

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10046]

### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because of an unanticipated event and possible public harm.

The new Administration plans to implement the Medicare-Endorsed Rx Discount Card Initiative by November 1, 2001 and wants to include this in the Fall beneficiary education campaign. In order to meet this date, we need immediate review and approval of collection.

CMS is requesting OMB review and approval of this collection by July 20, 2001, with a 180-day approval period.

Written comments and recommendations will be accepted from the public if received by the individuals designated below by July 19, 2001.

*Type of Information Collection Request:* New collection; *Title of Information Collection:* Medicare Endorsed Rx Discount Card Initiative; *Form No.:* CMS-10046 (OMB# 0938-XXXX); *Use:* CMS is soliciting applications from prescription discount card programs so that it may endorse qualifying programs for Medicare beneficiaries. CMS, on its Web site, the consortium, and the endorsed programs, on request, will make information available for Medicare beneficiaries to use to compare the programs for possible enrollment in one of them; *Frequency:* Annually, Semi-annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 15 (estimated); *Total Annual Responses:* 15 (estimated); *Total Annual Hours:* 2,700.

#### Background

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from qualified entities interested in entering into a Medicare endorsement agreement for their prescription discount card program. The general purpose of this Medicare endorsement agreement will be to publicize information that allows Medicare beneficiaries to compare prescription drug discount cards, assist Medicare beneficiaries in understanding and accessing private market methods for securing discounts on the purchase of prescription drugs, and raise beneficiary awareness of prescription drug discount card programs available in the commercial market. Around 73% of Medicare beneficiaries have drug coverage at any given time—but only 45% have uninterrupted coverage for 2 consecutive years. We expect this initiative will help beneficiaries, particularly those who lack prescription drug coverage, understand how drug discount card programs can lower beneficiary out-of-pocket prescription drug expenses. This effort is not, in any way, an offer of a Medicare-reimbursed drug benefit.

Readers can find the application for this initiative attached to this notice and on the Web site listed below. This notice is subject to OMB approval.

We have submitted a copy of this notice to OMB for its review of these information collections. This notice will be published in the **Federal Register**.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site

address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. The application will also be posted on [http://www.hcfa.gov/news/pr2001/pr010712\\_s.htm](http://www.hcfa.gov/news/pr2001/pr010712_s.htm).

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and record keeping requirements must be received by the designees referenced below, by July 19, 2001:

Centers for Medicare & Medicaid Services, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, Fax Number: (410) 786-0207, Attn: John P. Burke III, CMS-10046 and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Phone: (202) 395-4650, Fax Number: (202) 395-6974, Attn: Allison Eydt, CMS Desk Officer.

Dated: July 17, 2001.

**Julie Brown,**

Acting CMS Reports Clearance Officer, CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

### Medicare-Endorsed Rx Discount Card Initiative

#### Notice of Application

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### 1.0 Introduction

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from qualified entities interested in entering into a Medicare endorsement agreement. Applications are to be submitted according to the process described in this Notice under “Applicant Instructions.”

The general purpose of such agreements will be to publicize information that allows Medicare beneficiaries to compare prescription drug discount cards; assist Medicare beneficiaries in understanding and accessing private market methods for securing discounts on the purchase of prescription drugs; and to raise beneficiary awareness of prescription drug discount card programs available in the commercial market.

Model language of the endorsement agreement can be found in Section 7.0. Qualifying applicants will be required to sign such an agreement.

Around 73% of Medicare beneficiaries have drug coverage at any given time—but only 45% have uninterrupted coverage for 2 consecutive years. We expect this initiative will help beneficiaries, particularly those who lack prescription drug coverage, understand how drug discount card programs can lower beneficiary out-of-pocket prescription drug expenses. This effort is not, in any way, an offer of a Medicare-reimbursed drug benefit.

### Objectives

The objectives of this initiative are to:

- Provide a mechanism for Medicare beneficiaries to gain access to the effective tools widely used by prescription benefit managers in private health insurance plans to get lower drug prices and higher-quality pharmaceutical care.

- Publicize information (including drug-specific prices, formularies, and networks) that allows Medicare beneficiaries to compare prescription drug discount cards and choose the best card for them.

- Educate Medicare beneficiaries about private market methods for securing discounts on the purchase of prescription drugs.

- Enhance participation of seniors in discount systems, increasing the leverage and ability of these plans to negotiate discounts for seniors.

- Endorse qualified private sector prescription drug discount cards based on experience, customer service, discounts and access, and permit endorsed organizations to market their programs as Medicare-endorsed.

- Provide Medicare beneficiaries a low (\$25 maximum) or no-cost opportunity to enroll in a Medicare-endorsed prescription drug discount program.

To meet these objectives, CMS plans to endorse prescription drug discount card programs that meet qualification criteria, and to permit successful applicants to market and label their programs as “Medicare-endorsed.” Medicare’s endorsement will be based on meeting qualifications related to experience, customer service, discounts and access. The endorsement will be for 14 months. Announcements of the Medicare-endorsed discount card programs will begin in the Fall of 2001, with the first endorsement cycle being effective on November 1, 2001 through December 31, 2002.

CMS believes the Medicare endorsement will facilitate educating beneficiaries about discount card programs. “Medicare” is an extremely valuable and highly regarded program for nearly 40 million Medicare beneficiaries. Medicare focus groups indicate that virtually all seniors recognize the name “Medicare”. Medicare’s name recognition is so strong that it is unlikely to be duplicated in the commercial market.

CMS is committed to educating Medicare beneficiaries about the endorsed discount card programs, at the time the endorsements are announced and as part of ongoing education efforts thereafter. CMS anticipates that there

will be national media attention when the Medicare-endorsed discount card programs are announced in the Fall of 2001. Throughout the Fall, CMS will provide information to the public about the discount card programs. On an ongoing basis, CMS plans to highlight the Medicare-endorsed discount card programs in Medicare publications and in the pre-enrollment package received by all beneficiaries upon eligibility for Medicare. CMS plans to provide descriptive information for each Medicare-endorsed prescription drug discount card program on the Medicare Web site (<http://www.medicare.gov>) beginning in October 2001. The information posted will include a basic card program description, the date on which Medicare beneficiaries may begin to enroll, the date the beneficiaries have access to discounts (if different from the beneficiaries’ enrollment date), and the phone numbers of the endorsed card programs. In addition, general information will be available to Medicare beneficiaries through the toll-free information line (1-800-MEDICARE). CMS plans to educate beneficiary and consumer groups, health care providers, States and other interested groups about the discount programs.

As a result of the CMS endorsement, Medicare name recognition, and plans to educate Medicare beneficiaries about these discount card programs, we anticipate that successful applicants will have increased visibility for their discount drug card programs, which will lead to greater enrollment by Medicare beneficiaries. We expect that the formulary/network/education attributes of the program, coupled with exclusive enrollment, will provide card sponsors the necessary market leverage to negotiate significant and competitive drug manufacturer rebates. These rebates could be used to lower drug prices for program enrollees or shared with retail pharmacies.

#### Program Overview

CMS has established a set of qualifications commonly used in the marketplace that are more fully explained in Section 3.0 of this Notice. All applicants that meet or exceed these qualifications will be Medicare-endorsed. These qualifications are intended to provide Medicare beneficiaries with access to discount card programs with national or regional capabilities and discounts on at least one brand and/or generic prescription drug in each therapeutic class. In addition, the Applicant’s organization must be a non-governmental entity and must demonstrate relevant experience, a

high level of customer service, and size sufficient to handle the anticipated volume. Key aspects of each Medicare-endorsed discount card program shall include the ability to:

- Enroll all Medicare beneficiaries wishing to participate, recognizing that the discount card programs do not supplant drug coverage under an insured product. CMS' educational materials will address the differences between discount programs and insured products;

- Provide a discount on at least one brand and/or generic prescription drug in each therapeutic class;

- Offer a national or regional pharmacy network, providing strong retail access. CMS also strongly encourages applicants to include a mail-order service as part of their program;

- Charge no fees to CMS;

- Charge an enrollment fee of no more than \$25 per beneficiary to fund enrollment administration expenses.

The enrollment fee, if any, is assessed on initial enrollment in a particular card program only. No additional (e.g., annual) fees may be required for beneficiaries to maintain their enrollment in that card program;

- Provide customer service to participating beneficiaries, including enrollment and toll-free telephone customer service help;

- Verify (through consortium described below) that enrolled applicants are not already participating in another Medicare-endorsed drug discount card program. Beneficiaries will be permitted to enroll in only one Medicare-endorsed drug discount program at a time. Allowing enrollment in only one program better pools beneficiary market power to secure deeper discounts. Beneficiaries may disenroll from an organization and enroll in another program on a semi-annual basis; and

- Agree to participate in, fund, and abide by the guidelines of a private consortium with other Medicare-endorsed discount card programs to perform administrative functions, as defined in Section 7.2. The consortium's activities will include the operation of a system to verify enrollment exclusivity and the review of marketing materials used by each program.

The consortium will also make available comparative information on each Medicare-endorsed drug discount card program. Information will be available on the consortium's Web site and in hard copy.

- Beginning no later than November 1, 2002, the comparative information will include drug/dose-specific prices (inclusive of discount and dispensing

fee) for a sufficient number of drugs to allow beneficiaries to make an informed choice.

- Prior to November 1, 2002, the comparative information will include average discounts (expressed as a percentage off Average Wholesale Price, or AWP) for the most commonly used drugs, as determined by the consortium, for each Medicare-endorsed program.

Applicants are required to limit participation in their Medicare-endorsed discount card program to Medicare beneficiaries. CMS will not provide data or assistance to verify Medicare eligibility. Successful applicants will be responsible for verifying Medicare beneficiary eligibility.

Discount card programs may choose to enroll groups of beneficiaries (including Medicare+Choice plan members, Medigap enrollees, and beneficiaries with employer-sponsored retiree health insurance).

Applicants are expected to fund the cost of administering the discount card program. Consortium members will decide how to assess fees on member organizations for start-up and ongoing operations of the consortium. The Federal government shall not be charged for enrollment, administration, participation, or any other cost associated with a discount program.

Applicants are encouraged to negotiate with drug manufacturers for rebates. Applicants may retain any manufacturer rebates or other fees associated with the discount program, but are encouraged to pass a portion of these on to enrollees or retail pharmacies. Discount programs will not be expected to share rebates with Medicare, nor disclose this revenue information to CMS.

Successful applicants will be expected to administer and market their discount card program, and educate Medicare beneficiaries about the program. In order to secure deeper discounts for beneficiaries, Medicare-endorsed discount card programs could use formularies, patient education, pharmacy networks, mail order, and other commonly used tools.

Programs are expected to begin accepting enrollment as of November 1, 2001, and must begin providing discounts no later than January 1, 2002.

CMS encourages applicants and the consortium to develop features that could further add value through improved discounts to Medicare beneficiaries, customer service, reporting/analysis, educational or other efforts (e.g., drug interaction analysis).

Discount card programs must have in place a mechanism to ensure that

beneficiaries may elect not to receive non-prescription drug related marketing material from Medicare-endorsed programs (e.g., material related to other services provided by the same organization). The sharing of beneficiary information must comply with applicable State and Federal privacy laws, as well as the privacy regulations established under the authority of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Organizations that offer discounts on items or services other than prescription drugs may continue to offer them; however, Medicare's endorsement will not extend to such items and services. Organizations must disclose these features to beneficiaries, and provide them an opportunity to decline participation related to them.

Although this notice refers to the initiative's requirements to be implemented after the first year of operation, the Medicare endorsements granted under this notice will be valid only from November 1, 2001 through December 31, 2002. Thereafter, CMS will review organizations' qualifications for endorsement annually.

## 2.0 Applicant Instructions

### 2.1 Intent to Respond and Pre-Application Conference

- CMS will hold a Pre-application Conference on July 23, 2001 for all interested Applicants. The purpose of this conference is to give Applicants an opportunity to ask questions and to provide individual comments concerning this Notice. Based on the results of this conference, CMS may provide additional clarification in consideration of the individual suggestions of potential applicants. CMS may also modify the qualifications in Section 2.2 below after the pre-application conference.

- Any modifications made to the scope of the initiative as a result of comments received during the pre-application conference will be published on the CMS Web site [www.hcfa.gov](http://www.hcfa.gov) on or about July 27, 2001.

- In order to receive additional information about the Pre-Application Conference and for future correspondence, potential Applicants are asked to indicate their intention to respond to this Notice by July 20, 2001.

- Your intent to respond should indicate your primary contact, and include your contact's:

- Direct telephone number;
- Fax number;
- E-mail address; and,
- Mailing address.

• The intent to respond should be in writing and sent to: Ron Deacon, Email: [rdeacon@cms.hss.gov](mailto:rdeacon@cms.hss.gov), Phone: (410) 786-6622, Fax: (410) 786-1048.

## 2.2 Approach to Application, Qualifications, and Evaluation

• Applicants are expected to submit sufficiently comprehensive information to support their application. The application should be prepared in four parts:

*Part I: Proposed Prescription Drug Discount Card Program.* Provide a description of how you meet the qualifications described in Section 3.0.

*Part II: Implementation Approach.* Describe your implementation approach as requested in Section 4.0.

*Part III: Administrative Capabilities.* Describe your administrative capabilities as requested in Section 5.0.

*Part IV: Certification.* Submit the signed certification found in Section 6.0.

• Incomplete applications will not be evaluated.

• CMS reserves the right to request clarifications or corrections to a submitted application and to reject any and all applications.

• Applicants are advised that their application will become part of the official agreement file.

• This Notice does not commit CMS to pay any cost for the preparation and submission of an application.

• CMS reserves the right to amend or cancel this Notice.

## Evaluation

Part I of the application will contain the information necessary for CMS to determine whether the proposed discount card program meets the qualifications outlined in the table below. This Part will also contain the responses to the questions raised in Section 3.0. These responses will be the basis of a Pass/Fail evaluation of whether each of the qualifications is met. A proposed discount card program that successfully meets all qualifications will be endorsed.

## Summary of Qualifications

Category	Qualifications
Organization .....	<ul style="list-style-type: none"> <li>—At least 5 years United States private sector experience in pharmacy benefit management or discount card industries, with demonstrated financial soundness (see section 3.1.1).</li> <li>—<i>National Program:</i> Currently manages at least 2 million covered lives in an insured pharmacy benefit or a drug discount program. Covered lives are discrete individuals who have signed enrollment agreements or paid an enrollment fee or insurance premiums (see section 3.1.2).</li> <li>—<i>Regional Program:</i> Currently manages at least 1 million covered lives in an insured pharmacy benefit or a drug discount program and serves a contiguous, multi-state area similar to CMS regions (see section 3.1.2).</li> <li>—Agrees to participate in, abide by the guidelines of, and fund a private consortium with other Medicare-endorsed discount cards for (1) reviewing marketing materials, (2) assuring enrollment exclusivity, and (3) making available via Web site and hard copy (for each Medicare-endorsed discount card program) prices of the most common drugs in each therapeutic class included in the discount card program (see section 3.1.3).</li> <li>—Has written privacy policies that comply with all consumer protection and State and Federal privacy laws (including applicable privacy regulations promulgated under HIPAA) (see section 3.1.4).</li> <li>—Complies with all other applicable Federal and State laws (see section 3.1.4).</li> </ul>
Customer Service .....	<ul style="list-style-type: none"> <li>—Charges an enrollment fee of no more than \$25 to beneficiaries (see section 3.2.1).</li> <li>—Discloses in customer appropriate printed material (may additionally make electronic disclosure) to interested Medicare beneficiaries (prior to enrollment and after enrollment upon request) a detailed description of the program that includes participating pharmacies, enrollment fees (if any), drugs included, and their discounts (see section 3.2.1).</li> <li>—Enrolls all Medicare beneficiaries wishing to participate. Provide beneficiaries the option of enrolling by paper, telephone, fax or Internet (see section 3.2.1).</li> <li>—Provides a mechanism for beneficiaries to decline receiving marketing material (e.g., material related to other services offered by the organization) (see section 3.2.1).</li> <li>—Provides customer appropriate beneficiary and pharmacy services consistent with industry standards, including toll-free telephone help during normal business hours (see section 3.2.2).</li> <li>—Reports to CMS twice annually the number of Medicare beneficiaries enrolled in and disenrolled from the Medicare-endorsed Discount Card Program (see section 3.2.3).</li> </ul>
Discounts and Access .....	<ul style="list-style-type: none"> <li>—No later than January 1, 2002, provides a discount on at least one brand and/or generic prescription drug in each therapeutic class (see sections 3.3.2 and 3.3.3).</li> <li>—Guarantees participating Medicare beneficiaries receive (at the point of sale) the lower of the discounted price available through the program or price the pharmacy would charge a "cash" paying customer (commonly called the Usual &amp; Customary price) (see section 3.3.3).</li> <li>—Agrees to make available to the consortium information on discounts offered. In the first year, the information will include the average discount off the AWP for the most commonly used drugs, as determined by the consortium. In the second year and beyond, the information will include prices to the consumer of commonly prescribed drugs (see sections 3.1.3, 3.3.2, and 3.3.3).</li> <li>—Maintains a national or regional contracted pharmacy network consistent with industry practice in member travel distance and access to network pharmacies. Applicants are strongly encouraged to offer a mail order option in addition to their contracted pharmacy network (see section 3.3.1).</li> </ul>

## 2.3 Application Format

• In preparing your application, please repeat each question followed by your response. Provide complete answers, and detail the opportunities and value your organization and discount card program offer to Medicare

beneficiaries, in a clear, concise manner. All information requested is important and will be considered. If you have additional information you would like to provide, please include it as an appendix to your application, and cross

reference its relation to the information requested.

• Applicants should deliver one (1) original and nine (9) copies of the written application with one (1) diskette copy of the application in Microsoft Office format to the following address

by 5:00 EDT, August 27, 2001. Centers for Medicare & Medicaid Services (CMS), Center for Beneficiary Choices, Attn: Ron Deacon, 410-786-6622, 7500 Security Boulevard, Mail Stop C4-17-27, Baltimore, Maryland 21244-1850.

- All copies and the original application should be in 3-ring binders. Tab indexing should be used to identify all major sections of the application.

- Page size should be 8½ by 11 inches and the pages should be numbered. Type size should not be less than 12 point with a space and a half between lines.

#### 2.4 Important Dates

Date	Milestone
July 20, 2001 ....	Notification of Intent to Apply.
July 23, 2001 ....	Pre-Application Conference.
On or about July 27, 2001.	Any clarifications about the scope of the initiative published on CMS Web site ( <a href="http://www.hcfa.gov">www.hcfa.gov</a> ).
Aug. 27, 2001 ...	Applications Due.
Sept. 14, 2001 ..	Begin Announcements of Endorsements
Sept. 21, 2001 ..	Begin submission of marketing material for review.
Nov. 1, 2001 .....	Successful Applicants Permitted to Begin Marketing and Enrolling Participants in "Medicare-Endorsed" Discount Card program(s).

#### 2.5 Applicant Inquiries

- It would be helpful if questions regarding this Notice or requests for additional information were submitted prior to the Pre-Application Conference to be held on July 23, 2001. Any modifications or clarifications made to the scope of the initiative as a result of comments received during the pre-application conference will be published on the CMS Web site <http://www.hcfa.gov> on or about July 27, 2001.

- Contact the following to submit your questions and requests via e-mail or fax before the conference: Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Attn: Ron Deacon, Phone: 410-786-6622, Fax: 410-786-1048, E-mail: [rdeacon@cms.hhs.gov](mailto:rdeacon@cms.hhs.gov).

#### 2.6 Withdrawal of an Application

- An applicant may withdraw an application at anytime before the agreement (Section 7.0) becomes effective, by submitting a written notification for its withdrawal to the CMS contact noted above.

- For the purpose of selecting applicants for Medicare endorsement,

CMS will not accept any amendments, revisions, or alterations to applications after the due date of August 27, 2001 unless requested by CMS.

#### 2.7 Information Available From CMS

- In order for Applicants to prepare their applications, CMS will provide the following information upon request:

CMS will provide aggregate data on counts of Medicare beneficiaries by zip code. The "Annual Zip Code Enrollment File" is a public use file and contains aggregated aged and disabled enrollment data by age range, race, and gender within zip code. The file is usually produced in April and reflects enrollment as of July 1 of the previous year. This file has been edited to protect the privacy of beneficiaries. For purposes of the new privacy regulations, Applicants will also be required to complete a Data Use Agreement (DUA) which is appended as Attachment A to this Notice. There is an expedited process in place to review and approve DUAs for enrollment data and information should be available within 1 week after request. The data will be on a cartridge.

Upon request, CMS will also provide drug utilization data from the Medicare Current Beneficiary Survey. The data will be on a CD in ASCII format. The file will include a random sample of unnamed, non-identifiable, non-institutionalized Medicare beneficiaries. For each unidentified individual, the file includes: prescription drug utilization information (e.g., drug name, dosage, number of prescriptions), date of birth, gender and prescription drug insurance coverage status (e.g., no drug coverage, or covered through a payer such as Medicaid, a Medicare+Choice organization, Medigap, or employer-sponsored retiree plan). The data is self-reported by beneficiaries. The attached DUA can also be used for this information.

- To obtain the above information, please submit a signed and completed DUA to: Ron Deacon, Centers for Medicare & Medicaid Services (CMS), Center for Beneficiary Choices, 7500 Security Boulevard, Mail Stop C4-17-27, Baltimore, Maryland 21244-1850, Phone: 410-786-6622, Fax: 410-786-1048. (Original document must also be mailed to CMS.)

- Please call the above contact if you have any questions concerning the data.

#### 2.8 Protection of Confidential Commercial Information

- If any information within a submitted application (or attachments thereto) is labeled by the applicant as a trade secret or privileged or confidential

information, and constitutes a trade secret or privileged or confidential information (as such terms are interpreted under the Freedom of Information Act and applicable case law), then such information will be protected from release by CMS under 5 U.S.C. § 552(b)(4).

#### 2.9 Certification Instructions

Pursuant to the Certification Statement in Section 6.0, any changes to the information furnished in this application must be reported to:

*Prior to Endorsement Announcement:* Centers for Medicare & Medicaid Services (CMS), Center for Beneficiary Choices, Attention: Ron Deacon, 7500 Security Boulevard, Mail Stop C4-17-27, Baltimore, Maryland 21244-1850.

*After Endorsement Announcement:* Centers for Medicare & Medicaid Services (CMS), Center for Beneficiary Choices, Attention: Christopher Eisenberg, 7500 Security Boulevard, Mail Stop C4-23-07, Baltimore, Maryland 21244-1850.

#### 3.0 Proposed Prescription Drug Discount Card Program

- Please respond to the following questions regarding your qualifications. You may submit additional information that demonstrates your ability to meet and/or exceed the summary of qualifications found in Section 2.0.

##### 3.1 Your Organization

##### 3.1.1 Experience and Financial Soundness

- Provide a brief summary of the history, structure, and ownership of your organization. Include a chart showing the structure of the organization's ownership, subsidiaries and business affiliations.

- Provide the most recent audited financial statements (including auditor's opinions and related footnotes) for your organization or its parent firm (if applicable).

- Report financial ratings given to your organization for the past five years.

- List past or pending investigations and legal actions brought against your organization (and the parent firm if applicable) by any financial institution, government agency (local, State, or Federal) or private organization over the past five years. If directly related to prescription drug services, provide a brief explanation including the following: (1) Circumstances; (2) Status (pending or closed); and (3) If closed, provide details as to resolution and any monetary damages.

## 3.1.2 Business Volumes

• Complete the following table. If your organization underwent significant

change in 2000, or you expect 2001 to have substantially different business volumes please comment and provide

your 2001 projected business volumes (in addition to your business volumes for 2000).

## 2000 BUSINESS VOLUMES

Metric	Insured pharmacy benefits*		Drug discount card programs	
	Retail	Mail	Retail	Mail
Covered lives** .....	.....	.....	.....	.....
Senior lives (if available) .....	.....	.....	.....	.....
Claims processed or number of discounted prescriptions .....	.....	.....	.....	.....
Drug spending managed .....	.....	.....	N/A	N/A

\* Exclusive of any drug discount card programs.

\*\* Covered lives are discrete individuals who have signed enrollment agreements or paid an enrollment fee or an insurance premium.

• Please provide a description of your current clients including the number of covered lives and percentage who are seniors. Covered lives are discrete individuals who have signed enrollment agreements or paid an enrollment fee or paid insurance premiums.

• Please indicate if your proposed discount card program is a retail store only program or a retail store and mail order program.

• Please indicate if your program is national or regional. The CMS Web site where discount card program information will be posted searches by zip code and State. Provide enough information to clearly identify areas that you serve among the following: Each of the 50 States, Washington, D.C., Guam, and each of the U.S. territories.

## 3.1.3 Participation in and Funding of Consortium

• Describe how your organization anticipates working with the consortium (described in Sections 1 and 2, and in section 7.2) to ensure that the functions of the consortium are performed.

• Describe your organization's ideas for the development, implementation, and financing of the consortium. Assuming it is responsible for marketing review, enrollment exclusivity, and dissemination of comparative pricing data, discuss the level and extent of your organization's financial contribution to the initial and ongoing operation of the consortium.

• Describe your organization's capability and process for supporting the activities of the consortium and providing information on discounts offered. In the first year, the information will include the average discount off the AWP for the most commonly used drugs. In the second year and beyond, the information will include prices to the consumer of commonly prescribed drugs.

## 3.1.4 Compliance With Federal and State Laws

• Indicate compliance with Federal and State laws applicable to the conduct of your proposed discount card program (e.g., applicable regulations under HIPAA, State privacy laws, State licensure, and consumer protection laws).

## 3.2 Customer Service

## 3.2.1 Enrollment and Eligibility

• Describe the information about your discount card program that will be provided to Medicare beneficiaries prior to enrolling.

• Indicate whether your organization will charge an enrollment fee, and if so, the fee amount to offset enrollment administration costs.

• Programs are expected to begin accepting enrollment as of November 1, 2001. Describe your organization's abilities (e.g., paper, fax, phone, Internet) and process for enrolling Medicare beneficiaries in your proposed discount card program, and for maintaining this information (e.g., address changes, participant withdrawals).

• Will Medicare beneficiaries be able to enroll in your discount card program at the point-of-service (e.g., retail pharmacy)?

• What information would be collected from Medicare beneficiaries at the time of enrollment in your discount card program? What of this information would be required for enrollment? (See Section 7.6. for confidentiality requirements.)

• Upon your receipt of enrollment information, how long is required before a Medicare beneficiary can use the discount card program? Is this guaranteed? If so, what mechanisms do you have to monitor and enforce this guarantee?

• What mechanisms do you have to monitor and enforce the restriction that

enrollment is limited to Medicare beneficiaries?

• Explain the information members receive after enrolling in your discount card program, including program updates (e.g., listing of participating pharmacies, drugs included, discount amounts, how to obtain discounts, etc.)

—How soon after enrollment will they receive this information? How is the information provided (Applicant must have a system to provide notification by mail, but may provide option to beneficiaries for electronic notification.)?

• Describe how you will ensure that beneficiaries may decline receiving marketing material regarding your program or regarding additional services offered by your organization.

• Describe whether it will service Guam and the U.S. territories.

## 3.2.2 Customer Service—Education and Information Services

In all of the following areas please describe how your organization meets or exceeds industry standards:

• The capabilities of your call center, including:

—Peak and average call volumes, per week, and number of customer service representatives.

• Your ability and experience providing customer service and call center support to seniors, people with disabilities, and non-English-speaking beneficiaries.

• The level of toll-free support you will provide Medicare beneficiaries and pharmacies participating in your discount card program. Include your: —Forecast call volume and handle time for Medicare beneficiaries; —Hours of operation; —Average speed of answer; and —Abandonment rate.

• Explain in detail how your customer service function would respond to the following:

- Questions concerning differences between the Medicare-endorsed discount card program, other discount programs and prescription drug insurance;
- Discount card program inquiries, prior to enrollment;
- Problems in the enrollment process;
- Questions concerning drug costs;
- Lost or stolen ID cards;
- Mail service questions, issues and concerns (if applicable);
- Pharmacy questions.

- Describe your organization's experience and processes for managing customer complaints and grievances, and the processes your organization expects to have in place for Medicare beneficiaries under your discount card program.

### 3.2.3 Reporting

- Describe the standard report your organization will submit twice a year on the number of Medicare beneficiaries enrolled and disenrolled. Provide sample report format.

- Describe any additional standard reports your organization will provide CMS, at no charge. Provide sample report formats.

## 3.3 Access and Discounts

### 3.3.1 Pharmacy Access

#### *Retail Pharmacy*

- Using GeoAccess or a similar methodology, demonstrate that the contracted pharmacies participating in your proposed Medicare-endorsed discount card program meet standards consistent with industry practice for member travel distance and access to contracted network pharmacies. Provide the total number of pharmacies participating in your discount card program's network. A zip code data file is available on cartridge from CMS upon request and acceptance by CMS of the attached DUA (Attachment A).

- For the geographic area you propose to serve, please provide the number of Medicare beneficiaries within varying travel distances to contracted network pharmacies (i.e., within 5 and 10 miles).

- Please describe the nature of your network pharmacy contracts. Do your network pharmacy contracts explicitly cover discount card programs? Are they in compliance with all applicable state laws?

#### *Mail Order (If Applicable)*

- If your discount card program includes mail service, please provide a detailed description of this service, including:

- Turnaround time;

- Process for Medicare beneficiaries to use the mail service, including paperwork to be completed, any Internet and payment methods, and average processing time;
- Process for resolving the problems commonly found with mail pharmacies (e.g., lost prescription, lost medication);

### 3.3.2 Drugs Included

- Comment on the drugs your discount card program includes (including at least one drug in each therapeutic class). Please indicate which, if any, of the attached list of drugs commonly used by Medicare beneficiaries (Attachment B), your program will include.

### 3.3.3 Discounts

- Describe the discount you will provide to Medicare beneficiaries participating in your discount card program (a discount must be provided on at least one brand and/or generic prescription drug in each therapeutic class). Please indicate the average discount level (by brand and generic, by retail and mail order), and the maximum range for each category.

- Your discount should reflect network discounts, manufacturer rebates, dispensing fees and any revenue sources available to you net of your need to fund your administrative costs from these sources.

- Your pricing should be reported as a discount off average wholesale price (AWP), as reported by FirstDatabank, and be consistent with industry standards for reimbursing network pharmacies dispensing covered drugs to qualified members.

- Your discount must include all dispensing fees and other fees (if applicable).

- Describe any dispensing or other fees (if applicable).

- If your discount card program features maximum allowable cost (MAC) pricing, provide the AWP discount equivalent. For those drugs not receiving MAC pricing, provide the AWP discount.

- How does your program guarantee that Medicare beneficiaries will receive (at point of sale) the lower of the discounted price available through the program or the price the pharmacy would charge a cash paying customer?

- Explain how your organization enforces and monitors the pricing discount.

## 3.4 Additional Discounts and Services

- CMS encourages applicants to offer better pricing to those Medicare

beneficiaries willing to restrict drug choice to preferred brands or generics, fill prescriptions through a narrower pharmacy network, or use mail order pharmacy service. Organizations are encouraged to negotiate rebates with drug manufacturers. Medicare-endorsed organizations are not expected to share rebates or other revenues received with Medicare, but are encouraged to share the rebates with beneficiaries or retail pharmacies. Provide a description of your program's features in these areas including drugs included, discounts offered, scope of contracted pharmacy network, mechanism for sharing rebates with enrollees and pharmacies, and other features.

- Describe additional services that your organization offers with its proposed discount card program that significantly increases its value. Areas for consideration include:

- Approach to marketing and promoting your card program;

- Clinical services such as drug utilization review (DUR) that would help minimize inappropriate dosing, drug-drug interaction, drug-allergy interaction or similar situations;

- Educational material provided to participating Medicare beneficiaries that address medications, diseases, or wellness;

- Value added reporting to CMS or Medicare beneficiaries that could include the cost savings realized by Medicare beneficiaries participating in your card program.

- Describe discounts on other services (e.g., dental, vision) that will be offered to Medicare beneficiaries, if any.

- Describe how Medicare beneficiaries could decline to receive these additional services or marketing related to them.

- Would there be an additional fee related to these services? What is the annual fee for these services, if any, for 2001 and 2002?

- How will you assure that use of the Medicare name is not applied to these additional services?

## 4.0 Approach

- Please describe your approach to implementing your proposed discount card program:

- Include a work plan and schedule in Microsoft Office format or similar software.

## 5.0 Administrative Capabilities

- The Medicare endorsement is effective on November 1, 2001. Specify the date on which Medicare beneficiaries may enroll in your discount card program, (should it be

endorsed); what date potential enrollees may call the organization for more information about the Medicare-endorsed discount card program; what phone number beneficiaries should call for more information about your program; and on what date Medicare beneficiaries can expect to begin receiving discounts on prescription drugs, if earlier than January 1, 2002;

- Provide the number of Medicare beneficiaries you expect to enroll in your discount card program at 1 month, 6 months, and 12 months.
- Describe how your operations and service levels will change to accommodate Medicare beneficiary volume and to meet your proposed service levels. Include in your description the expected impact on your customer service functions (e.g., enrollment call center support, participant communications, etc.)
- Include a list of names and proposed duties of the key personnel that will be assigned to this program, including but not limited to, the account manager and customer service manager. Provide resumes for these people that include work history, education, background, and industry accomplishments.
- Provide contact information for 3 of your largest clients including reference name, title, phone and fax, company name and address, years as a client, and a brief description of the services you have provided.

## 6.0 Certification

### 6.1 Prohibition of Misuse of Symbols, Emblems, or Names in Reference to Social Security or Medicare

42 U.S.C. 1320b-10 prohibits the misuse of the Medicare name or emblem. In general, it authorizes the Inspector General of the Department of Health and Human Services to impose penalties on any person who misuses the term Medicare, the symbols, emblems, or names of Social Security, the Centers for Medicare & Medicaid Services, Health and Human Services, Medicare (or other similar government entities), or the letters CMS, HHS, HCFA, DHHS or other similar letters in a manner which the person knows or should know gives the false impression that it is approved, endorsed, or authorized by CMS.

Offenders are subject to fines of up to \$5,000 per violation or in the case of a broadcast or telecast violation, \$25,000.

### 6.2 Penalties for Falsifying Information on the Medicare-Endorsed Rx Discount Card Initiative Application

18 U.S.C. 1001 authorizes criminal penalties against an individual who in

any matter within the jurisdiction of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry.

Individual offenders are subject to fines of up to \$250,000 and imprisonment for up to five years. Offenders that are organizations are subject to fines of up to \$500,000. 18 U.S.C. 3571. Section 3571(d) also authorizes fines of up to twice the gross gain derived by the offender if it is greater than the amount specifically authorized by the sentencing statute.

### 6.3 Certification Statement

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).

(2.) I authorize CMS to verify the information contained herein. I agree to notify CMS in writing of any changes in this application prior to such change or within 30 days of the effective date of such change. I understand that a change CMS deems to be major may require a new application and may result in termination of endorsement.

(3.) I agree that if my program meets the minimum qualifications and is Medicare-endorsed, I will abide by the requirements contained in Section 7.0 of this Notice and provide the services outlined in my application.

(4.) Neither I, nor owner, director, officer, or employee of the company or other organization on whose behalf I am signing this certification statement, or any contractor retained by the company or any of the aforementioned persons, currently is subject to sanction under the Medicare or Medicaid program, or debarred, suspended or excluded under any other Federal agency or program, or otherwise prohibited from providing services to CMS or other Federal Agency.

(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 endorsement, 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 the endorsement.

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Authorized Representative Name (printed)

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Title

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Authorized Representative Signature

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Date (MM/DD/YY)

## 7.0 Model Agreement

[Qualified Applicant] agrees that, if Medicare-endorsed, the Applicant meets the requirements listed herein.

[Qualified Applicant] agrees to implement a prescription drug discount card program as described in its application and as approved by CMS. Further, [Qualified Applicant] agrees to implement a prescription drug discount card program in accordance with the Objectives and Program Overview described in Section 1.0 (Introduction) of the Notice of Application entitled "Medicare-Endorsed Rx Discount Card Initiative".

### 7.1 Beneficiary Information

[Qualified Applicant] agrees to develop marketing materials and customer service strategies that incorporate educational information appropriate for a Medicare population regarding accessing market-based strategies (e.g., role of formularies, network pharmacies, and mail order pharmacy, if applicable) for purchasing prescription drugs.

### 7.2 Consortium

- [Qualified Applicant] agrees to participate in, abide by the guidelines of, and fund a HIPAA-compliant consortium with other Medicare-endorsed discount card programs. The consortium must comply with the privacy regulations promulgated under HIPAA upon the date of compliance specified in those regulations, as well as any applicable State privacy laws. The [Qualified Applicant] agrees to collaborate with other qualifying applicants to design and implement the consortium so that it can perform the administrative functions identified below.

- Provide a system to ensure that Medicare beneficiaries are enrolled in only one Medicare-endorsed discount card program at a time (actual enrollment will be conducted by



individual discount card programs). The consortium must assure enrollment exclusivity no later than December 31, 2001. The system could be enhanced after that date to more efficiently perform this function.

- Make available information regarding average discounts (expressed as a percentage off Average Wholesale Price or AWP) for the most commonly-used drugs as designated by the consortium for each Medicare-endorsed discount card program as close to November 1, 2001 as possible. (A CMS-produced list of commonly-used drugs is provided as Attachment B for reference only.) The consortium will publish this discount information on the Web site of the consortium and make available hardcopies to beneficiaries, upon request.

- Beginning no later than November 1, 2002, make available comparative information on each Medicare-endorsed drug discount card program that will include drug/dose-specific prices (inclusive of discount and dispensing fee) for a sufficient number of drugs to allow beneficiaries to make an informed choice, formularies, and networks. The prices to be made available are the prices the beneficiary would pay at a retail store and/or mail order program, including the discount and dispensing fee. [Qualified Applicant] agrees to provide all the necessary information regarding its discount card program, for comparison purposes, to the consortium no later than September 1, 2002.

- Review marketing material used by Medicare-endorsed discount card programs based on guidance provided by CMS. The consortium agrees to work with CMS to assure adherence to CMS marketing material review guidance. The consortium should be prepared to assume review of all marketing materials from CMS beginning September 1, 2002. Marketing materials will be reviewed to ensure that they convey accurate information, and are delivering pharmacy benefit management services (e.g., drug/drug interactions) promised, consistent with guidelines established by the CMS. [Qualified Applicant] agrees to provide all marketing materials to the consortium for review no later than September 1, 2002.

### 7.3 Enrollment System

[Qualified Applicant] shall assure that any Medicare beneficiary wishing to enroll is permitted to do so consistent with any eligibility criteria specified in [Qualified Applicant's] application and approved by CMS.

A beneficiary who enrolls in an Rx discount card program shall not enroll

in another Medicare-endorsed card programs while enrolled. Beneficiaries who provide no disenrollment notice to the Applicant shall have their enrollment renewed following rules established by the Medicare-endorsed card program in its CMS approved application for endorsement, provided the Rx discount card program continues to be endorsed. Medicare beneficiaries may enroll in an alternative Medicare-endorsed discount card program if they are disenrolled or their card program withdraws or is terminated.

[Qualified Applicant] may charge an enrollment fee (not to exceed \$25 per beneficiary) only upon enrollment. [Qualified Applicant] shall not require its Rx discount card program enrollees to pay annual or other fees to maintain their enrollment.

A beneficiary who enrolls in an Rx discount card program shall have the opportunity to select another card only twice a year, with a new election to be effective January 1 or July 1 of each year, whichever date immediately follows a beneficiary's provision of notice of a new election. A beneficiary enrolling in a second card program during the year must pay any enrollment fee charged by the second program. Beneficiaries who are not enrolled in a card program may enroll at any time.

[Qualified Applicant] shall notify Medicare beneficiaries enrolled in its card program, if they are disenrolled from the discount card program according to the rules established in its CMS approved application. The notification shall indicate that the beneficiary may enroll in an alternative Medicare-endorsed discount card program.

### 7.4 Marketing Strategy

#### 7.4.1 Marketing Material

Marketing material includes any informational materials targeted to Medicare beneficiaries that promote a Medicare-endorsed Rx discount card program, inform Medicare beneficiaries that they may enroll or remain enrolled in a Medicare-endorsed prescription discount card program, and explain the features of the program, including rules that apply to enrollees. Examples of marketing materials include, but are not limited to, general audience materials, membership communication materials, communications to enrollees announcing changes in discount rates, and information relating to withdrawal and termination.

#### 7.4.2 Marketing Material Review

Through August 31, 2002, [Qualified Applicant] shall submit Medicare-

endorsed Rx discount card program materials to CMS for review 30 days prior to distribution to beneficiaries. CMS shall review marketing materials, communicate any required revisions in writing, and approve a final version during the thirty day period. [Qualified Applicant] may distribute marketing materials to Medicare beneficiaries after they have been approved. [Qualified Applicant's] use of the "Medicare" name shall be restricted to inclusion in those marketing materials that [Qualified Applicant] has submitted to CMS for review.

[Qualified Applicant] shall ensure that its Medicare-endorsed Rx discount card program marketing materials provide Medicare beneficiaries an adequate description of the rules for participation in the card program, including discounts and restrictions, if any, on enrollees' access to contracted network pharmacies through the program, and any other information necessary for Medicare beneficiaries to make a decision about enrollment. All marketing materials shall include a statement that the discount card program is endorsed by Medicare but is not a Medicare benefit and that [Qualified Applicant] is not a Medicare contractor. All marketing materials shall also include a statement that the discount card program is not intended to replace prescription drug benefits obtained through participation in any insurance plan, including a Medicare+Choice plan, Medigap policy, Medicaid, or employer retiree group plan. The text of all written marketing materials must be printed with a 12-point font size or larger.

### 7.4.3 Marketing Activities

[Qualified Applicant] shall not engage in activities that could mislead Medicare beneficiaries, or intentionally misrepresent the [Qualified Applicant] or the Medicare-endorsed Rx discount card program it offers. [Qualified Applicant] shall not solicit door-to-door to Medicare beneficiaries.

[Qualified Applicant] shall ensure that its marketing activities include marketing to beneficiaries with disabilities, beneficiaries with End-Stage Renal Disease (ESRD), and beneficiaries age 65 and over. The Applicant shall not employ discount card program names that suggest that it is not available to all Medicare beneficiaries (e.g., both beneficiaries who qualify based on disability status and those who are 65 and over).

### 7.5 Internal Performance Monitoring

[Qualified Applicant] shall establish internal performance monitoring for

verification of the discount, enrollment operations, customer service, network pharmacy and mail order operations (if applicable), as specified in the approved application for endorsement.

#### 7.6 Confidentiality Requirements

[Qualified Applicant] shall abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information, including applicable privacy regulations promulgated under HIPAA. The [Qualified Applicant] shall safeguard the privacy of any information that identifies a particular enrollee and shall ensure that medical information is released only in accordance with applicable Federal or State law or regulations, or pursuant to court orders or subpoenas, including [Qualified Applicants] work with the consortium. Further, [Qualified Applicant] shall put in place a mechanism to ensure that beneficiaries may elect not to receive non-prescription drug related marketing material from Medicare-endorsed programs (e.g., material related to other services provided by the same organization).

#### 7.7 Term of Agreement

Qualified applicants awarded Medicare endorsement under this Notice shall offer a Medicare-endorsed Rx discount card program for up to 14 months (November 1, 2001 to December 31, 2002), effective the date stated in the selection notification letter CMS sends to successful applicants.

CMS may terminate the endorsement at any time.

In the event of termination of the endorsement, [Qualified Applicant] shall notify its Medicare beneficiary enrollees that they may enroll in an alternative Medicare-endorsed discount card program within 10 days of receiving notice of termination.

#### Attachment A—Agreement for Use of Centers for Medicare & Medicaid Services (CMS) Beneficiary Encrypted Files

In order to ensure the confidence of the American public regarding the confidentiality of information collected and maintained by the Federal government, CMS expects the requestors and recipients of its data to agree to observe the following conditions and to comply with these requirements. These requirements apply to the use of the file(s) released or any data derived from such file(s).

This agreement pertains to the release of the following CMS data:

##### Filename(s)

Annual Zip Code Enrollment File (latest available)

Medicare Current Beneficiary Survey Prescription Drug Utilization

(Requestor Name—First and Last)

(Company/Organization)

(Street Address)

(City, State, and ZIP Code)

(Phone Number—including Area Code)

The User represents and warrants, and in furnishing the data file(s) specified, CMS relies upon such representation and warranty, that such data file(s) will be used for the following purpose(s).

Preparation of an Application for “Medicare-Endorsed Rx Discount Card Program”

The user represents and warrants further that the facts and statements made in any project plan submitted to CMS for each purpose are complete and accurate.

A. The Requestor shall make no attempt to identify any specific individual whose record is included in the file(s). No attempt will be made to unencrypt any person-level data in the file(s).

B. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s) may be retained by the User until December 31, 2001, hereinafter known as the “retention date.”

C. The requestor shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement.

D. The requestor shall not disclose any aggregations of data from the file(s) covered by this agreement without express written authorization from CMS.

E. Absent express written authorization from CMS, the Requestor shall make no attempt to link records included in the file(s) to any other beneficiary-specific source of information.

F. The Requestor shall neither publish nor release any information that is derived from the file(s) and that could reasonably be expected to permit deduction of a beneficiary's identity.

G. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Recipient to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security that is at least comparable to the level of security referred to in OMB Circular No. A-130, Appendix III—*Security of Federal Automated Information Systems* which sets forth

guidelines for security plans for automated information systems in Federal agencies.

H. In the event the Requestor makes an unauthorized disclosure of these data, CMS may impose any or all of the following measures: (1) request a formal response to an allegation of an unauthorized disclosure, (2) require the submission of a corrective action plan formulated to implement steps to be taken to alleviate the possibility of any future unauthorized disclosure; (3) require the return of the data; and/or (4) sanction against further release of CMS data to the organization/requestor in question.

I. The Requestor acknowledges that criminal penalties under section 1106(a) of the Social Security Act (42 U.S.C. 1306(a)), including possible imprisonment, may apply with respect to any disclosure of information in the file(s) that is inconsistent with the terms of the agreement. The Requestor further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. 552a(l)(3)) may apply if it is determined that the Requestor, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses.

1. (Requestor name and title—typed or printed)
2. (Signature) (Date)
3. (Typed or printed name of custodian of files, if different)
4. (Signature) (Date)
5. (Typed or printed name/agency/telephone number of Federal representative)
6. (Signature) (Date)

#### Attachment B—Prescription Drugs Commonly Used by Medicare Beneficiaries

The following list of drugs is based on an analysis of the 1998 Medicare Current Beneficiary Survey. Drugs are self-reported by beneficiary. List includes the top 100 drugs based on utilization and spending, yielding a total of 129 drugs.

Accupril, Albuterol, Allopurinol, Alprazolam, Amitriptidine, Amoxicillin, Aricept, Atenolol, Atrovent, Axid, Azmacort, Biaxin, Buspar, Capoten, Captopril, Cardizem, Cardizem CD, Cardura, Casodex, Cephalexin, Cimetidine, Cipro, Claritin, Clozaril, Conjugated Estrogens, Cordarone, Coumadin, Cozaar, Darvocet-N, Daypro, Depakote, Diazepam, Digoxin, Dilacor XR, Dilantin

Diltiazem, Doxipin, Dyamide, Dypyridamole,  
Folic Acid, Fosamax, Furosemide,  
Gemfibrozil, Glucophage, Glucotrol,  
Glyburide, Hctz, Hydrocodone,  
Hydrocodone/APAP, Hytrin, Ibuprofen,  
Imdur, Indapamide, Ipratropium Bromide,  
Isosorbide DN, K-Dur, Klor-Con, Lanoxin,  
Lasix, Lescol, Lipitor, Lopressor,  
Lorazepam, Lotensin, Lotrel, Meclizine,  
Methotrexate, Metoprolol, Mevacor,

Miacalcin, Monopril, Naproxen, Neoral,  
Neurontin, Nitro-Dur, Nitroglycerin,  
Nitrostat, Norvasc, Paxil, Pepcid  
Potassium, Potassium Chloride, Pravachol,  
Prednisone, Premarin, Prevacid, Prilosec,  
Prinivil, Procardia, Procardia XL, Prograf,  
Propoxy-N/APAP, Propoxyphene,  
Propranolol, Propulsid, Proscar, Proventil,  
Prozac, Ranitidine, Relafen, Rezulin,  
Risperdal, Serevent, Sinemet, Synthroid,

Tagamet, Tamoxifen, Tenormin, Theo-  
Phylline, Ticlid, Timoptic, Tomazepam,  
Toprol XL, Tramodone, Trental,  
Triamterene/HCTZ, Ultram, Vasotec,  
Verapamil, Voltaren, Xalatan, Xanax,  
Zantac, Zestril, Ziac, Zithromax, Zocor,  
Zolof, Zyprexa

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