



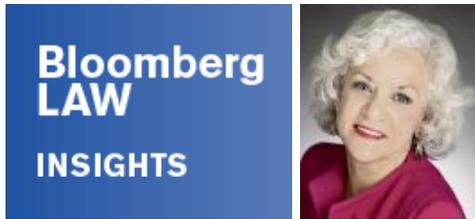
## BNA's Health Law Reporter™

---

Reproduced with permission from BNA's Health Law Reporter, 27 HLR 528, 4/12/18. Copyright © 2018 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

---

## Permissible Beneficiary Inducements



By Alice G. Gosfield

The federal government has long had the statutory authority to impose penalties and exclusion from federal health-care programs against any person who offers or transfers remuneration to a Medicare or Medicaid patient if it is likely to influence the patient to order or receive from a specific provider or practitioner any item or service payable by Medicare or Medicaid. §1128A(a)(5) of the Social Security Act; [42 CFR §1003.1000\(a\)](#). Early interpretation of this authority was set forth in a [Special Advisory Bulletin](#) in 2002. There, providers were permitted to offer to patients gifts of nominal value which were initially restricted to an individual gift with a retail value of no more than \$10 and an annual limit per patient of \$50, now raised to \$15 and \$75. Incentives to promote the delivery of certain preventive care services were allowed. These, however, were interpreted restrictively to be only those services that were either pre-natal or post-natal well baby services or were recognized by the United States Preventive Services Task Force. In federal regulations, the government has liberalized this position considerably, but has also created significant ambiguities.

### Transportation

A safe harbor under the anti-kickback statute allows providers to offer free local transportation to established patients. [42 CFR §1001.952\(bb\)](#). Local means within 25 miles in urban areas and 50 miles in rural areas. The service may not be advertised and must be provided to obtain medically necessary services. An outside transport company may be used, but they may not be paid per patient. If public transport, such as a taxi or bus, is provided, the patient may be given a voucher or may be reimbursed for the expenditure. For protection, any transport must be provided pursuant to a policy which is uniformly applied. The regulators have suggested that criteria such as need might be included or where the patient cannot safely get home from a procedure. They have not limited what the policy might include.

Providers may also offer a free shuttle service which is not limited to established patients, and may also be provided to visitors, family and employees. A shuttle service is defined as a vehicle that runs on a set route on a set schedule. The service may not be advertised; and the same definitions of "local" apply, as well. These are relatively straight-forward protections. Much more gray arises in other regulations.

### Promoting Access to Care

The government's authority to impose civil money penalties and exclusion for improper inducements offers an exception, by regulation, for remuneration which promotes access to care and poses a low risk of harm to patients and federal health-care programs. [42 CFR §1003.110 \(a\) and \(b\)](#). The care to which access is improved must be payable by Medicare or a state health-care program. Items or services that support or help patients to access care or that make access more convenient are protected. Eliminating socio-economic, educational, geographic, mobility or other barriers to access to necessary care, which explicitly includes preventive care are permitted. Three overarching criteria pertain: the inducement must (1) be unlikely to interfere with or skew clinical decision-making; (2) be unlikely to increase cost to federal health-care programs or beneficiaries through overutilization or inappropriate

utilization; (3) not raise patient safety or quality of care concerns. Against that background, the regulators observe that items that promote healthy living, like air conditioners, vacuum cleaners and mattress covers, cannot qualify.

They go on to discuss a wide range of examples of acceptable inducements, including a blood pressure monitoring device, free participation in smoking cessation, nutritional counseling or disease specified support groups and even free babysitting to attend appointments. There are no specific dollar limits. Free dinners, movie tickets or a general purpose debit card are not permitted. While the examples are helpful, they are clearly not dispositive of everything that might be permissible. Developing policies that support any such gifts or donations and especially who in the organization has authority to apply the policies will be important to avoid liability.

### **Financial Need**

An even broader exception is available for patients in financial need, which the regulators do not define. [42 CFR §1003.110 \(a\)\(7\)](#). They say the determination of need must be made in good faith on a case by case basis, looking at external evidence and not merely a representation by the patient that they are in need. They do set forth four principles, all of which must be present for protection: (1) the items or services are not advertised; (2) are not tied to the provision of other items or services reimbursed by Medicare or state health-care programs; (3) there is a reasonable connection between the items or services and the medical care of the individual; and (4) the recipient is in financial need. The regulators expect any provider to make donations pursuant to a formal policy uniformly applied.

Reasonably connected to “care” is broadly construed to include the treatment and management of illness or injury; the preservation of health; or services offered by the medical, dental, pharmacy, nursing and allied health professions. “Reasonably connected” means connected from a medical as well as from a financial perspective. If the incentive is disproportionately large by comparison to the value of the service it would be deemed unreasonable.

The regulators have offered a range of examples of what does and does not qualify for protection. Here the lines are far murkier. Car seats for infants are deemed crucial for patient safety and therefore protected, but free sports equipment to patients who need exercise is not. Providing meal deliveries for a limited time after discharge from a debilitating procedure is fine, but a long-term meal plan subscription is not. Tickets to a sporting event or a gift card for spa for an anxious or depressed patient is not protected, but school supplies or a stroller for patients who attend necessary preventive care appointments is permitted.

### **Conclusion**

Much of what will be permissible depends on facts, circumstances and context. The need to craft practical policies has been made clear, but is not so simple, since it would be virtually impossible to anticipate every possible donation that might occur to someone to give. Establishing a process for making the policy dynamic and achievable will be an important role for lawyers, who will have their own challenges in advising clients in this arena.

---

Alice G. Gosfield is the principal in the national boutique law firm [Alice G. Gosfield and Associates PC](#) in Philadelphia. Her practice has been devoted to health law with a primary emphasis on representing physicians and physician organizations and those who do business with them. She can be reached at [agosfield@gosfield.com](mailto:agosfield@gosfield.com).

Information on an upcoming teleconference on this topic, including inducements by physicians and review of six Advisory Opinions that have addressed inducements, is available at <http://www.gosfield.com/listen/teleconferences>.