

*One Hundred Eighth Congress
of the
United States of America
AT THE FIRST SESSION*

Begun and held at the City of Washington on Tuesday,
the seventh day of January, two thousand and three

An Act

To amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

(a) SHORT TITLE- This Act may be cited as the 'Medicare Prescription Drug, Improvement, and Modernization Act of 2003'.

(b) AMENDMENTS TO SOCIAL SECURITY ACT- Except as otherwise specifically provided, whenever in division A of this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

...

`(h) QUALIFICATION OF PRESCRIPTION DRUG CARD SPONSORS AND ENDORSEMENT OF DISCOUNT CARD PROGRAMS; BENEFICIARY PROTECTIONS-

`(1) PRESCRIPTION DRUG CARD SPONSOR AND QUALIFICATIONS-

`(A) PRESCRIPTION DRUG CARD SPONSOR AND SPONSOR DEFINED- For purposes of this section, the terms 'prescription drug card sponsor' and 'sponsor' mean any nongovernmental entity that the Secretary determines to be appropriate to offer an endorsed discount card program under this section, which may include--

- `(i) a pharmaceutical benefit management company;
- `(ii) a wholesale or retail pharmacy delivery system;

- `(iii) an insurer (including an insurer that offers medicare supplemental policies under section 1882);
- `(iv) an organization offering a plan under part C; or
- `(v) any combination of the entities described in clauses (i) through (iv).

`(B) ADMINISTRATIVE QUALIFICATIONS- Each endorsed discount card program shall be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more entities that have demonstrated experience and expertise in operating such a program or a similar program and that meets such business stability and integrity requirements as the Secretary may specify.

`(C) ACCOUNTING FOR TRANSITIONAL ASSISTANCE- The sponsor of an endorsed discount card program shall have arrangements satisfactory to the Secretary to account for the assistance provided under subsection (g) on behalf of transitional assistance eligible individuals.

`(2) APPLICATIONS FOR PROGRAM ENDORSEMENT-

`(A) SUBMISSION- Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, an application containing such information as the Secretary may require.

`(B) APPROVAL; COMPLIANCE WITH APPLICABLE REQUIREMENTS- The Secretary shall review the application submitted under subparagraph (A) and shall determine whether to endorse the prescription drug discount card program. The Secretary may not endorse such a program unless--

- `(i) the program and prescription drug card sponsor offering the program comply with the applicable requirements under this section; and
- `(ii) the sponsor has entered into a contract with the Secretary to carry out such requirements.

`(C) TERMINATION OF ENDORSEMENT AND CONTRACTS- An endorsement of an endorsed program and a contract under subparagraph (B) shall be for the duration of the program under this section (including any transition applicable under subsection (a)(2)(C)(ii)), except that the Secretary may, with notice and for cause (as defined by the Secretary), terminate such endorsement and contract.

`(D) ENSURING CHOICE OF PROGRAMS-

- `(i) IN GENERAL- The Secretary shall ensure that there is available to each discount card eligible individual a choice of at least 2 endorsed programs (each offered by a different sponsor).

`(ii) LIMITATION ON NUMBER- The Secretary may limit (but not below 2) the number of sponsors in a State that are awarded contracts under this paragraph.

`(3) SERVICE AREA ENCOMPASSING ENTIRE STATES- Except as provided in paragraph (9), if a prescription drug card sponsor that offers an endorsed program enrolls in the program individuals residing in any part of a State, the sponsor must permit any discount card eligible individual residing in any portion of the State to enroll in the program.

`(4) SAVINGS TO MEDICARE BENEFICIARIES- Each prescription drug card sponsor that offers an endorsed discount card program shall pass on to discount card eligible individuals enrolled in the program negotiated prices on covered discount card drugs, including discounts negotiated with pharmacies and manufacturers, to the extent disclosed under subsection (i)(1).

`(5) GRIEVANCE MECHANISM- Each prescription drug card sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor carries out the endorsed discount card program) and enrollees in endorsed discount card programs of the sponsor under this section in a manner similar to that required under section 1852(f).

`(6) CONFIDENTIALITY OF ENROLLEE RECORDS-

`(A) IN GENERAL- For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of title XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note).

`(B) WAIVER AUTHORITY- In order to promote participation of sponsors in the program under this section, the Secretary may waive such relevant portions of regulations relating to privacy referred to in subparagraph (A), for such appropriate, limited period of time, as the Secretary specifies.

...

`(7) LIMITATION ON PROVISION AND MARKETING OF PRODUCTS AND SERVICES- The sponsor of an endorsed discount card program--

`(A) may provide under the program--

`(i) a product or service only if the product or service is directly related to a covered discount card drug; or

`(ii) a discount price for nonprescription drugs; and

(B) may, to the extent otherwise permitted under paragraph (6) (relating to application of HIPAA requirements), market a product or service under the program only if the product or service is directly related to--

(i) a covered discount card drug; or

(ii) a drug described in subparagraph (A)(ii) and the marketing consists of information on the discounted price made available for the drug involved.

...

4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS- In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Security Act.

...

SEC. 1012. COMMISSION ON SYSTEMIC INTEROPERABILITY.

(a) ESTABLISHMENT- The Secretary shall establish a commission to be known as the 'Commission on Systemic Interoperability' (in this section referred to as the 'Commission').

(b) DUTIES-

(1) IN GENERAL- The Commission shall develop a comprehensive strategy for the adoption and implementation of health care information technology standards, that includes a timeline and prioritization for such adoption and implementation.

(2) CONSIDERATIONS- In developing the comprehensive health care information technology strategy under paragraph (1), the Commission shall consider--

(A) the costs and benefits of the standards, both financial impact and quality improvement;

(B) the current demand on industry resources to implement this Act and other electronic standards, including HIPAA standards; and

(C) the most cost-effective and efficient means for industry to implement the standards.

(3) NONINTERFERENCE- In carrying out this section, the Commission shall not interfere with any standards development or adoption processes underway in the private or public sector and shall not replicate activities related to such standards or the national health information infrastructure underway within the Department of Health and Human Services.

HIPAA Administrative Simplification Subtitle: Excerpts from Medicare Prescription Drug, Improvement, and Modernization Act of 2003 & Medicare Program Prescription Drug Discount Card Interim Rule & Notice

(4) REPORT- Not later than October 31, 2005, the Commission shall submit to the Secretary and to Congress a report describing the strategy developed under paragraph (1), including an analysis of the matters considered under paragraph (2).

...

From Conference Agreement; Section 1 of House bill; Section 1 of Senate bill:

“Each prescription drug card sponsor will be required to pass on to discount eligible enrollees the negotiated prices for covered drugs, including discounts negotiated with pharmacies and manufacturers, to the extent such discounts are disclosed under required disclosure rules. Each card sponsor will be required to provide meaningful procedures for hearing and resolving grievances between the sponsor and enrollees in a manner similar to that required for Medicare+Choice. The operations of an endorsed card program are covered functions and a card sponsor is a covered entity for purposes of applying the administrative simplification provisions established in Part C of Title XI of the Social Security Act. Included are regulations promulgated under that Part including privacy regulations. The Secretary could waive the relevant portions of privacy regulations for an appropriate limited period of time in order to promote participation of sponsors. The sponsor of an endorsed card program may not provide or market services under the program except if the product or service is directly related to a covered discount card drug or a discount price for a nonprescription drug. Sponsors will also be required to meet additional requirements as the Secretary identifies are needed to ensure that enrollees are not charged more than the lower of the negotiated price or the usual and customary price....”

...

[Federal Register: December 15, 2003 (Volume 68, Number 240)]
[Rules and Regulations]
[Page 69839-69927]
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Part III

Department of Health and Human Services

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HIPAA Administrative Simplification Subtitle: Excerpts from Medicare
Prescription Drug, Improvement, and Modernization Act of 2003 &
Medicare Program Prescription Drug Discount Card Interim Rule & Notice

Centers for Medicare & Medicaid Services

42 CFR Parts 403 and 408

Medicare Program; Medicare Prescription Drug Discount Card; Interim
Rule and Notice

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403 and 408

[CMS-4063-IFC]
RIN 0938-AM71

Medicare Program; Medicare Prescription Drug Discount Card

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: Section 101, subpart 4 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, codified in section 1860D-31 of the Social Security Act, provides for a voluntary prescription drug discount card program for Medicare beneficiaries entitled to benefits, or enrolled, under Part A or enrolled under Part B, excluding beneficiaries entitled to medical assistance for outpatient prescription drugs under Medicaid, including section 1115 waiver demonstrations. Eligible beneficiaries may access negotiated prices on prescription drugs by enrolling in drug discount card programs offered

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Eligible beneficiaries may enroll in the Medicare drug discount card program beginning no later than 6 months after the date of enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and ending December 31, 2005. After December 31, 2005, beneficiaries enrolled in the program may continue to use their drug discount card during a short transition period beginning January 1, 2006 and ending upon the effective date of a beneficiary's outpatient drug coverage under Medicare Part D, but no later than the last day of the initial open enrollment period under Part D.

Beneficiaries with incomes no more than 135 percent of the poverty line applicable to their family size who do not have outpatient prescription drug coverage under certain programs--Medicaid, certain health insurance coverage or group health insurance (such as retiree coverage), TRICARE, and Federal Employees Health Benefits Program (FEHBP)--also are eligible for transitional assistance, or payment of \$600 in 2004 and up to \$600 in 2005 of the cost of covered discount card drugs obtained under the program. In most cases, any transitional assistance remaining available to a beneficiary on December 31, 2004 may be rolled over to 2005 and applied toward the cost of covered discount card drugs obtained under the program during 2005. Similarly, in most cases, any transitional assistance remaining available to a beneficiary on December 31, 2005 may be applied toward the cost of covered discount card drugs obtained under the program during the transition period.

The Centers for Medicare & Medicaid Services will solicit applications from entities seeking to offer beneficiaries negotiated prices on covered discount card drugs. Those meeting the requirements described in the authorizing statute and this rule, including administration of transitional assistance, will be permitted to offer a Medicare-endorsed drug discount card program to eligible beneficiaries. Endorsed sponsors may charge beneficiaries enrolling in their endorsed programs an annual enrollment fee for 2004 and 2005 of no more than \$30; CMS will pay this fee on behalf of enrollees entitled to transitional assistance.

To ensure that eligible Medicare beneficiaries take full advantage of the Medicare drug discount card program and make informed choices, CMS will educate beneficiaries about the existence and features of the program and the availability of transitional assistance for certain low-income beneficiaries; and publicize information that will allow Medicare beneficiaries to compare the various Medicare-endorsed drug discount card programs.

DATES: Effective Date: The provisions of this interim final rule with comment period are effective December 15, 2003.

Comment date: Comments will be considered if we receive them no later than 5 p.m. on January 14, 2004, at the appropriate address, as provided below.

ADDRESSES: In commenting, please refer to file code CMS-4063-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Mail written comments (1 original and 3 copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-4063-FC, P.O. Box 8013,

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Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (1 original and 3 copies) to one of the following addresses: Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Teresa DeCaro, (410) 786-6604.

SUPPLEMENTARY INFORMATION: Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 (or toll free at 1-888-293-6498) or by faxing to (202) 512-2250. The cost for each copy is \$10. As an alternative, you can view and photocopy the Federal Register document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the Federal Register. This Federal Register document is also available from the Federal Register online database through GPO Access, a service of the U.S. Government Printing Office. The Web site address is:

<http://www.access.gpo.gov/nara/index.html>

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, please call: (410) 786-7197.

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9. HIPAA Administrative Simplification Provisions and Other Marketing and Security Provisions

a. General

Section 1860D-31(h)(6)(A) of the Act provides that for the purpose

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Section 1860D-31(h)(7)(B) of the Act provides that an endorsed sponsor only may market those products and services under its endorsed program that are directly related to a covered discount card drug, or discounts on non-prescription drugs to the extent such marketing is otherwise permitted under the Medicare discount drug card program, and the use of beneficiary information for such communications is permitted by the HIPAA Privacy Rule.

b. Overview of HIPAA Administrative Simplification Regulations

The HIPAA Administrative Simplification Regulations are a suite of regulations that provide for the standardization of certain electronic financial and administrative health care transactions, as well as for the privacy and security of individually identifiable health information.\4\ The regulations apply to three types of entities, which collectively are termed ``covered entities''--health care providers who transmit protected health information in electronic form in connection with a transaction for which the Secretary has adopted a standard, health plans, and health care clearinghouses. Section 1860D-31(h)(6)(A) of the Act essentially specifies a fourth type of covered entity, the endorsed sponsors. Therefore, as a condition of endorsement, endorsed sponsors must comply with the HIPAA Administrative Simplification regulations in the manner described in Sec. 403.812 of our regulations.

\4\ The suite includes regulations for the electronic health care transactions and code sets, unique health identifiers for health plans, health care providers, and employers, and security and privacy.

Section 1860D-31(h)(6)(A) of the Act provides that only the endorsed sponsor's operations of an endorsed program are covered functions. Consequently, activities performed by an endorsed sponsor outside of the scope of its endorsement under the Medicare drug discount card program are not made covered functions by the Act. However, if these other activities would make the endorsed sponsor a

HIPAA Administrative Simplification Subtitle: Excerpts from Medicare Prescription Drug, Improvement, and Modernization Act of 2003 & Medicare Program Prescription Drug Discount Card Interim Rule & Notice health plan, covered health care provider, or health care clearinghouse, as currently defined by HIPAA, then the endorsed sponsor may otherwise be a covered entity that is subject to the Administrative Simplification regulations. An endorsed sponsor performing non-covered functions may declare itself a hybrid entity in accordance with 45 CFR 164.105, with its health care component including any component performing operations that make the entity an endorsed sponsor.

As provided in Sec. 403.812(f) of our regulations, nothing in this discussion or Sec. 403.812 of our regulations should be considered a modification of the HIPAA Administrative Simplification regulations or as otherwise affecting the applicability of the Administrative Simplification regulations to covered entities other than endorsed sponsors. Moreover, as provided in Sec. 403.812(f) of our regulations, if an endorsed sponsor is also a health plan, covered health care provider, or health care clearinghouse, the Administrative Simplification

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regulations as set forth in parts 160, 162, and 164 will still govern the performance of those functions which make it a health plan, health care clearinghouse, or covered health care provider.

c. HIPAA Privacy Rule

As covered entities, endorsed sponsors are responsible for complying with the HIPAA Privacy Rule. The Privacy Rule limits the uses and disclosures a covered entity may make with individually identifiable health information (known as protected health information), requires that safeguards be applied to the information to protect it, and gives individuals rights with respect to the protected health information about them, including rights to access and correct the information. Thus, endorsed sponsors are responsible for safeguarding the protected health information of beneficiaries of the program, and must limit the uses and disclosures made with the information to only those permitted by the Privacy Rule and these regulations. In addition, under the program, beneficiaries have certain rights to be informed of the uses and disclosures the endorsed sponsor is permitted or required to make with their protected health information, to access their records, and to have corrections made to their records, among other rights. See 45 CFR part 160 and subparts A and E of part 164 for the full set of standards, implementation specifications, and requirements of the Privacy Rule.

1. Endorsed Sponsors To Be Treated in Same Manner as Health Plans

The standards, implementation specifications, and requirements in the HIPAA privacy regulations do not apply uniformly to all covered entities; rather, certain provisions apply only to one or two of the different types of covered entities. We believe we have the discretion to prescribe the manner in which the regulations will apply to endorsed sponsors, as section 1860D-31(h)(6)(A) is silent on this issue. Although endorsed sponsors are not by definition health plans under HIPAA, we believe that the HIPAA privacy regulations should apply to endorsed sponsors in the same manner as applicable to health plans because endorsed sponsors' operations more closely resemble those of health plans than health care clearinghouses or providers.

Health plans are organizations that provide, or pay the cost of, ``medical care,`` which is defined in section 2791(a)(2) of the Public

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HIPAA Administrative Simplification Subtitle: Excerpts from Medicare Prescription Drug, Improvement, and Modernization Act of 2003 & Medicare Program Prescription Drug Discount Card Interim Rule & Notice Health Service Act (42 U.S.C. 300gg-91(a)(2)) as amounts paid for (1) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body; (2) amounts paid for transportation primarily for and essential to such medical care; or (3) amounts paid for insurance covering such medical care or transportation. As endorsed sponsors do not themselves provide or pay the cost of medical care, they are not by this definition health plans under HIPAA. However, endorsed sponsors resemble health plans in several respects.

Whereas health plans typically negotiate discount rates for health care products and services, endorsed sponsors similarly will negotiate discounted prices for covered discount card drugs. In addition, health plans coordinate health care for its enrollees, in part by assessing the interaction of various modalities of treatment, which endorsed sponsors also provide albeit on a more limited basis by assessing and avoiding adverse drug interactions and providing educational activities that resemble some of a health plan's care coordination activities. Endorsed sponsors' processing payment for covered discount card drugs provided to transitional assistance enrollees is also somewhat similar to a health plan's payment infrastructure and processes, although unlike health plans, generally speaking, endorsed sponsors would not be bearing capitated risk under this program.

In contrast, the functions performed by endorsed sponsors do not resemble the functions performed by health care providers or health care clearinghouses. A health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), or any other person or organization who furnishes, bills, or is paid for health care in the normal course of business. Under the Medicare discount drug card program, endorsed sponsors will not provide medical or health services to beneficiaries, but instead will arrange for discount card enrollees to have access to negotiated prices and related products and services. A health care clearinghouse is a public or private entity that processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction or receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity. Endorsed sponsors, however, will not be required to perform such services. Accordingly, except as otherwise provided and discussed below, Sec. 403.812(b) of our regulations provide that the HIPAA privacy regulations will apply to endorsed sponsors in the same manner as they apply to health plans.

2. Waiver by the Secretary

Section 1860D-31(h)(6)(B) provides that, in order to promote participation of endorsed sponsors in the Medicare drug discount card program, the Secretary may waive portions of the HIPAA Privacy Rule for a limited period of time as the Secretary deems appropriate. While the Secretary expects endorsed sponsors to be able to comply with the Privacy Rule and, therefore, does not at this time anticipate a need to exercise his waiver authority, the Secretary reserves the right to do so at a later time, if such waiver is deemed necessary to promote participation of endorsed sponsors in the Medicare drug discount card

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3. Administering the Drug Card Program

The Privacy Rule permits covered entities to use or disclose protected health information without individual authorization for health care treatment and payment activities, as well as for certain legal, financial, and administrative functions--known as health care operations--that support treatment and payment activities. To carry out their obligations under the Medicare drug discount card program, endorsed sponsors will have to conduct a number of activities pertaining to products and services offered under the endorsement that may involve the use or disclosure of beneficiary information. These activities and services will include processing beneficiary applications and enrollment in the program, reducing the likelihood of medication errors and adverse drug interactions, providing customer service and information and outreach materials, and administering transitional assistance. (For a description of the services required as part of the endorsement, see section II.C.5 of this document.) The use or disclosure of beneficiary protected health information for these activities are encompassed within the Privacy Rule's definition's of ``payment'' and ``health care operations'' and, thus, may be conducted without beneficiary authorization.

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4. Special Marketing Restrictions for Endorsed Sponsors

Under the Medicare drug discount card program, as explained above, endorsed sponsors will be required to provide information and outreach about products and services offered under the endorsement. Section 1860D-31(h)(7)(B) of the Act provides that an endorsed sponsor may only market those products and services directly related to a covered discount card drug, or discounts for non-prescription drugs to the extent such marketing is otherwise permitted under the Medicare drug discount drug card program and the Privacy Rule. Accordingly, Sec. 403.813(a)(1) provides that an endorsed sponsor may only market those products and services offered within the scope of its endorsement, that is, products and services directly related to a covered discount card drug, and discounts for non-prescription drugs. Thus, only products and services offered by an endorsed sponsor within the scope of its endorsement may be included in an endorsed sponsor's information and outreach materials.

As discussed in section II.C.5. of this document, products or services offered by an endorsed sponsor following termination of its endorsement or termination of the Medicare drug discount card program are considered outside the scope of endorsement. Therefore, Sec. 403.813(b)(4) of our regulations provides that individually identifiable health information created, collected or maintained by an endorsed sponsor may not be used to market any product or service following termination of an endorsed sponsor's endorsement or the program.

Under the Privacy Rule, most uses or disclosures of protected health information to make marketing communications require individual authorization. The Privacy Rule at 45 CFR 164.501, however, defines the term ``marketing'' to mean the making of a communication about a product or service that encourages the recipient of the communication to purchase or use the product or service, with the exception of

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(1) Describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication;

(2) Are for treatment of the individual; or

(3) Are for case management or care coordination, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

Since information and outreach under the Medicare drug discount program is limited to communicating about products and services offered within the scope of endorsement, these activities fall within the exception to the definition of marketing under the Privacy Rule for describing health-related products or services provided by the covered entity. Thus, using or disclosing beneficiary protected health information to provide information and outreach is not marketing under the Privacy Rule, but rather, as described above, is permitted without beneficiary authorization as part of the endorsed sponsor's health care operations.

To use or disclose protected health information to make communications that do not fall within the exceptions to the definition of "marketing" under the Privacy Rule at 45 CFR 164.501, a covered entity must obtain individual authorization in accordance with 45 CFR 164.508(a)(3). However, section 1860D-31(h)(7)(B) of the Act limits the marketing that may be conducted by endorsed sponsors to only that which pertains to products and services offered under the Medicare drug discount program or discounts on over-the-counter drugs. For purposes of this marketing prohibition, we will consider a communication to be marketing if the communication is about a product or service and encourages recipients of the communication to purchase or use the product or service. Thus, a sponsor may not market if the marketing involves products or services falling outside the endorsed sponsor's endorsement, that is, services that do not directly relate to a covered discount card drug, or to discounts for a non-prescription drug. Section 403.813(a)(2) of our regulations expressly provides that an endorsed sponsor may not request of a drug card applicant or enrollee the use or disclosure of protected health information to market any products or services not offered under the program. Thus, endorsed sponsors may not market such products or services under Sec. 403.806(d)(3) of our regulations even if they obtain authorization from discount card enrollees to do so, as permitted by the Privacy Rule. Due to this prohibition, endorsed sponsors are not permitted, at the time of enrollment or any other time, to ask beneficiaries if they would be interested in receiving marketing materials related to products and services offered outside the program. Similarly, endorsed sponsors may not commingle any information and outreach materials that describe their endorsed program with any marketing materials related to products and services offered outside the program.

This prohibition applies regardless of whether the marketing of products or services outside the program involves the use or disclosure of protected health information of discount card enrollees. Accordingly, marketing of a product or service outside the program that does not involve the use of discount card enrollees' protected health information, such as advertising for contact lenses or travel on an endorsed sponsor's Web site, is not permitted under the Medicare drug discount card program, even though such marketing would not involve the

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Many entities that sponsor an endorsed program also may engage in activities outside the Medicare drug discount card program. For example, a Part C organization may be both a sponsor of an endorsed program and operate a Part C plan. The marketing prohibition set forth under section 1860D-31(h)(7)(B) of the Act only applies to entities when acting in their capacity as an endorsed sponsor. Accordingly, although an entity in its endorsed sponsor capacity may not commingle with other marketing materials any information and outreach materials related to products and services offered under its endorsed program, it may commingle such materials when acting in another capacity, to the extent otherwise permitted under law. For example, a Part C organization which sponsors an endorsed program may, in its role as a Part C plan, commingle information and outreach materials describing its endorsed program with Part C plan marketing materials to the extent permitted under the Privacy Rule and the Part C marketing rules under Medicare Part C. We will deem an entity as acting in its capacity as an endorsed sponsor when it either (1) uses beneficiaries' information created, collected or maintained under its endorsed program to conduct marketing, or (2) targets its marketing to all or a subset of its discount card enrollees (or potential discount card enrollees). We will deem an entity as acting in another capacity when it (1) does not use beneficiaries' information created, collected or maintained under its endorsed program to conduct marketing, and (2) does not target its marketing to all or a subset of its discount card enrollees (or potential discount card enrollees). For example, we will consider a Part C organization as acting in its endorsed sponsor capacity if it targets its marketing to members of its

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Part C plan who are also enrolled in its endorsed program, to the exclusion of other plan members. In contrast, we will consider a Part C organization as acting in its capacity as a Part C plan if it directs its marketing to all or a subset of its Part C plan membership, including those not enrolled in its endorsed program, and, to the extent it uses individual information, such information was not collected or maintained under the Part C organization's endorsed program. Similarly, we will consider an organization's Web site listing its full range of products and services, including but not limited to its endorsed program, as targeted to the public at-large; however, we will consider its web pages specifically describing its endorsed program as targeting potential discount card enrollees, and therefore such web pages may not include information related to products and services offered outside the scope of endorsement.

Section 403.813(a) of our regulations is not enforceable under HIPAA but will be enforced by CMS under the Medicare drug discount card program.

5. Other Uses and Disclosures Without Authorization

Under 1860D-31(i)(1) of the Act and as discussed in section II.A., II.C., and II.F. of this document, endorsed sponsors are required to disclose to the Secretary certain information, some of which may contain protected health information. The Privacy Rule at 45 CFR 164.512(a) permits covered entities to use or disclose protected health information without individual authorization where the use or

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6. Uses and Disclosures Requiring an Authorization

For uses and disclosures of protected health information that are not otherwise permitted under the Privacy Rule, an endorsed sponsor must obtain a beneficiary's written authorization for such uses or disclosures in accordance with 45 CFR 164.508. For example, a Medicare beneficiary may authorize the endorsed sponsor to disclose his/her protected health information to a third party, such as an employer. However, as explained above and provided for in Sec. 403.813(a)(2) of our regulations, an endorsed sponsor may not market products or services outside the scope of its endorsement under the Medicare drug discount card program even if it obtains from discount card enrollees authorization to do so. Additional information about this marketing prohibition can be found above in this section and also in section II.C.5 of this document.

7. Notice of Privacy Practices

In accordance with the Privacy Rule at 45 CFR 164.520, prior to enrolling a beneficiary in its endorsed program, or at the time of enrollment, an endorsed sponsor must notify each beneficiary as to how the endorsed sponsor is permitted or required to use and disclose the beneficiary's protected health information, as well as of the beneficiary's rights and the endorsed sponsor's duties with respect to that information. The notice must be in plain language and clearly explain these rights and the uses and disclosures permitted or required under this rule and other applicable law, including that the endorsed sponsor may use or disclose protected health information to communicate about products and services offered by an endorsed sponsor inside, and only inside, the scope of its endorsement. The notice may be combined with other information and outreach materials, provided that the content requirements of the Privacy Rule are fully met.

8. Endorsed Sponsors as Business Associates

As defined in the Privacy Rule, a business associate is a person or entity that performs or assists in the performance of certain functions or activities on behalf of, or provides certain services to, a covered entity, that involve the use or disclosure of individually identifiable health information. The Privacy Rule requires that the covered entity obtain satisfactory assurances, usually in the form of a written contract, from the business associate that the business associate will appropriately safeguard the protected health information it creates or receives on behalf of the covered entity. The contract or other written arrangement between the covered entity and its business associate must meet the requirements at 45 CFR 164.504(e).

For purposes of administering transitional assistance, endorsed sponsors are business associates of CMS under the Privacy Rule. Transitional assistance will be a benefit offered and paid for by the Medicare program, a health plan, with CMS contracting with endorsed sponsors to administer transitional assistance on behalf of CMS in

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The application of the Privacy Rule to endorsed sponsors under our regulations does not affect business associate arrangements or requirements between the endorsed sponsor and one or more covered entities for activities that are outside of the endorsed drug card program. However, because an endorsed sponsor is also a covered entity, when an endorsed sponsor is acting as a business associate of another covered entity, the endorsed sponsor will violate the Privacy Rule if it violates its business associate contract with the other covered entity (see 45 CFR 164.502(e)(1)(iii)).

9. Enforcement by the HHS Office for Civil Rights

The HHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints and to conduct compliance reviews, and may impose civil money penalties on covered entities for violations where appropriate. Thus, any violations by an endorsed sponsor with respect to its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a Web site with Frequently Asked Questions and other compliance guidance at <http://hhs.gov/ocr/hipaa>

OCR's enforcement authority pertains only to the HIPAA Privacy Rule. Thus, any violations with respect to compliance with the other HIPAA Administrative Simplification Rules or proper operation of an endorsed program will be enforced by CMS. In addition, if an endorsed sponsor's actions also violate the requirements of the Medicare drug discount card program, such actions also may be sanctioned under Sec. 403.820(a) of our regulations. See section II.F. of this document for further information about CMS oversight and monitoring of endorsed sponsors.

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d. Administrative Data Standards

As covered entities, endorsed sponsors must comply with any applicable standards, implementation specifications, and requirements set forth in 45 CFR part 162, subparts I et seq., when conducting a transaction (as that term is defined under section 1173 (a) of the Act and 45 CFR 160.103) as of the compliance date of a final rule issued under that Part. In addition, such sponsors are business associates of the Medicare program (a health plan covered entity), as they perform certain administrative functions related to transitional assistance on our behalf. We will, therefore, require in our contracts with endorsed sponsors that, when conducting all or part of a transaction on our behalf, they comply with, and require their agents and subcontractors to comply with, all requirements under 45 CFR part 162 applicable to CMS as a covered entity.

e. National Identifiers

As covered entities, endorsed sponsors must comply with the standards, implementation specifications, and requirements of 45 CFR parts 160 and 162, relating to the use of national identifiers, as of the compliance date of any final rule issued under part 162.

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f. Security

As covered entities, endorsed sponsors must comply with the standards, implementation specifications, and requirements of the HIPAA Security Rule ("Security Rule") set forth in 45 CFR parts 160 and 164, subparts A and C to ensure the confidentiality, integrity, and availability of all electronic protected health information they create, receive, maintain or transmit as of the compliance date of the final Security Rule (April 15, 2005). In addition, endorsed sponsors as covered entities must have appropriate administrative, technical and physical safeguards in place to protect the privacy of beneficiary information under 45 CFR 164.530(c) of the Privacy Rule. An applicant must include in its application the following:

[sbull] An attestation that as of the date upon which it will begin enrollment activities, 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

[sbull] An attestation that it will meet the standards, requirements, and implementation specifications as set forth in the Security Rule as of the date it begins enrolling beneficiaries in its endorsed programs, or, if the endorsed sponsor will be unable to provide this attestation, the applicant's plan for coming into compliance with the specifications as set forth in the Security Rule as of the compliance date for the Security Rule.

Endorsed sponsors are encouraged, but not required, to use Information Security Program references as provided by the National Institute of Standards and Technology (NIST), in documenting their efforts to implement reasonable security measures.

We believe these attestation requirements are critical to beneficiary confidence in the Medicare drug discount card program and their decision to enroll in an endorsed program. Furthermore, as endorsed sponsors are using the Medicare name and acting on our behalf in administering transitional assistance, we believe these requirements are important to promoting the continued confidence of beneficiaries in the Medicare program. We specifically require that applicants attest that they will be in compliance with the Security Rule as of their initiation of enrollment activities, or provide their plan for coming into compliance as of the compliance date. This approach will allow us to evaluate whether their information security measures will comply with the Privacy Rule standard under 45 CFR 164.530(c) and whether they will adequately protect the confidentiality, integrity, and availability of discount card enrollees' electronic protected health information.

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403.812 HIPAA privacy, security, administrative data standards, and national identifiers.

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Sec. 403.802 Definitions.

For purposes of this subpart, the following definitions apply:

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HIPAA means the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d and section 264 of Public Law 104-191.

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Sec. 403.812 HIPAA privacy, security, administrative data standards, and national identifiers.

(a) HIPAA covered entities. An endorsed sponsor is a HIPAA covered entity and must comply with the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164 as set forth in this section. Those functions of a endorsed sponsor the performance of which are necessary or directly related to the operations of the endorsed discount card program are covered functions for purposes of applying to endorsed sponsors the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164.

(b) HIPAA privacy requirements. An endorsed sponsor must comply with the standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR parts 160 and 164, subparts A and E, in the same manner as a health plan, except to the extent such requirements are temporarily waived by the Secretary.

(c) Security requirements. (1) Standard. An endorsed sponsor must comply with the applicable standards, implementation specifications, and requirements in the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C, in the same manner as other covered entities as of the compliance date of such Rule.

(2) Attestation. An applicant in its application shall--

(i) Attest that, as of the initial enrollment date, it will have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information in accordance with 45 CFR 164.530(c); and

(ii) Attest that its information security measures will meet the standards, implementation specifications, and requirements of 45 CFR part 164 subparts A and C as of the initial enrollment date, or, if unable to make this attestation, provide a plan for coming into compliance with these requirements by the compliance date of the Security Rule set forth in 45 CFR part 164, subpart C.

(d) Administrative data standards. An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR parts 160 and 162 subparts I through R.

(e) Unique identifiers. An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements regarding standard unique identifiers under 45 CFR parts 160 and 162 as of the compliance date of any final rule for standard unique identifiers.

(f) Applicability of other regulations. Nothing in this paragraph or in Sec. 403.813 shall be deemed a modification of parts 160, 162

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Dated: December 8, 2003.
Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Approved: December 8, 2003.
Tommy G. Thompson,
Secretary.
[FR Doc. 03-30753 Filed 12-10-03; 1:00 pm]

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