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Stormy Seas: Navigating the Cross-Currents of the Medicare Marketing Guidelines and the HIPAA Marketing Rules

By Jennifer S. Geetter and Anne W. Hance, McDermott Will & Emery LLP, Washington, DC

With the 2008 benefit year underway and strategy development for the 2009 open enrollment period just around the corner, sponsors of Medicare Advantage and Medicare Prescription Drug Plans (collectively, Plan Sponsors) are continuously searching for ways to enhance and improve Medicare beneficiary education and marketing initiatives.[1] Moreover, Plan Sponsors must develop and refine their activities to adjust to an evolving environment that includes (i) a population that is increasingly comfortable with their Medicare Advantage and Medicare Prescription Drug Plan (collectively, Plan) selection and less inclined to switch Plans and Plan Sponsors; (ii) an intensely competitive marketplace; and (iii) heavy regulation and close scrutiny by knowledgeable law enforcement agencies.

Within this environment, the relationship between Plan Sponsors and their network healthcare providers (Providers) is assuming an ever-increasing significance. Providers play an important role in patients' healthcare decisions and have a vested interest in educating their patients on their health insurance options, particularly those that reflect and correspond with the Providers' contractual relationships. Providers also offer to Plan Sponsors a direct and inexpensive entrée to potential enrollees. Additional information about Plans and Plan Sponsors can be useful to patients otherwise unaware of choices that may better suit their needs. But melding Provider-patient relationships with Provider-Plan Sponsor relationships, even with the best interest of the patient at the forefront, poses a number of challenges under the Medicare Marketing Guidelines (Guidelines) and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (Privacy Rule). Together, the Guidelines and the Privacy Rule regulate marketing activities and the use and disclosure of individuals' protected health information (PHI) in connection with these marketing activities.

To further complicate the picture, the Guidelines and the Privacy Rule set forth different, and sometimes inconsistent, requirements for marketing-related activities. How can Plan Sponsors and Providers use and disclose protected health information, undertake marketing activities for potential enrollees, and navigate these overlapping, and potentially conflicting, regulatory schemes? Very carefully.

I. *THE FUNDAMENTALS OF THE REGULATORY SCHEMES AND THEIR POWERFUL UNDERCURRENTS*

Marketing Under the Privacy Rule

While Plan Sponsors and healthcare providers alike have raised concerns generally that their day-to-day exchanges of health-related information has become more cumbersome under the Privacy Rule,[2] the rules for marketing are particularly strict. Marketing is viewed as a somewhat suspect category warranting more careful scrutiny and restriction.[3] Unlike other activities involving the use and disclosure of PHI, such as treatment and payment related activities that can be done with relatively less

fanfare under the Privacy Rule, covered entities wishing to engage in marketing activities have to be particularly precise about the nature of the marketing activities, the specific uses and disclosures of the PHI, and the particular Privacy Rule pathway by which they comply with the Privacy Rule.

The Privacy Rule describes marketing generally as "a communication about a product or service that encourages recipients of the communication to purchase or use the product or service."[4] Exceptions exist, such as one permitting use and disclosure of PHI to promote health-related products or services included in the individual's existing plan of benefits.[5] Thus, Plan Sponsors could use enrollees' PHI to create a mailing list to distribute flyers describing value-added items and services, such as gym membership discounts included in the plan benefit package. However, this exception is not available for marketing to *potential* enrollees that do not have an existing plan of benefits. Moreover, Providers would not be able to rely on this exception to discuss a health-related product or service offered by a Plan Sponsor as the Provider is not the covered entity providing the product or service. If an exception does not apply, and the purpose of communication is to encourage the individual's use of a product or service, the communication is considered marketing and the Privacy Rule's marketing provisions attach.

As a general rule, for a covered entity to engage in marketing, it must first obtain the authorization of the individual to use *or* disclose that individual's PHI in connection with that planned marketing activity. Thus, in most cases, if a Provider or Plan Sponsor wishes to engage in marketing, it must obtain the authorization of an individual prior to the use or disclosure of her PHI in connection with a marketing purpose,[6] unless another Privacy Rule pathway is articulated. This is a high bar because the marketing rules apply *even if there is no disclosure.* For example, if a Plan Sponsor wishes to use PHI of enrollees to develop marketing materials attractive to potential enrollees, even if those marketing materials will not themselves involve the disclosure of PHI, a "use" of PHI has occurred, and the Plan Sponsor must have identified a Privacy Rule pathway permitting that use. Similarly, if a Provider wishes to use an individual's PHI in connection with the marketing of another healthcare product, such as a Plan, the Provider must obtain the individual's authorization or identify an alternate Privacy Rule pathway.

The use and disclosure of PHI in connection with a covered entity's marketing activities also could be permissible if an exception to the definition of marketing is available or if other steps are taken. If the marketing is undertaken in a face-to-face communication (such as an information desk staffed by Plan Sponsor representatives maintained at a healthcare facility) or the communication is limited to distribution of a promotional gift of nominal value, the authorization requirement may not attach.[7] Alternatively, if the covered entity creates a de-identified data set from PHI sources (a healthcare operations activity),[8] and then uses the de-identified data set as its basis for developing the marketing materials, this may represent an acceptable Privacy Rule pathway.

Ultimately, most marketing activities can be undertaken in a Privacy Rule-compliant manner, although the key is to properly structure the activity from the beginning. If the identification of a pathway is not undertaken at the outset, and if the marketing activity is not well-structured at the outset, it can be difficult to adjust midstream.

The Medicare Marketing Guidelines' Regulation of Marketing Activities

The Guidelines present their own set of rules—and limitations—on Plan Sponsors' marketing activities as well as Plan Sponsors' reliance on Providers both to promote Plans and gain access to the Providers' patients. By virtue of their contracts with the Centers for Medicare and Medicaid Services (CMS), Plan Sponsors are subject to the Guidelines, among other regulations and CMS instructions.[9] Any marketing activity to be performed *by or on behalf* of a Plan Sponsor must comply with the Guidelines in addition to other applicable federal laws, such as the Privacy Rule.[10]

The Guidelines delineate between activities that are marketing in nature, meaning activities that "steer or attempt to steer" a potential enrollee to a specific Plan or limited group of Plans, and those activities that are educational because they objectively inform a Medicare beneficiary about Plans.[11] Answering questions about a Plan with objective information, such as the annual deductible or cost-sharing obligations for specific services, likely would be considered to be educating a Medicare beneficiary. Conversely, suggesting that a specific Plan or Plan Sponsor may offer "better coverage" for a Medicare beneficiary, for example based on her specific health conditions, likely would be viewed as marketing the Plan or Plan Sponsor.

Plan Sponsors may undertake all types of educational and marketing activities relating to the Medicare Advantage and Medicare Prescription Drug Benefit Programs generally and their Plans specifically. So long as the Plan Sponsor complies with the Guidelines, participation in health fairs, distribution of brochures and other marketing materials, and newspaper and television advertising all are appropriate Plan Sponsor-initiated

marketing activities. Providers, in contrast, may undertake education activities but are specifically prohibited by the Guidelines from engaging in marketing activities (even if a Privacy Rule pathway could be identified).[12] Under the Guidelines, Providers can identify to their patients the Plan Sponsors with which the Provider contracts and can offer factual information about the Programs and the Plans, but may not suggest or otherwise promote a specific Plan or group of Plans to their patients.

Although the Guidelines distinguish between marketing and education in a way that suggests a bright light exists, in practice, the distinction is murky, making navigating these concepts difficult. This can be particularly true with face-to-face communications when words and messages (both explicit and implicit) may not be as thoughtful or as carefully edited as written communications. Thus, as with the Privacy Rule, how Plan Sponsors and Providers negotiate these nuances depends on the details, and a well-structured activity carefully evaluated at the beginning will help prevent the need for adjustments mid-course.

Rough Waters Ahead?

The Privacy Rule and the Guidelines each present their own challenges that make navigation difficult. In certain instances, the two sets of rules nevertheless merge easily, providing smooth sailing for Plan Sponsors and Providers alike. For example, both the Privacy Rule and the Guidelines permit Providers to display Plan Sponsors' printed marketing materials in the Providers' waiting areas, as there is no use or disclosure of personal information that may trigger the Privacy Rule, and the Guidelines permit Providers to make available to their patients marketing materials for the Plans with which the Provider contracts.

At times more frustrating, though, is that these two regulatory schemes do not necessarily work in concert in every instance. What constitutes marketing under the Privacy Rule, for example, differs from that under the Guidelines, reflecting that these two regulatory schemes were created for different purposes—the Guidelines are concerned about persuasion and avoiding potential confusion and the Privacy Rule about the use and disclosure of information. The Guidelines' definition of marketing arguably is narrower than the Privacy Rule definition, as the former exempts objective presentations of Plans that are educational in nature. However, could a Provider's communication of purely objective information about a Plan be construed as encouraging the purchase of that Plan, and therefore a marketing activity under HIPAA? This example demonstrates the importance of careful planning and execution of marketing activities by Plan Sponsors and Providers alike.

II. *THE CROSS-CURRENTS CREATED BY THE PRIVACY RULE AND GUIDELINES*

The overlap of the regulatory provisions of the Privacy Rule and the Medicare Marketing Guidelines and the distinction between marketing and educational activities necessitate that Plan Sponsors and Providers evaluate every potential step and component of marketing activity to determine whether the Privacy Rule and/or the Guidelines are triggered. The following illustrative examples of several common activities—and potential pitfalls—reflect the need for this careful analysis.

In-Person Communications

A straightforward example of the potential discrepancy in the Privacy Rule's and Guidelines' approach to marketing, and the importance of careful planning, is in-person communications about a Plan.

The Privacy Rule's marketing rules include an exception for information relayed face-to-face. Such communications do not constitute marketing and therefore do not require prior, written authorization. Consider a Plan Sponsor representative maintaining a marketing booth at a long term care facility, with the facility's permission, to meet the residents and their families and share information about the Plan. This action likely would not constitute marketing under the Privacy Rule as any interactions with patients would be through in-person conversations, and there is no other use or disclosure of PHI.[13]

The Guidelines, however, place significant limitations on these types of marketing activities because of the concern that a patient (or his family) could be inappropriately influenced by a perceived endorsement by the Provider or a misunderstanding that a Plan marketing pitch suggests enrollment is a pre-condition to care. Although maintenance of a booth in a provider location is permitted, the Guidelines specify that such marketing may occur only in common areas, such as reception areas and cafeterias, and not in areas where patients receive or wait to receive healthcare services.[14] How each provider facility is set up, and what is considered a common area versus a patient waiting area, of course, must be assessed on a facility-by-facility basis.

The end result with respect to in-person communications is that

although the Privacy Rule seems less restrictive regarding the activities themselves, the Guidelines impose more limitations stemming from concern of implicit endorsements, potential misunderstanding, and inappropriately aggressive marketing towards a more vulnerable population. Plan Sponsors, in designing and maximizing their marketing opportunities permitted under the Privacy Rule, must be aware of the Guidelines' restrictions with respect to the same. Providers, similarly, may have steered clear of the Privacy Rule as there is no use nor disclosure of PHI, but nonetheless must take care that their patients are protected from marketing activities that may violate the letter—or spirit—of the Guidelines.

Purchased Marketing Lists

The analysis regarding the use of purchased marketing lists is the exact opposite of that with respect to in-person communications, reflecting how the regulatory schemes can so easily diverge, reverse, and complicate Plan Sponsors' marketing efforts.

Plan Sponsors often rely on marketing lists to reach potential enrollees, particularly when breaking into new geographic service areas. As the Guidelines permit Plan Sponsors to engage in mailings with few restrictions,[15] a Plan Sponsor could purchase mailing lists (or use its own, existing mailing lists) to reach out to potential enrollees with minimal risk of violating the Guidelines.

Under the Privacy Rule, however, there is some debate about whether a covered entity is bound to the marketing provisions if it uses a marketing list developed by a non-covered entity. For example, if a Plan Sponsor purchases a list of names and addresses of people over the age of 65 from a non-covered entity company, is this information protected in the same way as information generated by the covered entity as PHI? Although names and addresses are among the identifiers that transform health-related information into PHI subject to the Privacy Rule,[16] the reason the information was originally collected could influence its regulatory status. PHI is a subset

To further complicate the picture, the Guidelines and the Privacy Rule set forth different, and sometimes inconsistent, requirements for marketing-related activities.

of Individually Identifiable Health Information, which is defined as "information . . . collected from an individual and . . . is created or received by a . . . health plan . . . *and* 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 the past, present or future payment for the provision of health care to an individual" that could identify that individual.[17] If a for-profit survey organization collected information such as name, address, and age and a Plan Sponsor "receives" the information by purchasing the data set, is this information, which does not relate to past, present, or future health or reimbursement for treatment, still considered protected?

Some Plan Sponsors may conclude, after reviewing the particular source of the data set to be used, that their marketing activities are not subject to the Privacy Rule because the information used does not include PHI. However, other Plan Sponsors may take the position that they must, or should, abide by the same rules that would apply if the information purchased from the survey organization had been obtained through general payment transactions. Similarly, some Plan Sponsors may be sensitive to the potential optics (and operational challenges) of having different data sets subject to different use and disclosure rules. As such, a Plan Sponsor must carefully evaluate its use of information, regardless of the original source or the basis for its collection. Unless the Plan Sponsor has a sophisticated system for tagging the data to identify data sets subject to the authorization requirement and data sets that may not be subject to the authorization requirements, it may have difficulty tracking the data and using it appropriately.

The use of purchased mailing lists reflects how the Privacy Rule can create significant risks and compliance requirements without triggering comparative concerns under the Guidelines. Moreover, this example—and the different analysis than that which emerges in relation to in-person communications—reflects the complicated nature of the regulatory schemes and the difficulty navigating both in the pursuit of effective marketing activities.

Provider Leads on Potential Enrollees

Provider leads of individuals potentially interested in enrolling in a Plan requires yet another variation of the analysis under both the Privacy Rule and the Guidelines.

The Privacy Rule generally requires that covered entities obtain an indi-

vidual's written authorization to use or disclose PHI for marketing purposes. The covered entity's activities undertaken to obtain the individual's written authorization are activities "relating to the implementation of and compliance with" HIPAA and therefore are recognized "health care operations" activities under the Privacy Rule.[18] Thus, from a Privacy Rule standpoint, there are three distinct steps that must be analyzed: first, the *use* of PHI to identify those individuals from whom the covered entity wishes to seek authorization to use/disclose PHI; second, the *use* of PHI to contact these individuals and obtain their authorization; and third, *use and/or disclosure* of PHI as described in the authorization.

Consider a scenario where a Plan Sponsor asks its Providers to share the names and contact information (i.e., to disclose PHI) of patients who may be eligible to enroll in one of the Plans. The Provider, recognizing that the Privacy Rule prevents her from sharing the requested PHI with the Plan Sponsor without the patient's prior, written authorization, undertakes to identify each over-65 patient and contact them to obtain authorization to share PHI with the Plan Sponsor. The limited acts of (i) identifying those individuals from whom an authorization must be obtained and (ii) seeking and obtaining that authorization both are likely encompassed within the Provider's healthcare operations. Once authorization is received, the Provider may disclose the information to the Plan Sponsor and the Plan Sponsor may use the information to market its Plans to the individual as described within the scope of authorization.

The line between the contained activity of obtaining an authorization and participating in the marketing activity itself is a fine one that easily blurs. The example above assumes that the Provider does not assess the desirability of particular patients as marketing targets, but contacts every patient over the age of 65. In addition, the authorization presumably does not highlight the benefits of the particular Plan; in other words, the authorization does not do double duty as a marketing document itself. These steps, together, underscore that the identification of individuals and the obtaining of the authorization are done solely in furtherance of the Provider's healthcare operations. In contrast, any effort by the Provider to "screen" patients—to identify those most desirable to the Plan Sponsor or to determine the likelihood that the individual would be receptive to and/or interested in a Plan Sponsor's marketing pitch—likely would be viewed as outside the scope of the Provider's healthcare operations. The Provider's action could be viewed as more akin to marketing activities (and restricted under the Privacy Rule) because the patient "screenings" would be conducted on behalf of the Plan Sponsor's marketing initiative, rather than in furtherance of the Provider's limited healthcare operations needs.

In addition to potential financial penalties or other intermediate sanctions, Plan Sponsors and Providers face significant reputational risks for perceived or actual Privacy Rule

Thus, although the Provider could, as a healthcare operations task, seek written authorization to disclose PHI from *every* Medicare-eligible patient, the Provider likely could not further review the information of this group of patients (e.g., based on insurance coverage, health status, or other characteristic) to identify those individuals to whom the Plan Sponsor would like to market its Plans. Such "screening" activities by Providers would be permissible under the Privacy Rule only if the patient's written authorization to perform such a screening had been obtained beforehand.

The analysis under the Guidelines, and the permissibility of the Provider's activities, similarly depends on the scope of the activities. The Guidelines permit Providers to pass along to Plan Sponsors leads on potential enrollees, so long as the disclosure complies with the Privacy Rule.[19] When obtaining patients' authorizations, however, the Provider must be careful to not promote a Plan or Plan Sponsor such that the communication is viewed as marketing on behalf of a Plan Sponsor.

In the circumstances described above, the Provider's communication to patients about the authorization's purpose may be educational, rather than marketing, because the Provider is intending to educate patients about the availability of Plans in which the patients may be interested. However, one also could argue that the Provider's mere act of reaching out to a patient on behalf of only one Plan or Plan Sponsor is an implicit endorsement of that Plan or Plan Sponsor and therefore more akin to marketing than education. A neutral communication in tone and content could be the safest route for the Provider (even more so if the communication

references all of the Plans or Plan Sponsors with whom the Provider contracts), although this obviously is less appealing to Plan Sponsors that would prefer a more unique, Plan/Plan Sponsor-specific message.

The analysis—and arguably the permissibility—shifts if the Provider screens patients before initiating the outreach. Neutral screening, such as reviewing patient files to identify all of the patients with diabetes that would be eligible to enroll in a Special Needs Plan for diabetic patients, would closely align with the educational purpose of the authorization and disclosure to the Plan Sponsor. Screening for specific characteristics that could suggest a greater interest in a particular Plan or type of Plan or greater likelihood of enrolling would cross the line into marketing.

In this example, the Privacy Rule and Guidelines take a similar approach to both the action of screening patients and the patient outreach. Providers may act in both instances so long as they remain objective and neutral both with respect to identifying the pool of potential recipients and when conducting the outreach itself.

Provider Affiliation

In contrast to the previous example, communication of Provider affiliations may represent an example of synergy of the different perspectives of the Privacy Rule and the Guidelines.

The Guidelines permit Providers to communicate their affiliations through various mechanisms. Announcements of a new affiliation distributed by mail or email, for example, may identify only the Plan with which the Provider now contracts, although such announcements may be distributed only once. Subsequent communications must identify all of the Plan Sponsors with which the Provider contracts. Displays, banners, and other communications (both at the Provider's location as well as mailings, etc.) similarly must identify all of the Plan Sponsors with which the Provider contracts, so as to avoid any suggestion of a Plan or Plan Sponsor endorsement.

Although it would not apply to banners, posters, and other displays that do not involve the use or disclosure of PHI, the Privacy Rule is implicated in mailings to patients announcing a new Plan affiliation when patient PHI—in this case, mailing addresses—is used to generate the mailing. The question becomes how this activity should best be understood under the Privacy Rule:

- Is such an announcement marketing of the Plan because the Provider is "promoting" a product or service offered by a third party?
- Is the announcement describing a new payment mechanism for the Provider's own products and services and therefore carved out of the definition of marketing?
- Is the announcement part of the Provider's "care coordination" activities, a subset of the Provider's healthcare operations, because the Provider is assisting in coordinating patients' care by informing them of the Plans with which the Provider contracts?

The Privacy Rule and interpretive guidelines make clear that a Plan could inform its enrollees of the physicians participating in its network[20] because this activity is excluded from the definition of marketing. The Privacy Rule and guidance are less clear as to whether a *Provider* could rely on the same exception to announce a new payor for the Provider's activities or the care coordination pathway to notify her patients that she now participates in a particular Plan, although there is strong support for this position.[21] Similar questions exist regarding Provider-initiated announcements of the end of a Plan-Provider affiliation.

The U.S. Department of Health and Human Services' Office for Civil Rights (OCR) has not addressed these examples of Provider-originated communications. If the Plan Sponsor is initiating or paying for the Provider's mailing, a conservative approach suggests the activity could be construed as marketing of the Plan by the Provider, thereby necessitating that the Provider obtain patients' prior written authorization before *using* their mailing address in connection with the marketing activity. Absent Plan Sponsor-initiation or payment for the Provider mailing, the Provider should consider all of the facts and circumstances of the mailing to identify the most appropriate Privacy Rule pathway.[22]

* * * * *

What the foregoing examples illustrate is that marketing activities need to be plotted carefully to identify the applicable Privacy Rule pathway and Guidelines pathway for each twist and turn.

III. POTENTIAL PENALTIES

There are very few marketing activities that Plan Sponsors and Providers are expressly prohibited from undertaking. Rather, the Privacy Rule and the Guidelines, both individually and in combination, require that the parties take care to plot their course and ensure team compliance with the activities, including their limitations. Many marketing activities permitted under the Guidelines require a written authorization—this is an enormous operational chal-

lenge, but the potential consequences may be more troublesome.

The potential penalties associated with violations of the Privacy Rule—including unauthorized use and disclosure of PHI to a third party—would entail the risk of civil money penalties (CMPs) and criminal penalties, such as monetary fines and imprisonment. The OCR may impose CMPs on a "covered entity" for violations of the Privacy Rule, although the CMPs may not exceed $100 per violation or $25,000 for identical violations in a calendar year.[23] Criminal penalties may be imposed on any person who knowingly and in violation of the Privacy Rule obtains or discloses PHI, including monetary penalties of up to $50,000, imprisonment for up to one year, or both. If the offense "is committed with the intent to sell, transfer or use" PHI "for commercial advantage," the monetary penalty can be increased up to $250,000 and the term of imprisonment can be extended to 10 years.[24]

Unlike the Privacy Rule, by which the person or entity that uses or discloses information improperly is the "bad actor," the Guidelines are explicit that it is the Plan Sponsor that will be accountable for violations of the Guidelines. Thus, a Provider that inappropriately markets a specific Plan could lead to CMS imposing sanctions on the Plan Sponsor. CMS has the authority to impose CMPs on Plan Sponsors in amounts ranging from $10,000 to $25,000 per violation, depending on the nature of the activity. Intermediate sanctions in the form of suspension of marketing activities, enrollment, and/or payment as well as contract termination, may be imposed in addition to or instead of CMPs.[25] Plan Sponsors also should be aware that there appears to be some risk that CMS would seek to bootstrap on an alleged violation of the Privacy Rule as a violation of a Plan Sponsor's contract with CMS, even if OCR did not pursue the allegation of improper use of disclosure of PHI, on the grounds that compliance with HIPAA is a contractual obligation.

Although the Guidelines distinguish between marketing and education in a way that suggests a bright light exists, in practice, the distinction is murky, making navigating these concepts difficult.

In addition to potential financial penalties or other intermediate sanctions, Plan Sponsors and Providers face significant reputational risks for perceived or actual Privacy Rule violations. In the past year, there have been several high-profile government and private sector instances of inadvertent disclosures, raising the public's alarm about how and by whom their health information is used.[26] A Plan Sponsor wishing to compete in a crowded marketplace and reassure existing enrollees of, and highlight for potential new enrollees, the Plan Sponsor's commitment to confidentiality could experience a significant set back if there was public exposure regarding improper marketing practices. Unlike mistakes that occur with treatment or payment—which offer benefit to the covered entity and individual alike—marketing is truly for the benefit of the marketer. Thus, the reputational effect of impermissible uses and disclosures could be particularly strong because the public may assume that it was corporate profits that interfered with conscience.

IV. A FEW QUESTIONS TO CHECK YOUR MARKETING "COMPASS"

Ultimately, Plan Sponsors and Providers planning marketing activities should ask themselves several questions:

- What is the marketing activity to be undertaken?
- Is the activity permissible under the Guidelines, and do any limitations apply?
- If the Guidelines permit the activity, what are the specific expectations of each party involved? For example, what is expected of the Provider? Plan Sponsor?
- For each activity undertaken by a covered entity, be it a Plan Sponsor or Provider, will PHI be used or disclosed? If so, how?
- How Plan/Plan-Sponsor-specific is the marketing? Is it targeted to all individuals over 65 years old who live in a geographical market, or is insurability and other healthcare characteristics also under evaluation?
- Is the marketing activity in person? If no, what is the Privacy Rule pathway for this use or disclosure?
- Has the Plan Sponsor provided adequate training to its employees—including Providers and agents—so they can appropriately answer questions?

By chartering a course prospectively, Providers and Plan Sponsors can work together, consistent with the Privacy Rule and the Guidelines, to prepare for the upcoming open enrollment season without running aground on rocky shoals.

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1 The Medicare Marketing Guidelines apply to sponsors of Medicare Advantage (MA) Plans, Medicare Advantage-Prescription Drug (MA-PD) Plans, stand-alone Medicare Prescription Drug Plans (PDPs) as well as 1876 cost plans. This article focuses on marketing activities by MA Plans, MA-PD Plans, and PDPs, although it is not intended to exclude the applicability to 1876 cost plans.

2 Patrick Howington, *Privacy Rules To Alter Way Health-Care Pros Do Business; Disclosure Of Data Limited To Those Who Need To See It,* Louisville, Ky. Cour. J., Apr. 13, 2003, at 1E; Patricia V. Rivera, *Changes To Privacy Law Start To Hit Physicians; Cost Restrictions Worry Some Providers,* Dallas Morning News, July 8, 2001, at 14L; Michelle Derus, *New Privacy Paperwork Confuses; Many Find Notices' Language Frightening, Not Empowering,* Milwaukee J. Sent., May 12, 2003, at 01D; Andy Dworkin, *Health Industry Comes To Grips With Federal Patient-Privacy Law,* Sun. Oregonian, Mar. 12, 2006, at D01; Greg Groeller, *Medicaid Reimbursements Require HIPAA Compliance,* Orlando Sent., Sept. 8, 2003, at CFB; Karen J. Bannan, *Rules On Patient Privacy Force Companies To Seek New Ways To Distribute Samples And Information,* N.Y. Times, July 30, 2003, at C1.

3 Standards for Privacy of Individually Identifiable Health Information Part II, 65 Fed. Reg. 82462, 82493 (Dec. 28, 2000) (to be codified at 45 C.F.R. pts. 160 and 164). Standards for Privacy of Individually Identifiable Health Information, Part V, 67 Fed. Reg. 53182, 53187-53188 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160 and 164). Note, *see also* the general discussion of marketing at 53187.

4 45 C.F.R. § 164.501.

5 Additionally, exceptions exist for other types of communications, including communications regarding (i) entities participating in a healthcare provider network or health plan network; (ii) case management or care coordination; (iii) alternative treatments, therapies, healthcare providers, settings of care or other treatment; (iv) face-to-face communications; and (v) promotional gifts of nominal value. *See* 45 C.F.R. §§ 164.501, 164.508. Some of these exceptions are described in further detail in this article.

6 45 C.F.R. § 164.508(a)(3)(i).

7 45 C.F.R. § 164.508(3)(i)(A-B).

8 45 C.F.R. §§ 164.501, 164.502(d).

9 42 C.F.R. §§ 422.80, 423.110.

10 Centers for Medicare and Medicaid Services, *Medicare Marketing Guidelines,* p. 122 (Aug. 25, 2006) (Guidelines), *available at* www.cms.hhs.gov. Please note that as of the date of publication of this article, CMS has issued a proposed rule that would, among other proposed changes, create a new subpart of the Medicare Advantage and Medicare Part D regulations (Parts 422 and 423 of Title 42 of the Code of Federal Regulations, respectively) that would establish new regulatory standards for marketing Medicare Advantage and Part D Plans. *See generally* Centers for Medicare and Medicaid Services, "Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs; Proposed Rule," 73 Fed. Reg. 28555 (May 16, 2008). Additionally, CMS has indicated its intent to issue revised Medicare Marketing Guidelines, presumably which would reflect any regulatory changes adopted through the corresponding Final Rule.

11 *Id.* at pp. 6, 8.

12 *Id.* at p.123.

13 45 C.F.R. § 164.508(3)(i)(A); § 164.514(e). The legislative history indicates that the Department did not believe the typical restrictions on marketing would be "practicable" for face-to-face communications or that involved nominal value products.

14 Guidelines, *supra* note 10, at p.124

15 The Guidelines specify certain requirements relating to the format and content of marketing brochures, such as the inclusion of certain language in marketing brochures and the font and typeface of the materials. *See* Guidelines, *supra* note 10, at p. 22.

16 45 C.F.R. § 164.514(b)(2)(A), (B).

17 45 C.F.R. § 160.103 (emphasis added).

18 45 C.F.R. § 164.501.

19 Guidelines, *supra* note 10, at p. 125.

20 Office for Civil Rights Marketing (OCR) Guidance, revised April, 2003, noting that it is not marketing to make a "communication . . . 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, including communications about . . . .The entities participating in a health care provider network or health plan network."

21 *See, e.g.,* the preamble to the Final Privacy Rule stating that it would not be marketing for a covered entity to describe a "product or service, or payment for a product or service" provided by that covered entity, including whether a "provider is part of a network or whether (and what amount of) payment will be provided with respect to the services of particular providers." The preamble states that the purpose of this exception "expresses our intent not to interfere with communications made to individuals about their health benefits." 65 Fed. Reg. 82462. *See also* the OCR Marketing Guidance, revised April, 2003, confirming that a "communication is *not* 'marketing' if it is made for case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.").

22 This analysis does not take into account any contractual obligations or prohibitions that may apply to a Plan Sponsor or Provider.

23 45 C.F.R. §§ 160.400-426.

24 42 U.S.C. § 1320d-6. *See also* 42 U.S.C. § 1320d-6. *Numbers at a Glance,* HIPAA Compliance and Enforcement, U.S. Department of Health and Human Services, March 31, 2008, *available at* www.hhs.gov/ocr/privacy/enforcement/numbersglance0308.html. *See* chart *Investigated Resolutions,* April 14, 2003 to December 31, 2007. The numbers increased from 339 in 2003 to 2,199 in 2007.

25 42 C.F.R. pt. 422, subpt. O; 42 C.F.R. pt. 423, subpt. O.

26 Sarah Rubenstein, *Are Your Medical Records at Risk? Amid Spate of Security Lapses, Health-Care Industry Weighs Privacy Against Quality Care,* Wall St. J., Apr. 29, 2008, at D1; Charles Ornstein, *Ex-Worker Indicted in Celebrity Patient Leaks; Former Employee of UCLA Medical Center Is Accused of Selling Data To the Media,* L.A. Times, Apr. 30, 2008, at Part A Pg. 1; John Eligon, *Worker Charged in Hospital File Thefts,* N.Y. Times, Apr. 13, 2008; Carolyn Park, *Nurse Guilty of Privacy Violation 1st Conviction in State On '03 Law,* Ark. Democrat-gazette, Apr. 17, 2008.