

**AHLA**

**Beneficiary Inducements in an Evolving Market:  
Assessing the Risks, Understanding the Benefits  
and Drawing the Lines**

*A Publication of the American Health Lawyers  
Association Public Interest Committee*

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# Beneficiary Inducements in an Evolving Market: Assessing the Risks, Understanding the Benefits and Drawing the Lines

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## I. INTRODUCTION

The Public Interest Committee of the American Health Lawyers Association (“**AHLA**”) sponsored a “Convener on Inducements to Beneficiaries” (“**Convener Session**”) held on October 2, 2013 in Washington D.C. AHLA’s public interest activities are intended to promote a better understanding of health law issues and to encourage a constructive dialogue among members of the industry, all branches of government, academics, patients, and consumers. Over the past few years, the AHLA Public Interest Committee has addressed a range of significant issues, including emergency preparedness, corporate compliance, corporate governance, the federal physician self-referral or Stark Law and the Self-Referral Disclosure Protocol.

The purpose of the Convener Session was to provide a forum for a candid discussion of the federal Anti-Kickback Statute’s and the Civil Money Penalty Law’s prohibitions on inducements to beneficiaries (referred to collectively as the “**Beneficiary Inducement Prohibitions**”) and to consider what, if any, changes to the law or additional guidance from the government might be beneficial in light of both the current structure of the health care delivery system and the implications of health care reform. Participants endeavored to consider the issues from both an industry and government perspective.

The Convener Session participants represented a broad range of viewpoints, including in-house counsel, attorneys in private practice who work primarily with hospitals and/or physicians, attorneys representing pharmaceutical industry and long term care clients, counsel engaged in patient advocacy including representation of AARP and attorneys now in the private sector who were formerly involved in government service on behalf of both regulatory and enforcement agencies. Representatives from the Centers for Medicare and Medicaid Services (“**CMS**”), Centers for Medicare & Medicaid Innovation (“**CMMI**”) and the Office of the Inspector General (“**OIG**”) for the Department of Health and Human Services attended the Convener Session to listen to the discussion but did not participate.<sup>1</sup>

The Convener Session prompted a vigorous discussion of policy issues and practical considerations. The purpose of this White Paper is to provide a summary of that discussion and the resulting proposals for changing either Beneficiary Inducements Prohibitions or the manner in which they are administered or enforced. To put the discussion in context, this White Paper includes a brief overview of the Beneficiary Inducement Prohibitions and their regulatory history.

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<sup>1</sup> A list of all Participants and the government attendees is attached as Exhibit 1.

## II. OVERVIEW OF THE LAW

### A. The Anti-Kickback Statute

Under the federal Anti-Kickback Statute (“AKS”),<sup>2</sup> it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by federal health care programs. “Remuneration” is defined broadly as meaning anything of value, directly or indirectly, overtly or covertly, in cash or in kind. Violation of the AKS is a felony with maximum fine of \$25,000 and imprisonment up to five years, or both. Conviction results in automatic exclusion from federal health care programs. The OIG may initiate administrative proceedings based on a violation of the AKS and impose Civil Monetary Penalties (“CMPs”) or exclude the offending party from federal health care programs.

The AKS includes both statutory exceptions and regulatory safe harbors. The safe harbors relevant to a discussion of Beneficiary Inducements include: (1) waiver of beneficiary coinsurance and deductibles by hospitals and selected other providers,<sup>3</sup> or (2) increased coverage, reduced cost sharing or reduced premiums offered by health plans.<sup>4</sup>

### B. The Civil Monetary Penalties Law

The Civil Monetary Penalties Law (“CMP Law”)<sup>5</sup> includes a prohibition against offering or transferring remuneration to a Medicare or State health care program beneficiary that the person knows or should know is likely to influence beneficiary selection of a particular provider, for which payment may be made in whole or part by Medicare or State health care program. “Remuneration” is defined as any transfer of items or services for free or other than fair market value. Violation of the Beneficiary Inducement CMP may be penalized by a civil fine of \$10,000.00 per item or service. In addition, the OIG may initiate administrative proceedings to exclude the offending party from federal health care programs.

Listed below are several exceptions to the Beneficiary Inducement CMP prohibition.<sup>6</sup>

- Nominal Value Exception: Incentives that are only nominal in value are not prohibited by the CMP Law.
  - “Nominal” is defined as no more than \$10.00 per item and \$50.00 total per year.<sup>7</sup>
- Preventive Care Exception: Incentives given to individuals to promote the delivery of preventive care services where delivery is not tied to the provision of other services reimbursable by federal health care programs are not prohibited by the CMP Law.<sup>8</sup>

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<sup>2</sup> 42 U.S.C. § 1320a-7b.

<sup>3</sup> 42 C.F.R. § 1001.952(k).

<sup>4</sup> 42 C.F.R. § 1001.952(l).

<sup>5</sup> 42 U.S.C. § 1320a-7a.

<sup>6</sup> Note that none of these exceptions permits providing cash or cash equivalents to a beneficiary.

<sup>7</sup> 65 Fed. Reg. 24400, 24410-24411 (Apr. 26, 2000) (preamble to the final rule on the CMP Law).

<sup>8</sup> See 42 C.F.R. § 1003.101.

- “Preventive care service” is any prenatal service or post-natal well-baby visit or a specific clinical service described in current U.S. Preventive Services Task Force’s Guide to Clinical Preventive Services.<sup>9</sup>
- Copayment Waiver: “Remuneration” under the CMP Law does not include— The waiver of coinsurance and deductible amounts by a person, if:
  - The waiver is not offered as part of any advertisement or solicitation;
  - The person does not routinely waive coinsurance or deductible amounts; and
  - The person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection effort.<sup>10</sup>
- Assistance to Needy: The offer or transfer of items or services for free or less than fair market value does not constitute “remuneration” under the CMP Law if:
  - The items or services are not offered as part of any advertisement or solicitation;
  - The items or services are not tied to the provision of other services reimbursed in whole or in part by Medicare or Medicaid;
  - There is a reasonable connection between the items or services and the medical care of the individual; and
  - The person provides the items or services after determining in good faith that the individual is in financial need.<sup>11</sup>
- Retail Rewards Exception: Retail rewards do not constitute “remuneration” under the CMP Law if:
  - The rewards consist of coupons, rebates, or other rewards from a retailer;
  - The rewards are offered or transferred on equal terms available to the general public, regardless of health insurance status; and
  - The offer or transfer of the rewards is not tied to the provision of other items or services reimbursed in whole or in part by the Medicare or Medicaid programs.<sup>12</sup>
- Remuneration Promoting Access: Any remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs does not constitute “remuneration” under the Beneficiary Inducement CMP.<sup>13</sup> It is unclear whether this exception is self-effectuating or if the OIG must issue an implementing regulation.

<sup>9</sup>

Id.

<sup>10</sup>

65 Fed. Reg. 24400, 24403-24404 (Apr. 26, 2000) (preamble to the final rule on the CMP Law).

<sup>11</sup>

42 USC§ 1320a-7a(i)(6) (H).

<sup>12</sup>

42 USC§ 1320a-7a(i)(6) (G). See Section 6402(d)(2)(B) of the Patient Protection and Affordable Care Act (P.L. 111–148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111–152, 124 Stat. 1029).

<sup>13</sup>

42 USC§ 1320a-7a(i)(6) (F). See Section 6402(d)(2)(B) of the Patient Protection and Affordable Care Act (P.L. 111–148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111–152, 124 Stat. 1029).

### **III. ASSESSING THE RISKS**

The Beneficiary Inducement Prohibitions are intended to prevent the following moral hazards:

- Overutilization which inappropriately increases federal and state health care program (collectively referred to as “Programs”) costs and potentially harms beneficiaries;
- Improperly influencing patient treatment decisions by offering items or services of value;
- Skewing patients’ selection of providers by shifting focus to the value of the inducement as opposed the value or quality of the health care services; and
- Creating a competitive disadvantage for providers who cannot afford or choose not to provide beneficiary incentives.

In defining the parameters of the Beneficiary Inducement Prohibitions, the government has struggled to assess the extent to which a specific inducement or incentive creates a risk of harm to the Programs, patients or the delivery system. On occasion, Congress has identified specific practices where either the risks of the inducement were too great (i.e., routine waivers of copayments) or outweighed by other factors (i.e., promotion of preventive care). For the most part, however, the enforcement agencies and providers have been left to their own devices to assess the risks of specific programs, inducements or incentives. The Participants in the Convener Session acknowledged the challenges faced by the government and the difficulty of determining when a particular program posed a significant risk of harm. On the other hand, there was a strong sentiment that clearer guidance in this area will enable providers to implement beneficiary inducements that assist the Programs, improve patient care and promote the goals of health care reform.

### **IV. UNDERSTANDING THE BENEFITS**

Providers offer things of value to beneficiaries for a variety of reasons. In many instances, the “inducement” or “incentive” results in tangible benefits to the patient, the Programs or both. As illustrated above, beneficiary incentives can:

- Promote community and individual awareness of health risks and resources;
- Promote access to care;
- Promote patient adherence to treatment regimens;
- Reduce cost of care (both in a specific encounter and in the aggregate);
- Coordinate care delivery;
- Enable providers to meet performance or certification standards;
- Engage at-risk populations;
- Back stop a failing social safety net; and
- Provide invaluable beneficiary education.

Participants in the Convener Session generally agreed that the degree to which a particular incentive program will improve the quality of care, promote public health goals, reduce costs, educate beneficiaries, and/or enhance a provider’s performance should be taken

into account by the government when determining whether the incentive program should be permitted.

## V. ILLUSTRATIVE INDUCEMENTS AND INCENTIVES

The Beneficiary Inducement Prohibitions potentially apply to a wide range of conduct and a host of common practices in the industry. The Convener Session discussion addressed: (1) wellness programs/health fairs/health promotion; (2) Patient Assistance Programs; (3) transportation/lodging assistance; (4) promotion of adherence to treatment regimens; (5) incentives to remain in network; (6) readmission reduction; (7) end of life–palliative care programs; and (8) payment of premiums for Qualified Health Plan (“QHP”) exchange enrollees.

Set forth below are short summaries of specific programs or practices discussed during the Convener Session:

- Wellness Programs Including Free Screening Services, Seminars and Health Fairs: The discussion focused on the way health care has changed since the beneficiary inducement guidance was promulgated. Participants noted that there is greater emphasis on wellness and managing chronic diseases as well as better empirical data on management and wellness techniques. Participants advocated gathering more empirical evidence about programs to determine if they actually work in improving and managing care. The data demonstrating efficacy should be used to support the imposition of fewer restrictions on health fairs and wellness programs. One participant noted that informational seminars are much less of an inducement today because of the availability of health and wellness-related information on the internet. With respect to health fairs, there was discussion about the distinction between providers offering screening services at a health fair and health fair attendees requesting follow-up services from a provider at a health fair. Participants noted that health fairs and wellness programs allow for communication between providers and patients and may actually reduce mistrust of providers in some populations. The group discussed safeguards that may reduce the risk of fraud and abuse including a health fair or wellness program host supplying a list of follow-up resources and available community alternatives instead of only promoting its own services. Ultimately, participants agreed that wellness and chronic disease management programs are worthwhile because they could substantially reduce the cost of health care over time. Participants also noted that several OIG advisory opinions provide useful guidance on how to structure screening services to comply with the CMP Law.
- Patient Assistance Programs: Patient assistance programs range from pharmaceutical company programs to promote access to certain medications to providing car seats to needy mothers when they are discharged from the hospital with their newborns. Participants discussed the need to consider the context in which the patient assistance program operates and to recognize that the need for safeguards may vary. One participant noted the particular challenges faced by rural providers operating in communities that do not have other social safety net programs to assist patients in need. That challenge combined with the fact that these providers are serving a predominantly Medicaid or dual eligible population, suggests that the government could clarify the

Beneficiary Inducement Prohibitions in this context without significant risk of program or patient abuse.

Participants also noted the CMS requirement that providers not discharge patients to an unsafe environment. If the patient is homeless, it seems appropriate for the provider to arrange for temporary housing. The group concluded that the industry would benefit if the government could clarify the circumstances under which this type of assistance would not run afoul the Beneficiary Inducement Prohibitions.

- Transportation and Lodging Assistance: Participants noted their confusion as to what safeguards are required for these types of programs. This confusion was attributed to a combination of factors: the government's acknowledgement of the benefits of local transportation programs combined with the absence of a formal regulatory exception and advisory opinions addressing transportation programs that list a multitude of safeguards. Some participants indicated a need for greater clarity as to which safeguards are necessary in order for a transportation program to pass muster.

For transportation programs, participants noted that conditioning access to the benefit based on financial need may not be appropriate because many situations arise where patients with adequate financial resources do not feel well enough to drive, are no longer able to drive themselves, or do not have family members or other transportation options available to take them to their appointments. Participants questioned whether competition through transportation and lodging assistance programs creates a moral hazard if all the providers meet certain quality standards. Participants also questioned the effectiveness of curtailing advertising these programs because this safeguard has no effect on repeat patients who already know of the benefit.

As discussed in more detail in Section VI below, participants noted that the ACA's protection of remuneration which promotes access to care while creating a low risk of harm to patients and the federal health care programs is of particular relevance to patient-related transportation and lodging assistance programs.

- Promotion of Adherence to Treatment Regimen: Participants discussed free apps that provide reminders to take medication, monitor the condition of the patient, and that serve as general health education tools. The group discussed how to value apps, whether it is appropriate to offer apps that are more than nominal value because of the educational benefits, and how to make the apps patient driven. Participants discussed the need for patient education and the proper ways to deliver such education, including whether each patient should have his/her complete patient history available electronically.

Participants provided examples of innovative programs such as those that involve giving cell phones to drug addicts and HIV patients to promote adherence to treatment regimens. These patients are sent reminders via text and if they do not respond to the text within an established time period the cell phone is disconnected. Participants suggested expanding the use of this type of inducement to patients with chronic diseases such as asthma and diabetes. Another program designed to encourage appropriate patient behaviors involves making all patients who adhere to their treatment regimen for a specific time period eligible for a lottery drawing. Those who did not adhere would lose the opportunity to win the lottery prize. One participant noted that behavioral economics studies have established the desire to avoid loss is stronger than the desire to secure a gain. Lottery

programs structured so that the patient will lose the opportunity to participate have been found to be more effective than programs that offer straight financial incentives.

Participants questioned whether the inducements such as the cell phone and lottery programs described above were actually inducements or just better ways to provide care. The group noted that there is greater leeway for inducements that encourage patients to continue treatment as opposed to programs that induce patients to begin a new treatment. Participants noted the lack of clear guidance as to whether such programs are currently permissible.

The Participants also discussed a popular program for monitoring patient behavior that involves providing patients an iPad. The device is used for patient reminders, remote monitoring and other functions during an episode of care but can also be used by the patient for other purposes. The government has voiced concerns about such programs, particularly if the patient is allowed to keep the iPad after the episode of care has ended.

- Incentives to Remain in Network: One participant noted that health plans with narrow provider networks are becoming more common. Such plans are being offered on the Health Insurance Exchanges and in the commercial marketplace. The group acknowledged that health plans' and providers' ability to lower costs improves when size of the network is limited. Despite this, the government has generally taken a dim view of most programs designed to encourage Medicare or Medicaid fee-for-service patients to seek care within a defined network of providers. The ACO fraud and abuse waivers, for example, do not appear to permit incentives to beneficiaries to remain in network. Participants discussed the advantages of permitting ACOs to offer inducements with greater than nominal value to keep patients in the integrated ACO provider network. The use of a lottery program was also discussed as an incentive to remain in network. More specifically, patients who received all of their care for a month from network providers would be eligible for a lottery. Patients who sought care out of network would lose the opportunity to win the lottery prize. One participant suggested that the expected value of a lottery ticket can be determined and it could well fit within the nominal value exception to the Beneficiary Inducement Prohibition. Others questioned how the government would value a lottery ticket and the variables one could consider.
- Readmission Reduction: Participants noted medical providers' responsibilities to promote continuity of care. The group discussed whether patient navigators and other care coordination programs are "inducements" and how to protect adequately against patient steering in such programs. Participants also discussed the educational aspects of navigator/care coordination programs and whether the requirement imposed on hospitals during discharge planning to inform patients about their options in choosing a home health provider should be expanded to other Medicare covered services. Participants emphasized that the amount of the information provided to a patient needs to be manageable and that transparency is essential. Participants supported the proposition that hospital providers should be able to provide incentives or inducements to patients during the 30 day period after discharge given the government's efforts to reduce readmissions by imposing financial penalties. Participants agreed that providers are at financial risk and should be able to provide services to patients post discharge if such services are reasonably related to preventing readmission. Participants also considered expanding



free care coordination services beyond the context of an ACO into a non-ACO setting by implementing the safeguards that allow these programs under the ACO waivers.

- **End of Life – Palliative Care Programs:** Participants discussed how hospitals, home health care agencies, and hospice programs can appropriately incentivize physicians to engage in conversations about palliative care. Such conversations enable patients to understand their treatment options and to make more informed decisions. The value of educating patients about their treatment options is not limited to palliative care or end of life decisions. The participants considered whether patient education could be used in other contexts to safeguard against inappropriate steering or overutilization that might result from a particular beneficiary inducement.
- **Payments of Premiums for Exchange Enrollees:** Participants discussed programs where providers would pay for Health Insurance Exchange enrollees' premiums. This discussion was essentially superseded by the subsequent statements of CMS.<sup>14</sup>

## VI. DRAWING THE LINES

Depending on the context, beneficiary inducements can either improve or undermine the delivery of care. Some inducements have the potential to threaten the integrity of the federal health care programs, increase costs and undermine quality-based provider competition. Other inducements have great benefits, improving access, enhancing patient health, improving coordination of care and reducing inefficiencies. Congress in the ACA adopted a new exception to the Beneficiary Inducement CMP Law that protects any remuneration which promotes access to care and poses a low risk of harm to patients and federal health care programs. To a large extent, the participants in the Convener Session urged the government to adopt an approach to the Beneficiary Inducement Prohibitions consistent with this directive of Congress.

Using the balancing approach suggested by this new exception may permit the government to provide clearer guidance on the range of permissible beneficiary inducements. In determining whether the risk of harm to the federal health care programs has been adequately mitigated, the government should consider the presence, absence or importance of safeguards and benefits such as the following:

- Does the benefit either reduce or have a neutral effect on the cost of care?
- Is the benefit designed so that it will not encourage overutilization?
- Are there limitations on the value of the good or service?
- Is the benefit offered only to those patients with demonstrated financial need?
  - In context is financial need an important safeguard?
- Is the availability of the benefit promoted or advertised?

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<sup>14</sup> See Letter from Kathleen Sebelius, Secretary, Dept. of Health and Human Services, to Rep. Jim McDermott (D-WA) (Oct. 30, 2013): <http://mcdermott.house.gov/images/The%20Honorable%20Jim%20McDermott.pdf>; and Centers for Medicare and Medicaid Services, FAQ, "Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces (Nov. 4, 2013: <http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/third-party-qa-11-04-2013.pdf>).

- In context does the promotion of the benefit increase the risk of program or patient abuse?
- Is the benefit offered only to patients likely to be more lucrative for the provider?
- Is the benefit properly targeted to the population in need?
- Transparency of the benefit and its administration.
- Is the benefit offered in a context where the patient is able to make an informed choice?
- Is the benefit likely to encourage patient adherence to his/her treatment regimen?
- Is the benefit likely to improve the health status of the patient?
- Is the benefit needed to enable the provider to maintain program certification or licensure or to satisfy conditions of participation?
- Does the benefit promote public health and safety?

Participants agreed that it would be helpful to understand the relative importance of each safeguard and benefit and which, if any, of the safeguards are essential. Participants requested clearer guidance particularly regarding those arrangements that the government would not allow regardless of the number of safeguards implemented.

One suggested approach for testing whether a particular beneficiary inducement should be permissible focuses on the program having both a purpose consistent with the goals of the ACA and safeguards appropriate to the context. As illustrated below, this approach involves a two-step process: (1) identifying a legitimate purpose; and (2) determining the relevant safeguards.

### **Step 1: The Purpose**

1. A. Is the purpose of the program or inducement to facilitate patient care or improve access? This can be demonstrated by:

- Offering the benefit to all patients not just those patients likely to be more lucrative to the provider;
- Designing the benefit so that it will not encourage overutilization; and
- Designing the benefit so that it will not adversely affect the patient's ability to make an informed choice.

1. B. Alternatively, does the program or inducement improve the health of beneficiaries and/or the community because it:

- Encourages patient adherence to a treatment regimen;
- Improves the health status of the patient; or
- Improves public health and safety (*i.e.*, vaccines, preventive care, testing).

## **Step 2: Safeguards**

2. A. Is the cost of the program or inducement nominal such that it is:

- Not likely to increase the cost of care; and
- Likely to have a limited effect on the patient's choice of provider?

2. B. Alternatively, is the program or inducement either:

- Administered in a transparent manner and necessary to enable the provider to maintain program certification or licensure; or
- Administered in a transparent manner and properly targeted to patients in need?

Other participants suggested that government guidance in this area should consider empirical evidence about a beneficiary inducement program's capability of achieving its desired outcomes. One participant argued that empirical studies of beneficiary inducements sponsored by either the government or the private sector should be encouraged by policymakers. If appropriate research is conducted it may be possible under some circumstances to condition approval of a particular beneficiary inducement or program upon empirical proof that the program would have a positive effect on influencing patient behavior, lowering costs and/or increasing quality.

Participants noted that patient incentive programs under the respective ACO waiver could result in Medicare patients receiving better treatment than privately-insured patients. The group invited government guidance on the creation of similar patient incentive programs for Medicare and Medicaid fee-for-service patients that include some of the safeguards required by the ACO waiver. In addition, some participants believe that the OIG has demonstrated flexibility in its advisory opinions addressing beneficiary inducements and that the industry should take advantage of the advisory opinion process to obtain better guidance. The group also acknowledged that the advisory opinion process can be time consuming and that any opinion would be limited to the issues posed by the requesting party.

Participants of the Convener Session generally believe that some of the original parameters for the exceptions are outdated. For example, participants agree that the nominal value exception (promulgated in 2002) should be updated to adjust for inflation and that the preventive care exception should be expanded to incorporate chronic disease management.

## **VII. CONCLUSION**

This White Paper is intended to provide our members and the public at large an overview of the discussion at the Convener Session. AHLA hopes that it will also facilitate a constructive dialogue among policy makers, industry participants and the government concerning how the Beneficiary Inducement Prohibitions might evolve in a manner that promotes changes to the health care delivery system to improve quality and access and reduce costs.

## **EXHIBIT 1**

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**Continued ...**

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The following individuals were present during the convener session but did not participate in any of the discussions that took place during the event.

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