THE HENRY J. KAISER FAMILY FOUNDATION

THE MEDICARE Rx DRUG LAW

Marketing and Privacy Issues: An Analysis of the MMA and Proposed Regulations

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Introduction

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) creates a new voluntary prescription drug benefit for Medicare beneficiaries in Part D, Title XVIII of the Social Security Act (the Act). The prescription drug benefit envisions a marketplace with stand-alone prescription drug plans (PDPs) and Medicare Advantage programs with prescription drug plans (MA-PDs) competing with each other on costs and beneficiary benefits. Because enrollment is voluntary, consumers will need to be adequately informed of the plans that are available in their area, the benefits that the plans offer, and of the potential to qualify for low-income subsidies. To ensure that consumers are adequately informed, the MMA directs the Secretary to broadly disseminate comparative information on prescription drug plan benefits, premiums and cost-sharing to eligible individuals. The Act also allows sponsors of prescription drug plans to market their products to potential enrollees.

Prescription drug plans will be marketed to Medicare eligible consumers, a population with a history of vulnerability to marketing abuses. Reports by the General Accounting Office and the Office of Inspector General have documented past marketing abuses in other Medicare programs including inappropriate marketing practices by agents such as enrolling the cognitively-impaired elderly and selectively marketing to healthier individuals. Congress and CMS have acted to protect Medicare beneficiaries from some of these past practices by explicitly prohibiting such acts as selective marketing and door-to-door solicitations. Yet there are concerns that the new Medicare drug benefit program could generate new opportunities for marketing abuses.

Given this history, the Medicare Prescription Drug Benefit Proposed Rule (Proposed Rule) recently issued by the Secretary of the U.S. Department of Health and Human Services (Secretary) to implement the prescription drug benefit plan raises a number of potential marketing and privacy issues. This brief identifies key marketing and privacy issues that could be addressed in the final rule making including:

- Disclosure of individually-identifiable information to prescription drug plans to facilitate marketing and enrollment
- Adequacy of protections to prevent prescription drug discount card sponsors from sharing individually-identifiable information with affiliated prescription drug plans
- Potential for marketing and offering other products and services, such as financial services, in conjunction with prescription drug benefits

Sharing Individually-Identifiable Information with Prescription Drug Plans

MMA

The MMA added to the Social Security Act §1860D-1(b)(4)(A), which permits the Secretary to share identifiable information on Medicare part D eligible individuals with prescription drug plans to facilitate marketing to, and enrollment of, eligible individuals in prescription drug plans. Section 1860D-1(b)(4)(B) provides that prescription drug plans that receive this identifiable information from the Secretary may only use it for these specified marketing and enrollment purposes. Congress intends "this provision to facilitate outreach to beneficiaries to ensure participation in the program."[1]

Proposed Rule
The Proposed Rule does not contain any provision that governs whether and how the Secretary may provide identifiable information on eligible enrollees to prescription drug plans.[2] Rather, the preamble to the Proposed Rule raises a number of "operational issues" and then seeks comment on these issues as well as on the provision in general.[3]

Discussion
The Secretary's authority to disclose identifiable information to prescription drug plans for marketing under §1861D-1(b)(4) raises numerous privacy concerns. Disclosing the information without individual authorization for these purposes is contrary to established fair practice principles. Additionally, providing identifiable information poses the risk that the information may be used inappropriately, such as to selectively market to desirable individuals. These privacy concerns must be balanced against the Act's intent to facilitate outreach to beneficiaries to ensure participation in the program. Striking the balance requires weighing a number of factors such as the type and amount of information to be disclosed and the exact nature of the marketing for which the information would be used. Some potential approaches to implementing §1861D-1(b)(4) are discussed below.

1. Types of Information Appropriate for the Secretary to Disclose to Prescription Drug Plans
Assuming the Secretary decides to exercise his authority under §1860D-1(b)(4) to disclose identifiable information to prescription drug plans, he may only do so to the extent necessary to "facilitate efficient marketing of prescription drug plans and MA–PD plans to such individuals and enrollment of such individuals in such plans."[4] The Secretary has requested comment on what identifiable information should be disclosed to PDP's and MA-PDs for these purposes.

The Secretary would appear to maintain identifiable information that falls in the following categories:

- Names and addresses
- Telephone numbers
- Financial information, such as income and asset levels
- Claims data that might reveal health status

Each of these categories of information presents different privacy concerns.

a. Names and Addresses
Eligible enrollee names and addresses would appear to be the minimum amount of identifiable information that the Secretary could disclose to facilitate marketing and enrollment. The risk for misuse of this information is relatively minor. Many advocates believe that this is the *only* identifiable information that the Secretary should disclose under Section 1860D-1(b)(4).

b. Telephone Numbers
Implicitly recognizing that disclosing telephone numbers presents heightened concerns, the Secretary specifically asks for comments on whether, "To the extent [individually] identifiable information is shared for purposes of marketing, should PDP sponsors and MA organizations be

able to use this information to contact beneficiaries only through written communications or should telephone contact be permitted, and, if so, under what circumstances?" [5]

Many consumers consider telemarketing an invasion of privacy. Over 62 million people signed up for the FTC's "Do Not Call" registry in the first year of its operation.[6] Many of these individuals would likely take issue if the Secretary were to give out their phone number for telemarketing purposes. The Secretary should carefully weigh the implications of disclosing beneficiaries' telephone numbers in order to facilitate a practice that many consumers dislike.

Furthermore, the Secretary could generally prohibit prescription drug plans from initiating telephone or e-mail contact with potential beneficiaries to promote their plans. Telemarketing presents many of the same dangers as door-to-door solicitation, which is prohibited under the Proposed Rule.[7] There have been examples of telemarketing scams under the Medicare Drug Discount Card Program[8], and there is certainly the potential for similar abuses under the prescription drug benefit. To help consumers distinguish between scam marketers and legitimate prescription drug plans, the Secretary could adopt the approach taken in the Medicare Drug Discount Card Program and limit prescription drug plans to contacting beneficiaries via telephone or e-mail only if the beneficiary requests contact through such vehicles as a response to a direct mail advertising piece or an advertisement.[9] At the very minimum, individuals could be given the choice of opting out of receiving telephone solicitations.

c. Financial Information

Since plans are supposed to market their products to beneficiaries of all income levels, there does not appear to be a compelling reason for the Secretary to disclose financial information to prescription drug plans for marketing purposes. Many consumer advocates raise concerns that financial information will be used to selectively market to individuals with low prescription costs, avoiding lower-income people with substantial medical needs. Providing financial information to prescription drug plans presents a tangible risk that the information may be used improperly to selectively market to higher income (low-cost) individuals. There is, of course, a need to ensure that low-income individuals are aware of the prescription drug benefit and that they may qualify for subsidies. CMS, in conjunction with community-based organizations, will be the primary entities conducting outreach for these purposes.

Neither does there appear to be a compelling reason for the Secretary to disclose detailed financial information to facilitate enrollment. Prescription drug plans are not responsible for making determinations with respect to individuals' eligibility for the low-income subsidy. Those determinations are to be made either by the state Medicaid agency or the Social Security Administration.[10] At enrollment, prescription drug plans will need to know whether an individual qualifies for a low-income subsidy and whether it is the full or partial subsidy. To facilitate this process, it may be necessary for the Secretary to disclose general identifiable financial information such as the fact that an individual is eligible for the subsidy and the amount of the subsidy. However, the Secretary would not need to disclose detailed financial information for this purpose. For example, the Secretary could disclose that John Smith qualifies for the full low-income subsidy without disclosing John Smith's specific income or assets. In order to protect individual privacy rights, disclosures of identifiable financial information to facilitate

enrollment could be limited to whether the individual is eligible for a low-income subsidy, and the type and level of subsidy for which she is eligible.

d. Health condition or status

The Secretary may maintain some claims data or other information that reveals a beneficiary's health condition or status. The Secretary, for example, has information identifying certain individuals as having end stage renal disease and has claims data that could reveal specific conditions, such as cancer. However, because the prescription drug benefit is guaranteed issue, prescription drug plans have no need for information on individuals' health status or claims.[11] The Secretary need not release information related to health conditions or status to prescription drug plans for marketing or enrollment purposes, although it should be recognized that by providing even basic information about an individual, like their place of residence (e.g., a nursing home), the Secretary would indirectly be offering information about an individual's health status.

2. Consumer consent

Assuming the Secretary decides to exercise the authority to disclose identifiable information, should consumers be given the choice over whether their information is disclosed?

One of the widely accepted core principles of fair information practices is that consumers should have choice (consent) over whether their information is disclosed for a purpose other than for which it was originally collected information to third parties.[12] Under this principle, individuals should be able to choose whether the Secretary discloses identifiable information to prescription drug plans for marketing and enrollment, should the Secretary exercise this authority. Adopting such an approach would be consistent with the Administration's stated goal of expanding consumer choice.

a. Opt-in or Opt-out?

Both the general approaches to providing consumer's choice, "opt-in" and "opt-out," have their benefits and drawbacks. Under the opt-in approach, individuals must give their permission (such as a signed consent or authorization) prior to the disclosure of their identifiable information. Generally, this approach is seen as being the most consumer-oriented since it assumes that the consumer is the one who decides whether their information is released. Some oppose an opt-in approach because they see it as burdensome. However, because the MMA provides that the Secretary may disclose identifiable information notwithstanding other laws[13], a formal HIPAA-compatible authorization is not required. The Secretary could use a simpler form for consent. For example, CMS could include in the prescription drug plan information to be disseminated to beneficiaries a return-addressed post card with check off boxes that indicate whether the individual chooses to have their information disclosed.

A potential drawback to the opt-in approach is that historically, many consumers fail to take the affirmative step of sending in the consent form even if they want their information disclosed. Consequently, some are concerned that a number of individuals may not receive information that they need to enroll in PDPs and MA-PDs, presuming the plans' marketing materials will provide substantive information.

Under the opt-out approach, it is permissible to disclose information unless the consumer takes an affirmative step to prevent the disclosure of their information (such as registering with a "do not call" list). This approach is traditionally seen as being less consumer-oriented since it assumes that it is permissible to disclose an individual's information. An opt-out approach also has the drawback that individuals often do not take the affirmative step to opt out even if they do not want their information released. The benefit of this approach is that more information is delivered to consumers.

The relative merits of an opt-in or opt-out approach depend largely on the identifiable information the Secretary may determine to disclose. If the Secretary were to disclose only the names and addresses of eligible individuals, the privacy risks would be relatively small and an opt-out approach may be appropriate. On the other hand, if the Secretary were to disclose health status or financial information, an opt in approach may be more appropriate since the consequences of disclosure are potentially more serious. To the extent the Secretary determines that it may be appropriate to release telephone numbers, individuals should be given the specific choice whether their telephone numbers can be disclosed.

b. *Means for Opting In or Opting Out*

Whether the Secretary adopts an opt-in or opt-out scheme, it is important that the means by which a consumer will opt in or out be transparent, easy to read, specifically state the category of information to be disclosed, and easy to use. In other contexts, information notifying individuals that they have a choice whether their personal information is disclosed is often in small text buried in middle of a lengthy document. For example, bank notices under the *Gramm-Leach-Bliley Act* are notoriously poorly written. The information is often legalistic and is stated in terms so vague that the consumer does not know precisely what information is to be disclosed.[14]

Should the Secretary adopt an opt-out or opt-in approach, the notice advising consumers of their ability to choose should be designed with the diverse needs of the Medicare population in mind. Such notices could be in large type and written at an 8th grade literacy level. The opt-out or opt-in notice could state in plain language what specific information the Secretary intends to disclose (*e.g.*, "We will share your name, address and telephone number") and not be ambiguous *(e.g.*, "We will share your contact information"). The notice could also make clear that even if individuals choose not to receive materials from prescription drug plans, they will continue to receive materials from the Secretary and CMS. Additionally, there could be a number of different, easy to use means to opt in or opt out to meet the varying needs of the Medicare population. For example, the Medicare website, the Medicare toll free number and a written form (such as a post card) are various methods by which individuals could choose whether their information is shared.

If more than one method of contact for marketing is ultimately approved (e.g., mailings and telemarketing), the opt in or opt out form could give individuals the option of being contacted by only one of these methods (*e.g.*, "CMS may share my information but I only give permission to be contacted by mail.")

3. Restrictions on Use of Information Provided by Secretary

The MMA provides that information provided by the Secretary under Section 1860D-1(b)(4) may be used by the receiving prescription drug plan only to facilitate marketing of, and enrollment of part D eligible individuals in prescription drug plans.

Should the Secretary exercise the authority to disclose identifiable information under this provision, the Final Rule should expressly re-iterate the limitation that prescription drug plans may only use such information for marketing and enrollment in their plans. In addition the Final Rule could amend § 423.50 to include targeted marketing to individuals who have demonstrated relatively lower drug expenditures or use as an example of a prohibited discriminatory activity. The Final Rule could also amend 42 C.F.R. §422.80(e)(ii) (applicable to MA-PDs) in a consistent manner.

Accessing and Using Identifiable Drug Discount Card Information for Marketing Prescription Drug Plans

Medicare drug discount card sponsors collect and create individually identifiable information such as enrollee-level prescription drug use and expenditure data. The general expectation is that sponsors of discount drug card programs will also sponsor or be directly involved in administering prescription drug plans. It is likely that many related drug discount card sponsors and prescription drug plans will be operating at the same time during portions of 2005-2006.[15] These combined factors raise the concern that drug discount card sponsors may be able to share identifiable enrollee and applicant information with related prescription drug plans that will then inappropriately use this information to selectively market to individuals who have low drug use and expenditures.

Existing laws, including the Medicare Prescription Drug Discount Card Program Interim Rule (Drug Card Rule) and the Privacy Rule issued under the Health Insurance Portability and Accountability Act (HIPAA Privacy Rule) do not adequately prevent a drug discount card sponsor from using and disclosing identifiable enrollee information to market prescription drug plans. As written, the Proposed Rule does not fill this gap.

To remedy this problem, the Proposed Rule could be amended to expressly prohibit prescription drug plan sponsors from obtaining or using individually identifiable health information collected or maintained by a sponsor of a Medicare Drug Discount Card Program for any purposes non-related to treating an individual.

Restrictions on Drug Discount Card Sponsors under the MMA and Drug Card Rule

The MMA added §1860D-31(h)(7) to the Act to prohibit Medicare drug discount card sponsors from providing or marketing *under the drug discount program* services or products that are unrelated to that program.[16] For example, this provision prohibits advertising for contact lenses or travel on an endorsed drug card sponsor's Web site.[17] However, §1860D-31(h)(7) does not expressly prohibit a drug discount card sponsor from *using or disclosing* drug discount program information to market other products it offers. For example, this provision does not appear to prohibit Drug Discount Card Program A from sharing its card enrollee information with Prescription Drug Plan B, so that PDP B can market its plan.

In response to Section 1860D-31(h)(7) of the Act, the Secretary issued §403.813(a)(4) of the Drug Card Rule (42 C.F.R.) which expressly states that "*following termination"* of a sponsor's endorsement or the Medicare Drug Discount Card Program, an enrollee's individually identifiable health information collected or maintained by an endorsed sponsor may not be used or disclosed for marketing any product or service. This provision clearly prohibits any entity from using or disclosing a drug discount card program enrollee's identifiable information for marketing any product or service *after* that discount card program ceases to exist. For example, Drug Discount Card A could not upon its termination transfer its enrollee information to Prescription Drug Plan B, so that PDP B could compile a mailing list to market its prescription drug plan. On its face, however, §403.813(a)(4) does *not* apply while a drug discount card program *is still in operation*.

Another subsection, §403.813(a)(1) provides that an "endorsed sponsor may only market those products and services offered *under its endorsed* program that are within the scope of endorsement" (*i.e*., directly related to covered discount drugs and discounted over the counter medicine).[18] This subsection would prohibit a drug discount card sponsor from marketing a prescription drug plan as part of its drug discount program endorsement since these are two distinct programs. For example, Drug Discount Program A could not include in its mailings explaining the cost of drugs under its drug discount program any material that promotes Prescription Drug Plan B.

In contrast §403.813(a)(1) of the Drug Card Rule does not prohibit a drug discount card sponsor from *using or disclosing* drug discount program enrollee information to market another product. For example, §403.813(a)(1) does not appear to prohibit Drug Discount Card Program A from sharing its enrollee information with Prescription Drug Plan B, so that PDP B can compile a mailing list to market its prescription drug plan.

However, CMS clearly intended Section 403.813(a)(1) to prohibit this type of activity[19] and has issued guidelines to this effect. The guidelines unequivocally provide:

> Under no circumstance may an Endorsed Card Sponsor use or disclose protected health information[20] to market products or services outside the scope of the endorsement, nor may an Endorsed Card Sponsor ask an enrollee or potential enrollee to provide an authorization in order to market such products or services.[21]

Under these guidelines, a drug discount card sponsor would *always* be prohibited from using or disclosing its enrollee and applicant information for marketing prescription drug plans.

The guidelines' prohibition offers strong protection against the possibility of prescription drug plans' obtaining and using drug discount card enrollee information. Because the prohibition is only in guidance, however, it does not have the same force and effect as it would have if it were a regulation. Furthermore, the restrictions imposed under the HIPAA Privacy Rule and the prescription drug benefit provisions of the MMA are insufficient.[22]

To remedy this potential problem, the Final Rule could incorporate the guideline's strong

prohibition against using drug discount card enrollee information for marketing.

The HIPAA Privacy Rule

Drug discount card program sponsors and prescription drug plans are covered entities under the HIPAA Privacy Rule, and must comply with its requirements.[23] Under certain business structures, the HIPAA Privacy Rule would permit a drug discount card program to use or share its enrollee information with a related prescription drug plan for promotion of the PDP without individual authorization.[24]

Under HIPAA, a "covered entity" is the "legal entity" that performs a covered function (such as providing health care or payment for health care).[25] For example, a corporation that offers different health insurance products is generally considered to be the "covered entity." The HIPAA Privacy Rule permits a covered entity to use and disclose its individually identifiable information for its own treatment, payment and health care operations without individual authorization.[26] Under HIPAA, the provision of information and outreach materials about a health plan are considered health care operations.[27]

This means that if a corporation offers different health plans, it is permitted to use identifiable information generated in one plan to provide outreach materials about the other plan.[28] For example, when "[a] health plan sends a mailing to subscribers approaching Medicare eligible age with materials describing its Medicare supplemental plan and an application form" this activity is seen as being a "health care operation" which does not require individual authorization.[29]

Similarly if Corporation A (the covered entity) offers both Drug Discount Card Program A and Prescription Drug Plan A, Company A could use and disclose its discount drug card enrollee information to provide information and outreach material about its prescription drug plan under HIPAA. This activity would be a health care operation and would not require individual authorization under the Privacy Rule. By contrast, under the CMS guidelines for the drug discount card program, this activity would be prohibited.

The HIPAA Privacy Rule also provides that legally separate covered entities that are affiliated may designate themselves as a "single covered entity" for purposes of the Privacy Rule.[30] In order to qualify as a single covered entity, the separate covered entities must be under common control or ownership.[31] To implement this provision, the single covered entity must merely designate itself as such in writing and maintain the written documentation.[32] Once this designation is made, the affiliates are treated as if they were one covered entity for purposes of HIPAA. As HHS explained, "For example, a corporation with hospitals in twenty states may designate itself as a covered entity and therefore, [be] able to merge information for joint marketplace analysis."[33]

Under this provision a parent corporation that owns a discount drug card program sponsor and an affiliated prescription drug plan sponsor as separate legal entities would be able to designate itself as a single covered entity. The single covered entity could use discount drug card enrollee information to provide information and outreach material about its prescription drug plan. Assume, for example that Corporation X owns and operates both Drug Discount Card Program Y and Prescription Drug Plan Z through separate subsidiaries. Corporation X could designate

itself as the single covered entity and use and share information freely between the different programs. Corporation X could use discount drug card enrollee information to provide information and outreach material about its prescription drug plan without individual authorization because this would be a health care operation of the single covered entity. While permitted under HIPAA, this activity would be prohibited under CMS guidelines for the Medicare Drug Discount Card Program. In sum, HIPAA permits the use and disclosure of drug discount card enrollee data in a manner that would be prohibited under the CMS guidelines on the Medicare Prescription Drug Discount Card.

Restrictions on Prescription Drug Plan Sponsors under the MMA and the Proposed Rule

There is nothing in the MMA that expressly prohibits prescription drug plans from obtaining or using drug discount card enrollee information.[34] Neither does the Proposed Rule prohibit this practice. Proposed Rule 42 C.F.R. §423.136 essentially requires PDPs to abide by the HIPAA Privacy Rule.[35] Proposed Rule §423.50 prohibits PDPs from "engag[ing] in any discriminatory activity such as, . . .targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas."[36] MA-PDs are subject to a similar requirement under established MA (formerly M+C) regulations.[37]

While these provisions prohibit prescription drug plans from engaging in discriminatory practices, they do not prohibit prescription drug plans from obtaining drug discount card enrollee information in the first place. Nor do they prohibit a prescription drug plan from using identifiable drug discount card enrollee information. In contrast, both of these activities would be prohibited under the CMS guidelines on the Medicare Prescription Drug Discount Card.

In sum, it appears that the Secretary intended to prohibit under all circumstances the use and disclosure of drug discount card program enrollee and applicant information to market products or services outside the scope of the endorsement. Because this provision is only included in CMS guidelines, it does not have the full force and effect of law. Other provisions of law, such as the HIPAA Privacy Rule and the Drug Discount Card Rule, do not adequately address this issue.

To remedy this problem, the Proposed Rule could be amended to expressly prohibit prescription drug plan sponsors from obtaining or using individually identifiable health information collected or maintained by a sponsor of a Medicare Drug Discount Card Program for any purposes non-related to treating an individual.

Marketing and Providing Additional Products and Services In Conjunction with Prescription Drug Benefits

MMA

Section 1860D-1(b)(1)(B)(vi) of the Act directs the Secretary to use rules similar to (and coordinated with) those established for Medicare Advantage Programs to review prescription drug plans' marketing materials and application forms.[38] The Act does not provide that prescription drug plans are limited to marketing and offering only Medicare prescription drug plans.[39]

Proposed Rule

Proposed §423.50 generally replicates the marketing provisions established under §422.80 for MA plans.[40] The Proposed Rule does not explicitly limit PDPs and MA-PDs to marketing and offering only Medicare prescription drug benefit plans. However, the proposed rule prohibits other specific marketing activities (such as door-to-door solicitation) and generally prohibits marketing activities that could mislead or confuse Medicare beneficiaries.[41] This provision is similar to and consistent with the well-established restrictions imposed on M+C plans (now MA plans).[42]

The Secretary is considering interpreting or altering this provision to permit PDP sponsors to market and provide additional products (such as financial services) in conjunction with PDP services and asks for comments on the advisability of allowing this practice.[43] The idea is to encourage financial service firms such as banks to sponsor prescription drug plans by allowing them to cross-market financial service products to Medicare beneficiaries.[44] This proposal raises a number of concerns.

First, major sectors of the financial service industry (including banks) take the position that they are exempt from the provisions of the HIPAA Privacy Rule under Section 1179 of the Act.[45] The Secretary may want to revisit whether it is prudent to encourage these financial service firms to sponsor Medicare prescription drug plans when they generally take the position that they are exempt from the major federal law governing the privacy of health information.[46]

Second, even if financial institutions were to concede that the HIPAA Privacy Rule applies to them, many of the activities being proposed are precluded by other law. To the extent the marketing activities are not prohibited by other law, these activities could potentially mislead and confuse Medicare beneficiaries.

Under the proposal, financial institutions could act as PDP sponsors and be permitted to market credit cards, brokerage services, and other types of insurance (such as long term care or dental insurance) in conjunction with the Medicare prescription drug benefit plan.[47] Theoretically, PDPs could send these marketing materials while soliciting individuals to enroll in their prescription drug benefit plan and after they have enrolled in the plan. Both of these activities are prohibited under law.

The MMA expressly states that to the extent the Secretary provides individually identifiable information to prescription drug plans under Section 1860D-1(b)(4), the information can "only be used to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA–PD plans."[48] This provision clearly prohibits prescription drug plans from using any identifiable information they obtain under 1860D-1(b) to market financial services. Plans would need to obtain contact information from another source, such as enrollment or claims data.

The HIPAA Privacy Rule would also restrict prescription drug plans' use of enrollment or claims data for marketing. Assuming prescription drug plans sponsored by financial service institutions are covered by HIPAA, they must comply with its restrictions on using[49] and disclosing

protected health information, including enrollment and claims information.[50] The Health Privacy Rule requires a covered entity to obtain individual authorization "for any use or disclosure of protected health information for marketing" i.e., communicating to promote products or services that are not health-related.[51]

Many financial services and products, such as credit cards, securities and life insurance, are not related to health. Under the HIPAA Privacy Rule, PDPs would be prohibited from using individually identifiable information (such as names and addresses for marketing these financial services) unless they obtain the individual authorization from everyone on the mailing list. The HIPAA Privacy Rule also appears to prohibit PDPs from using individually identifiable information to compile mailing lists for *soliciting* authorizations to market financial products. They would need to obtain this information from another resource.

It therefore appears that the MMA and HIPAA Privacy Rule would prohibit many of the activities contemplated by the Secretary's proposal and such activities should not be permitted in the Final Rule. However, if the Secretary were to permit marketing and providing other products in conjunction with PDP services, the Secretary should consider limiting through this rule the specific individually identifiable information that drug plans may use for these purposes. It would also be prudent to consider an alternative by which PDP enrollees may decline to have their personal information used for marketing and soliciting of additional products.

Regardless of whether it is permitted or prohibited by other law, offering and providing other products and services "in conjunction with" Medicare prescription drug plans is counter to the Secretary's long-standing policy that organizations do not improperly imply that Medicare recommends their products. The Proposed Rule permits prescription drug plans to state in their marketing materials that their plan is "Medicare approved."[52] Offering financial services "in conjunction with" "Medicare approved" prescription drug plans gives the impression that the financial services are also approved by the Medicare program. For example, a Medicare beneficiary may be persuaded to sign up for a credit card with an 18 percent annual interest rate because the beneficiary believes the card is endorsed by Medicare. Clearly, this activity is likely to lead to considerable misunderstanding and confusion among Medicare beneficiaries.

Conclusion

A number of potential marketing and privacy issues are raised by the proposed rule. The Secretary could take a number of steps, through regulation, to alleviate such issues in the Final Rule, including:

- Limiting the amount and type of individually identifiable information the Secretary will share with prescription drug plans for marketing and enrollment purposes
- Prohibiting prescription drug plan sponsors from obtaining or using individually identifiable health information collected or maintained by a sponsor of a Medicare Drug Discount Card Program for marketing purposes
- Prohibiting prescription drug plans from marketing and providing other products and services, such as financial services, in conjunction with the Medicare prescription drug plan

Such changes would improve protections for Medicare beneficiaries.

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[1] H.R. CONF. REP. NO. 108-391, at 432 (2003).

[2] See *Medicare Prescription Drug Benefit, Proposed Rule* ("Proposed Rule*")* 69 Fed. Reg. 46632 at 46808 through 46830 (Aug. 3, 2004).
See 69 Fed. Reg. 46808 through 46830.

[3] In particular, the Secretary seeks comment on the following issues:
To the extent the Secretary were to share information,
- Should beneficiaries be given the ability to choose not to have their information shared with these entities?
- What specific information should the Secretary provide to PDP or MA organizations to facilitate their marketing and enrollment activities?
- Should PDP sponsors and MA organizations be able to use this information to contact beneficiaries only through written communications, or should telephone contacts be permitted, and, if so, under what circumstances?
- Should such information be provided by CMS upon request, or only at specific, scheduled times during the year (for example, just prior to the Annual Coordinated Election Period).

In addition, the Secretary is interested in receiving comments on the "provision in general." *Preamble, Proposed Rule,* 69 Fed. Reg at 46644.

[4] §1860D-1(b)(4).

[5] *Preamble, Proposed Rule* 69 Fed. Reg. at 46644.

[6] Caroline Mayer, *In 1 Year, Do-Not-Call List Passes 62 Million; Complaints About Telemarketers Pile Up,* Washington Post, June 24, 2004 at E4.

[7] Proposed Rule §423.50(e).

[8] See Lori Racki, *Medicare Scams Prey on Seniors*, Chicago Sun-Times, News Special Edition at 8 (May 24,2004).

[9] See CMS*, Medicare Prescription Drug Discount Card and Transitional Assistance Program Information & Outreach, Materials Guidelines* at 92 *(*January 22, 2004, *revised* July 2004)

[10] See Proposed 42 C.F.R. §423.774.

[11] §1860D-1 (b)(1)(B)(v) of the Act.

[12] See Federal Trade Commission, *Privacy Online: A Report to Congress* (June 1998) at 8, available at http://www3.ftc.gov/reports/privacy3/fairinfo.htm

[13] See § 1860D-1(b)(4)(A) of the Act.

[14] See generally *Latest Privacy Mailings Are Hard to Decipher*, Wall Street Journal, May 30, 2002

[15] Prescription drug plans will need to organize, fulfill certification and contracting requirements, and commence their marketing activities during 2005 in order to provide coverage as of January 1, 2006. Although drug discount cards may not be issued after December 31, 2005, the discount programs will continue to exist into 2006 in order to pay for drugs dispensed prior to December 31st. See §§1860D-1(a)(2) and 1860D-31(a)(2)(C) of the Act.

[16] §1860D-31(h)(7) of the Act provides:

(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.

[17] *Preamble, Medicare Drug Discount Card Interim Rule*, 68 Fed. Reg. 69840 at 69872 (Dec. 15, 2003).

[18] 42 C.F.R. §403.813(a)(1) provides that an endorsed sponsor may only market those products and services offered under its endorsed program that are inside the scope of endorsement as defined in §403.806(h). Section 403.806(h) generally provides that products and services inside the scope of the endorsement are limited to those that are directly related to a covered discount card drug; or a discounted price for an over-the-counter drug.

[19] See *Preamble, Medicare Drug Discount Card Interim Rule*, 68 Fed. Reg. 69864 (“[A]s provided in §403.813(a)(1) . . . an endorsed sponsor may not use or disclose a card enrollee’ individually identifiable information created, collected, or maintained under the Medicare drug discount program for the purpose of marketing products or services offered outside the scope of their endorsement.”)

[20] “Protected health information” as defined in the HIPAA Privacy Rule would include any individually identifiable information that is created by a health plan that “relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual or; or the past, present, or future payment for the provision of health care to an individual.” See 45 C.F.R. §160.103 (defining “protected health information,” and “individually identifiable health information.”)

[21] CMS, *Medicare Prescription Drug Discount Card and Transitional Assistance Program: Information & Outreach Materials Guidelines* at 5 (January 22, 2004, *revised* July 2004) *available at:* http://www.cms.hhs.gov/discountdrugs/guidelines8-12-04.pdf

[22] See *Drug Card Information & Outreach Guidelines* at 5.

[23] §1860D-31(h)(6) of the Act and 42 C.F.R. §403.812 (making drug discount card sponsors covered entities); The Privacy Rule expressly provides that “Medicare+Choice” plans are “health plans” under HIPAA. 45 C.F.R. §160.103 Because Section 201 of the MMA deems that the term “Medicare + Choice” refers to MA plans, MA-PD organizations are health plans under HIPAA. Additionally HIPAA defines “health plan” as including “[a]ny other individual or group plan . . . that pays for the cost of medical care…” (with certain exceptions not applicable here). 45 C.F.R. §160.103. This provision would encompass PDPs. See *Preamble Medicare Prescription Drug Benefit: Proposed Rule,* 69 Fed. Reg. 46631 at 46666 (August 3, 2004) (where the Secretary states that PDPs are “health plans” under HIPAA).

[24] The HIPAA Privacy Rule restricts the uses and disclosures of health information. See 45 C.F.R. part 164. It does not govern whether or how a covered entity can receive health information.

[25] A single legal entity is an entity that cannot be further differentiated into units with their own legal identities. See 65 Fed. Reg. 82502-82503.

[26] See 45 C.F.R. §164.506.

[27] See 42 C.F.R. §164.501 (defining health care operations) and *Drug Card Information & Outreach Guidelines* at 5. While the HIPAA Privacy Rule requires individual authorization for marketing (45 C.F.R. §164.508(a)(3)), these activities are excluded from the definition of “marketing” under HIPAA. C.F.R. §164.501 defines “marketing” as:

(1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, *unless* the communication is made:

(i) To 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 …

Because the communications here are communications that describe health-related products or services that are provided by the covered entity making the communication, they are not considered to be “marketing.” See *Drug Card Information & Outreach Guidelines* at 5; CR *Guidance on the Privacy Rule: Marketing* available at http://www.hhs.gov/ocr/hipaa/privacy.html (December 3, 2002, *revised* April 3, 2003*) (*last visited Sept. 3, 2004*)*and

OCR, *Frequently Asked Questions*, Answer ID No. 279 responding to "How do I distinguish treatment and health care operations versus marketing activities?" available at http://www.hhs.gov/ocr/hipaa/ (where OCR explains that "If a communication falls under one of the [marketing]definition's exceptions, the marketing rules do not apply. In these cases, covered entities may engage in the activity without first obtaining an authorization."

[28] While a covered entity that performs multiple covered functions (*e.g.*, a health plan and a health care provider) is limited in how it uses and shares information between functions, that limit does not appear to apply when the covered entity performs a single function (*e.g.*, health plan) through different business components. See 45 C.F.R. §164.504(g) and *Preamble, Standards for Privacy of Individually Identifiable Health Information: Final Rule,* 65 Fed. Reg. 82462 at 82509 (explaining limitation).

[29] See OCR, *Guidance on the Privacy Rule: Marketing* and OCR, *Frequently Asked Questions*, Answer ID No. 279.

[30] 45 C.F.R. §164.105(b).

[31] "Common control" exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity. "Common ownership" exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity. 45 C.F.R. §164.103.

[32] 45 C.F.R. §164.105(b).

[33] *Preamble, Standards for Privacy of Individually Identifiable Health Information, Final Rule* 65 Fed. Reg. 82462 at 82503 (Dec. 26, 2000).

[34]See §1860D-4(i) of the Act (making the provisions of §1852(h) applicable to PDP sponsors); §1852(h) of the Act (requiring Medicare+ Choice organizations to establish safeguards to safeguard the privacy of individually identifiable enrollee information) and §201 of the MMA (deeming all references to "Medicare+Choice" to be a reference to "Medicare Advantage and "MA"). See also §1860D-1(b)(1)(A) and (B)(vi) and §1851(h) of the Act (generally requiring prescription plans to conform to fair marketing standards and directing the Secretary to establish rules for marketing.)

[35] Proposed §423.136 makes the provisions of §422.118 applicable to PDPs. §422.118 requires M+C organizations to abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information and to safeguard the privacy of identifiable enrollee information.

[36] See Proposed Rule 42 C.F.R. §423.50(e).

[37] See 42 C.F.R. §422.80. See *Preamble, Proposed Rule,* 69 Fed. Reg. 46632. (which states that proposed rule 42 C.F.R. §423.50 generally replicates the marketing standards established under §422.80 for MA plans).

[38] See §§ 1860D-1(b) and 1851(h) of the Act.

[39]In contrast, the MMA expressly prohibits sponsors of drug discount card programs from providing or marketing under that program products and services that are not directly related to the program. See §1860D-31(h)(7) of the Act. The lack of such a restriction for prescription drug plans is probably attributable to the fact that Congress never envisioned a prescription drug plan offering such financial services as credit cards.

[40] See *Preamble, Proposed Rule,* 69 Fed. Reg. 46643.

[41] See Proposed Rule §423.50(e).

[42] See 42 C.F.R. §422.80.

[43] The Secretary notes:

> We are also aware that the ability to provide additional products (for example, financial services) to Medicare beneficiaries could provide additional tools to help beneficiaries manage their expenses and financial security, and could be a strong incentive for potential PDP sponsors to participate in Part D. We ask for comments on the advisability of allowing such products to be provided in conjunction with PDP services and the appropriate limitations on such activities. We note that in accordance with HIPAA privacy rules, the PDP sponsor may have to obtain beneficiary authorization to market certain products.
>
> 69 Fed. Reg. 46644 .

[44] See CNBC report on CMS "courting" financial service plans available at: http://www.mbproject.org/media_center.php

[45] SEC. 1179. of the Social Security Act provides:

> To the extent that an entity is engaged in activities of a financial institution (as defined in section 1101 of the Right to Financial Privacy Act of 1978), or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution, this part [the Administrative Simplification Provisions of HIPAA], and any standard adopted under this part, shall not apply to the entity with respect to such activities

Section 1101 of the Right to Financial Privacy Act generally defines a "financial institution" as any office of a bank, savings bank, card issuer, industrial loan company, trust company, savings association, building and loan, or homestead association (including cooperative banks), credit union, or consumer finance institution.
The American Bankers Association and NACHA (a trade association which represents 12,000 financial institutions with automated clearing house [payment] functions) take the position that Section 1179 exempts from any regulations promulgated under the Administrative Simplification title [including the HIPAA Privacy Rule] any entity engaged in the activities of a financial institution. See letter from the American Bankers Association to Tommy G. Thompson, Secretary U.S. Department of Health and Human Services October 24, 2003, which states in pertinent part, "…the plain language of the statute exempts from any regulations promulgated under the Administrative Simplification title, any entity engaged in the 'activities of a financial institution.' Nothing in section 1179 restricts the exempted activities to those involving the payment system." See also Morrison & Foerster Memo to NACHA at 3 and 5 (asserting that financial institutions which would otherwise be covered as "health care clearinghouses" under HIPAA are exempt under Section 1179) *available at* http://www.hipaabanking.org/MoFo_final.PDF

[46] It is not clear that the MMA implicitly repeals the earlier-enacted Section 1179, since the MMA does not explicitly provide that all prescription drug plans are "health plans" under HIPAA. Rather the MMA and the Proposed Rule more generally require PDP sponsors to abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information. Under the banks' theory they could abide by all federal law regarding privacy while not complying with the Privacy Rule because federal law (Section 1179 of the Act) exempts them from complying with HIPAA. See §1860D-4(i) of the Act (making the provisions of §1852(h) applicable to PDP sponsors); §1852(h) of the Act (requiring MA organizations to establish safeguards to safeguard the privacy of individually identifiable enrollee information) and §201 of the MMA (deeming all references to "Medicare+Choice" to be a reference to "Medicare Advantage and "MA"). Proposed §423.136 provides that the provisions of §422.118 of this chapter apply to a PDP sponsor and prescription drug plan in the same manner as they apply to an MA organization and an MA plan. Section 422.118 provides that a M+C (now MA) organization must abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information.

[47] "Financial services" can potentially include a wide range of financial activities. See for example Section 4(k) of the Bank Holding Company Act which defines financial activities as including (among other things):

- Lending, exchanging, transferring, investing for others, or safeguarding money or securities.
- Insuring, guaranteeing, or indemnifying against loss, harm, damage, illness, disability, or death
- Providing financial, investment, or economic advisory services

[48] Section 1860D-1(b)(4)(B)

[49] HIPAA defines "use" with respect to protected health information as:

> The sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information

45 C.F.R. §160.103.

[50] "Protected health information" includes individually identifiable information that relates to the past, present, or future payment for the provision of health care to an individual and, therefore, includes enrollment data. See 45 C.F.R. 164.501 (defining "protected health information") 160.103 (defining "individually identifiable health information")

[51] 45 C.F.R. §164.501 defines "marketing" as:

> (1) To make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service, *unless* the communication is made:
>
> > (i) To 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 …

[52] Proposed 42 C.F.R. § 423.50.

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