP vendor could not provide that specific brand and/or NDC; and_
- (3) -Documentation to validate the information in (1) and (2) is being maintained by the participating CAP physician and will be provided upon the <u>local carrier'scarrier/MAC's</u> request.

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VII. Fraud_

The participating CAP physician agrees to the following: In accordance with 18 U.S.C. Section 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 verify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law._

VIII. Other Conditions of the CAP_

-The participating CAP physician must:

- Submit a written order for the drug with complete patient information consistent with 42 CFR §414.908 (a)(3)(iii), and (v). -
- •
- ____Notify the approved CAP vendor when a drug is not administered, or a smaller amount is administered than was ordered, and reach agreement with the vendor how to handle the unused drug consistent with 42 CFR §414.908(a)(3)(viii).
- ← Maintain a separate electronic or paper inventory for each drug obtained consistent with 42 CFR §414.908(a)(3)(ix).
- ← Agree not to transport CAP drugs from one place of service to another consistent with 42 CFR §414.908(a)(3)(xii).
- ← Agree to provide the CMS developed CAP fact sheet to beneficiaries consistent with 42 CFR §-414.908(a)(3)(xiii).

← Obtain drugs newly added to the CAP from the approved CAP vendor rather than bill for them under ASP + 6(buy and bill) methodology. In certain situations, for example if a drug has been recently introduced to the market, CMS will consider an approved CAP vendor's request to supply a drug not previously supplied under the CAP. If changes to the CAP drug list are approved, updates to the CAP drug list and physician notification regarding updates will occur on a quarterly basis. Physicians will then be required to obtain drugs new to the CAP from the approved CAP vendor rather than bill for them under the ASP + 6(buy and bill) methodology.

The participating CAP physician understands that beneficiaries who are enrolled in a Medicare Advantage plan may not receive those drugs through the CAP.

A participating CAP physician may not assign or transfer to another physician, practitioner, or group practice, their rights or obligations under this agreement._

The participating CAP physician agrees to cooperate fully with CMS, its contractors, and its agents in

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coordinating the activities of the CAP<u>, including post payment review</u>, and to resolve promptly issues or questions identified by CMS, its contractors, or its agents._

Election Form Submission:

For successful completion of the CAP election process, the electing physician or authorized official must SIGN and MAIL a copy of this election form to each carrier which receives part B claims from the practice location(s)._

Election Form Definitions:

Authorized Official—___An authorized official is an appointed official to whom the provider has granted the legal authority to enroll it in the Medicare program, to make changes and/or updates to the provider's status in the Medicare program (e.g., new practice locations, change of address, etc.), and to commit the provider to fully abide by the laws, regulations, and program instructions of Medicare. The authorized official must be the provider's general partner, chairman of the board, chief financial officer, chief executive officer, president, direct owner of 5% or more of the provider (see Section 5 for definition of a "direct owner"), or must hold a position of similar status and authority within the provider's organization. _

Legal business name—**Business Name** – The name that is reported to the Internal Revenue Service (IRS) for tax reporting purposes and specified in Box 1 of this agreement._

Participating CAP Physician—<u>-</u>The physician, or in the case of a physician group practice that bills under a group billing number, each physician in the physician group practice when billing under the group's billing number, that is electing to have an approved CAP vendor supply Medicare Part B drugs and biologicals to Medicare beneficiaries under conditions described by the CAP Physician Election Agreement. -If a physician group practice elects to have drugs supplied by CAP, all physicians in that group are covered by the CAP Physician Election Agreement when billing under the group's billing number._

Authorized Official's Signature:

The participating CAP physician identified above hereby elects to participate in the CAP for Medicare Part B Selected Drugs and Biological Categories and to comply with items I through VIII above. If a physician group practice using a group billingnumber elects to participate in the CAP, all physicians in the group elect to participate in the CAP when billing under thegroup's billing number.

7. Type Name and Title of Authorized Official	8. Authorized Official's Telephone Number
7. Type Name and The of Nationized Official	o. Munorized official 3 relephone Munoer
9. Authorized Official's Signature	10. Date

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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0987. The time required to complete this information collection is estimated to average 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

For each location from which the participating CAP physician submits Medicare Part B claims, list all names and identification codes under which the participating CAP physician files claims. This form may be used by an individual physician or by a group practice. Use copies of this form if additional space is needed to list all PIN, UPIN, or NPI numbers. Fully complete and submit a separate election form to each carrier that processes claims for your practice.

Participating CAP COMPETITIVE ACQUISITION PROGRAM (CAP) FOR MEDICARE PART B DRUGS CAP PHYSICIAN ELECTION AGREEMENT (UNDER SECTION 1847B OF THE SOCIAL SECURITY ACT)

GENERAL INFORMATION: Please complete all sections of this form. If assistance is needed, please contact the carrier that processes the Part B claims for the practice locations.

1. Organization or Physician's Legal Business Name from Block 1 of this election form.

-as reported to the IRS

Check the box below if the following applies		on this page:		
Practice Address: If additional practice sites exist, use copies of this sheet to list the additional practice addresses and physicians who practice at that location. Note that CAP drugs may not be transported to other practice locations or places of service. CAP drugs must be shipped to the practice address where they will be administered.			Indicate the total number of practice sites included in this election:	
Carrier Name and Address:				
Participating CAP Physician Name Physician PIN Number- Physician UPIN- Physician NPI (when-				
		Number	available)	

2. City	<u>3.</u>	<u>State</u>	4. ZIP Code

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DEPARTMENT OF HEALTH AND HUMAN SE	Form Approved		
CENTERS FOR MEDICARE & MEDICAID SEE	OMB No. 0938-0987		
<u>5. NPI</u>	<u>6. PTAN</u>	7. Email Address for CAP Updates	
8. Election/Renewal Information	(Check		
One)		ection; same approved CAP vendor	
□ New CAP Election	CAP Election		
	CAP LIECTION		
Renewing Election; changing			
approved CAP vendor			
9. Check this box if changes to t	he physician list on page 6	are being made	
	ne physician list on page of		
10. Select One Approved CAP Vendo	or		
CONTACT INFORMATION: The in	dividual identified in the	following soction will be contacted for	
		following section will be contacted for	
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any follow-up inquiries about the 11. Contact Name AUTHORIZED OFFICIAL'S SIGNA	<u>Physician Election Agr</u> 12. Co TURE: The participating	eement. htact Telephone Number CAP physician identified below hereby	
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DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES	

COMPETITIVE ACQUISITION PROGRAM (CAP) FOR MEDICARE PART B DRUGS CAP PHYSICIAN ELECTION AGREEMENT

(UNDER SECTION 1847B OF THE SOCIAL SECURITY ACT)

PRACTICE INFORMATION: List all locations where the CAP Physician(s) administers drugs and files Medicare Part B claims. This form may be used by an individual physician or by a group practice. Make copies of this form if additional space is needed to list all practice locations, physician name(s), and NPIs. If providing services across a state border and the claims processing service is provided by separate carriers/MACs, the form must be submitted to both carriers/MACs.

17. Organization or Physician's Legal Business Name as Reported to the IRS

18. Check the box below if the following applies to the practice location listed on this page: The practice using the addresses below is a group practice. \Box

19. Practice Address. If additional practice sites exist, use copies of this sheet to list the additional practice addresses and physicians who practice at that location. All listed addresses must be on file with your carrier/MAC. **CAP drugs may not be transported to other practice locations or places of service and must be shipped to the practice address where they will be administered.**

20. Indicate the total number of practice locations included in this year's election:

Form Approved OMB No. 0938-

21. Carrier/MAC Name and Address

NOTE: All physicians in a group practice elect to participate in the CAP when billing under the group billing number.

Participating CAP Physician Name	Physician NPI Number	Physician PTAN Number	Phone Number for Practice Location
₽			

COMPETITIVE ACQUISITION PROGRAM (CAP) FOR MEDICARE PART B DRUGS				
CAP PHYSICIAN ELECTION AGREEMENT (Under Section 1847B of the Social Security Act)				
DEPARTMENT OF HEALTH AND HUMAN SERVICES				
CENTERS FOR MEDICARE & MEDICAID SERVICES				
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Check this box if additional pages are being submitted to list physicians using the practice address on this page._