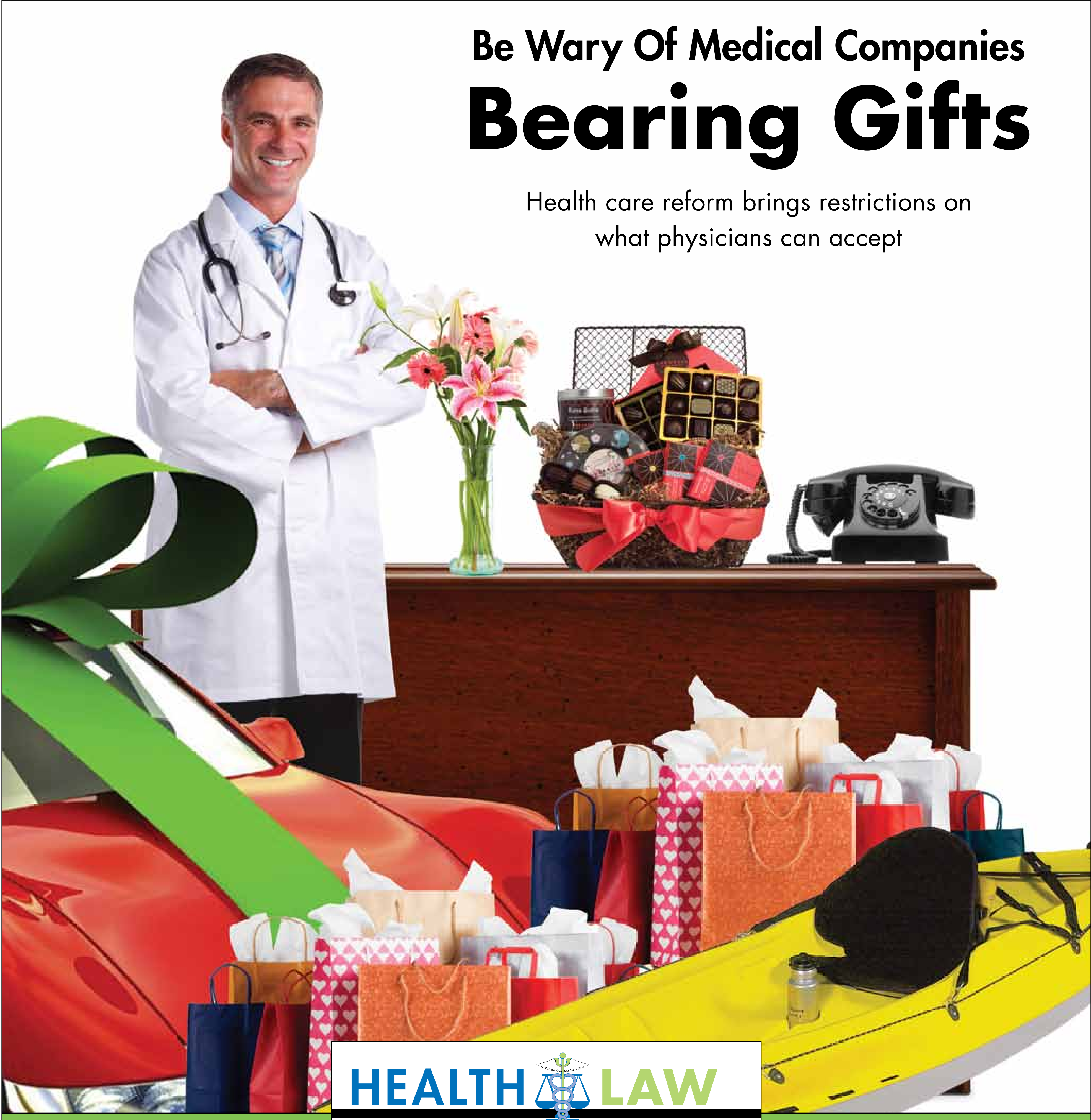
Be Wary Of Medical Companies Bearing Gifts

Health care reform brings restrictions on what physicians can accept



By JOAN W. FELDMAN and WILLIAM J. ROBERTS

For many years, both Congress and numerous states have debated adopting laws which would either prohibit or restrict physicians from receiving gifts and other transfers of value from pharmaceutical, medical device and medical supply companies. Advocates for such laws have argued that when a physician receives gifts or other items of value, his or her judgment becomes clouded and could potentially result in the physician having a conflict of interest.

While many of the legislative efforts, including a 2009 proposal, in Connecticut, languished due to various concerns and opposition from physicians and pharmaceutical, medical device and medical supply companies, the federal health care reform enacted in March of 2010 (the "Affordable Care Act") includes comprehensive disclosure and reporting rules applicable to many participants in the health care and bioscience sectors.

SEE PAGE 17

New Entities Will Coordinate Medicare Coverage

Government releases regulations for Accountable Care Organizations

By PAMELA H. DEL NEGRO and MEAGHAN MARY COOPER

The federal government established the Shared Savings Program in the Patient Protection and Affordable Care Act of 2010 to reduce Medicare costs while improving patient care. Under the Shared Savings Program, which is anticipated to begin in 2012, certain health care entities, providers and suppliers that meet specific eligibility criteria may form "Accountable Care Organizations" or "ACOs" to provide and coordinate medical care for Medicare beneficiaries, and potentially share in cost savings. On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS) released proposed regulations governing the formation and operation of ACOs.

Under the proposed regulations, Accountable Care Organization participants are held accountable for the costs and quality of care provided to Medicare beneficiaries assigned to the ACO. If the ACO holds costs below certain benchmarks and satisfies quality standards established by the federal government, it receives a portion of the savings that it generates, in addition to the "fee-for-service" payments that its providers and suppliers receive from Medicare for services rendered. The government estimates that the Shared Savings Program could potentially generate up to $960 million in savings for the Medicare program over three years.

ACO Requirements

The proposed regulations include numerous requirements relating to the ACO's structure, operation and performance. For example, an ACO must be recognized as a legal entity in the state in which it is established, authorized to do business in each state in which it operates, and have its own taxpayer identification number. Its governing body must have broad responsibility for the ACO's operations and include both ACO participants and at least one Medicare beneficiary served by the ACO. Accountable Care Organization participants must have substantial control of the organization's governing body, and each ACO participant must have proportionate control over governing body decision-making.

ACOs must implement evidence-based guidelines and demonstrate that care is focused on patients and consistent with the federal government's three goals of improved care for individuals, better health for populations, and reduced costs. Examples of "patient-centered" measures include beneficiary surveys, customized plans of care, and open communication with patients about their values and priorities with respect to health care decisions. ACO participants must be subject to performance evaluations and remedial actions, or expulsion, in the event they fail to meet applicable performance guidelines. ACOs will be required to publically report quality performance scores and certain other information required by CMS.

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An Accountable Care Organization must have at least 5,000 Medicare beneficiaries assigned to it. Medicare beneficiaries will be assigned to the ACO in which their primary care providers choose to participate. However, a Medicare beneficiary's assignment to a particular ACO will not prohibit him or her from choosing to seek care from a provider unaffiliated with the ACO.

The proposed rule requires that Accountable Care Organizations agree to participate in the Shared Savings Program for at least three years. While primary care physicians can only participate in one ACO per three-year period, all other ACO providers and suppliers can participate in more than one ACO during any such period.

Shared Savings Payment

An ACO that keeps costs below applicable benchmarks, and in doing so exceeds a set minimum savings rate while meeting the quality and other requirements of the Shared Savings Program, will qualify to receive a shared savings payment. CMS will establish the benchmark for each ACO by determining the per capita Medicare Part A and B expenditures for beneficiaries who would have been assigned to the ACO in any of the prior three most recent years, adjusted for beneficiary health status and demographics, as well as overall growth trends.

The Centers for Medicare & Medicaid Services has proposed two models for ACO participation, referred to as the "one-sided" model and the "two-sided" model. Under the one-sided model, an ACO is eligible to receive Shared Savings Program payments but is not at risk for any loss if it fails to meet the applicable cost benchmarks and quality requirements. Under the two-sided model, an ACO is eligible to receive a greater share of savings it may generate but is also responsible for sharing losses if its expenditures are above its benchmark.

An ACO may elect to participate under the one-sided model at the outset, but must convert to the two-sided model in its third year of participation, and must continue under the two-sided model thereafter. In the alternative, an ACO may elect to participate under the two-sided model from the start.

Termination From Program

An Accountable Care Organization may voluntarily terminate its participation in the Shared Savings Program, and may be subject to termination by CMS for failure to comply with applicable regulations. CMS may terminate an ACO based on the conduct of the ACO itself or on the conduct of any of its participants, providers, suppliers or contracted parties. For example, an ACO will be subject to termination if it attempts to exclude Medicare beneficiaries with high health care costs. The Centers for Medicare & Medicaid Services has discretion to take certain actions prior to termination, including providing the ACO with a warning notice or imposing a special monitoring plan. A terminated ACO must wait until the original three-year period expires before it reapplies to participate in the Shared Savings Program.

Additional Guidance

In an effort to provide a degree of flexibility for Accountable Care Organizations seeking to establish innovative models envisioned by the Shared Savings Program, several other federal agencies released much-awaited ACO guidance concurrently with CMS's release of the proposed ACO regulations. These include proposed waivers, jointly released by CMS and the Department of Health and Human Services Office of Inspector General, of several fraud and abuse laws that prohibit certain financial arrangements between physicians, hospitals, and other individuals and entities; Internal Revenue Service guidance for tax-exempt organizations participating in ACOs; and a proposed statement of antitrust enforcement policy from the Antitrust Division of the Department of Justice and the Federal Trade Commission describing the application of antitrust law to ACOs. All agencies welcome timely-submitted comments on their proposals. ■

Pamela H. Del Negro and Meaghan Mary Cooper are associates in Robinson & Cole's Health Law Group.

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HEALTH LAW

■ From BE WARY on PAGE 15

Under the Affordable Care Act, if a drug, device, biological or medical supply is one that is covered under Medicare, Medicaid or the Children's Health Insurance Program, Congress requires that the manufacturer track and disclose payments and other "transfers of value" to "teaching hospitals" and physicians. The first disclosures are due to the U.S. Department of Health and Human Services (HHS) on March 31, 2013 for the preceding calendar year. Therefore, manufacturers will need to begin tracking the necessary information on Jan. 1, 2012 and should take time now to either curtail their practices or develop and implement an appropriate tracking system.

The definition of "anything of value" is broad and includes consulting fees or other compensation, honoraria, gifts, entertainment, travel, food, education, research, charitable contributions, royalties and licenses, ownership interests and grants. Notwithstanding, certain transfers are excluded, such as: transfers of anything of value less than $10 (or $100 in the aggregate per calendar year – to be increased after 2012); product samples intended for patient use and not to be sold; educational materials for patient use; short-term equipment loans (up to 90 days); items or services provided under contractual warranty, discounts and in-kind items used for charity care. Many physicians will be pleased with this exemption because it allows them to continue to give patients free samples.

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To properly disclose these transfers to the Department of Health and Human Services, the manufacturer must track the name and address of the recipient, the recipient's National Provider Identifier number and specialty (if applicable), the amount of the transfer, the form and nature of the transfer, the date of the transfer and whether the transfer was related to marketing, education or research specific to a drug, device, biological or medical supply.

Reporting Physician Ownership

Beginning March 31, 2013, manufacturers and certain group purchasing organizations (GPOs) must report ownership or investment interests held by a physician or a physician's immediate family member in that GPO or manufacturer (other than ownership or investment through a publicly traded security or mutual fund).

The GPO or manufacturer must disclose to the federal government the dollar amount, value and terms of the ownership or investment interest and any payments made to the physician holder of the ownership or investment interest. Again, the reason for this disclosure is to assure full transparency, especially in the areas of research and physician education.

Public Availability

The information disclosed by manufacturers and GPOs will be collected by the Department of Health and Human Services and then made publically available via a web site. While not yet established, the web site will be public and allow for easy aggregation and downloading.

The web site will also contain background information on industry-physician relationships, descriptions of enforcement actions against entities that fail to make the required disclosures and other information that may be required by HHS.

Reporting Drug Samples

As of Jan. 1, 2011, manufacturers and distributors of prescription drugs must track and report certain information regarding the distribution of drug samples to licensed practitioners and pharmacies of hospitals or other health care entities.

Since the first report must be filed with HHS by April 1, 2012 for the 2011 calendar year, compliance efforts should begin now. The report must include, among other things: the identity and quantity of drug samples requested by a licensed practitioner; the identity and quantity of drug samples distributed pursuant to such request; the name, address, professional designation and signature of the practitioner (or his or her designee) making the request; and any other information deemed appropriate by HHS.

Physicians should know that even though they are not charged with the responsibility of reporting, if they accept the samples, their name will become part of the public record.

Failure to Report

Failing to report gifts or payments to physicians or physician ownership interests may result in penalties between $1,000 and $10,000 per incident (up to $150,000 per year). A "knowing" failure to report may result in even higher penalties.

Looking Ahead

The Affordable Care Act's reporting and disclosure requirements will entail a significant administrative burden for manufacturers, group purchasing organizations and distributors. Entities should act now to ensure compliance, especially since the Office of the Inspector General has identified the tracking and reporting of payments to physicians and drug samples as "key areas of focus" for future enforcement activity.

The key to an effective tracking and reporting program is training. Sales representatives, marketing personnel, and other relevant staff and contractors should be trained to appropriately track and report data within the entity's information collection system. An entity should also consider implementing periodic internal compliance reviews to ensure that tracking and reporting are conforming to the Affordable Care Act and any future implementing regulations. ■

Joan Feldman is a partner in the Hartford office of Shipman & Goodwin. She advises health care providers on matters such as mergers and acquisitions, state and federal regulatory issues, corporate compliance and Medicare and Medicaid reimbursement. She can be reached at jfeldman@goodwin. William Roberts also practices in the area of Health Law. He is an associate in the firm's Hartford office, where he can be reached at wroberts@goodwin.com.

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Consultants Can Help Recommend Care For Clients

Services range from phone conversations to home visits

By PAT PANNONE

Often attorneys meet with families who are beginning to look at future needs of the parents or are already in crisis when the parents are not managing well. And as health care becomes more and more complex, a client may need a health care advocate to navigate the system and advocate for them with health organizations and insurance providers.

This is the role of the Care Consultant professional. Often registered nurses or social workers, they also have extensive training and certification as care consultants. They help caregivers or elders themselves learn the questions to be asking. They help families find the right care and support services.

Families may not know what to do when challenged by changes in health, function, or memory.

Frequently Asked Questions

Do any of these questions sound familiar?

- How can I help my aging parent remain as independent and safe as possible?
- I don't even know the questions to ask. How can I determine and meet my loved one's care needs?
- Could a geriatric assessment help guide us?
- I feel confused about options. Who can help me sort things out?
- I am overwhelmed by understanding the costs of services. What do Medicare and other insurances cover?
- How can we plan for future costs?
- When should I take away the car keys? What is a driving assessment?
- How can I help Mom and Dad when I live so far away?
- Dad keeps bouncing back and forth to the hospital with his chronic illness (COPD, hearth failure, diabetes). Isn't these some health care system that can help us get him off this treadmill, reducing his flair ups and getting him stable so he can remain in the home he loves?
- Can I get advice on healthy aging and planning ahead for unexpected life changes?
- Mother is in the hospital and needs someone to be sure she gets what she needs there and where she should go next. I'm too far away, who do you recommend?

Guiding Families

Care consultants guide families when they are unsure of what to do. The goal is to help clients live as independently and as safely as possible. Often this can be with services in the home and sometimes it may be best to live in another home setting. But how does someone begin to look and compare? That's where the consultant can be so effective with her extensive knowledge of illness, aging, services, options and funding sources such as veterans' benefits and Title XIX.

Families may not know what to do when challenged by changes in health, function, or memory. They help out-of-state family members learn about services available in this area for a loved one and monitor the services once the care plan is begun. They help families think through options for aging parents. Care consultants also help active retirees develop wellness plans to preserve independence and plan proactively for future needs.

A consultant is fully focused on the elder and the family's specific needs, questions and concerns. Consultants generally offer a full range of services from a telephone conversation to discuss concerns, to a visit to the home to provide a comprehensive assessment of strengths and needs.

The care consultant can help a family prepare a plan of care. The plan will be based on each individual's preferences. The consultant can monitor and reassess care and changing, as necessary. She will help clients and their families choose the right solutions for each client's needs. The consultant can offer cost-conscious recommendations and explains what is and is not covered by your insurance plans.

Pat Pannone

This can be a short term arrangement or be an on-going relationship for support and guidance from the consultant. A Consultant can advocate for a client before, during and after a hospitalization, a nursing home stay, or short- term home health care services. As health care professionals, care consultants often recognize the need for a variety of helpful services before the client or family. A consultant encourages healthy behaviors and ways to best manage chronic conditions like heart failure and lung disease.

Meeting With Doctors

With your permission**,** the care consultant regularly communicates with the primary physician and other care providers on the team, sharing needs, plans, and wishes. No physician order is needed to request that a care consultant start to help a family.

However, consultation services are not currently reimbursed under the Medicare, Medicaid or private health insurance. Some long-term care insurances may have benefits for care consultation (also called care management or patient advocate). ■

Pat Pannone leads the Care Consultant Team in addition to serving as the McLean Home Care & Hospice administrator. She is a nurse with a master's degree in Public Health and a Care Manager certification through NACCM with 30-plus years in community-based care for elders.

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Self-Reporting Of Violations Has Benefits, Drawbacks

Protocol helps providers comply with law regarding improper referrals

By REBECCA A. MATTHEWS and JODY ERFARB

On April 7, 2011, the Centers for Medicare and Medicaid Services (CMS) announced that it was processing 60 disclosures pursuant to the Self-Referral Disclosure Protocol (SRDP) introduced last fall. Under the SRDP, providers may voluntarily disclose violations of the Physician Self-Referral Law, more commonly known as Stark.

Stark prohibits a physician from making referrals for certain designated health services payable by Medicare or Medicaid to an entity with which he or she has a financial relationship, unless an exception applies. Because Stark is a strict liability law, its severe penalties may be imposed even for technical violations, including common mistakes such as failure to renew an expired contract. Many providers, therefore, face Stark compliance problems and, because the SRDP is voluntary may struggle with deciding whether or not to disclose under the new protocol.

To date, there has been only one publicized SRDP settlement: on Feb. 20, 2011, Saints Medical Center in Lowell, Mass., announced that it agreed to pay $579,000 to resolve its Stark liability. Because Saints Medical Centers' potential liability was alleged to be $14 million, it appears that the Centers for Medicare and Medicaid Services is looking to resolve acknowledged Stark liabilities in a flexible, collaborative manner through use of the self-referral protocol.

In theory, the greatest benefits of self disclosure are that the provider can potentially pay reduced monetary amounts and avoid a costly government investigation.

Until more of these cases are resolved and additional information on the centers' review of disclosures is known, providers who are considering disclosure should carefully evaluate the potential benefits and dangers.

Eligibility

Participation in the self-referral protocol is limited to actual Stark violations. If the disclosure includes violations of other laws, such as the Anti-Kickback Statute, which is enforced by the Office of the Inspector General, the protocol cannot be used. The inspector general's Self-Disclosure Protocol, which has been in place since 1999, should be considered in such instances.

According to the Self-Referral Disclosure Protocol, if a disclosing party argues that the circumstances do not violate Stark, the disclosure will not be accepted. Therefore, providers are well-advised to ensure that a true Stark violation occurred and should be prepared to enter a corresponding monetary settlement before disclosing pursuant to the SRDP.

Benefits

An immediate benefit to disclosing pursuant to the Self-Referral Disclosure Protocol is that the submission of a disclosure suspends the obligation to return overpayments within 60 days of identification. This suspension lasts until a settlement agreement is entered or the disclosing party withdraws or is removed from the SRDP.

In theory, the greatest benefits of self disclosure pursuant to the SRDP are that the provider can resolve the violation, potentially pay reduced monetary amounts, and avoid a costly government investigation. The Centers for Medicare and Medicaid Services is not, however, obligated to reduce any overpayment amounts identified.

In March 2012, CMS must submit a report to Congress on the SRDP detailing the number of settled self disclosures, the amounts collected, and other data. Until then, other than anecdotal settlements that may become public, providers have little precedent or other guidance to predict how their cases may be resolved, causing the greatest potential benefit of the SRDP to also be one of its greatest potential dangers.

Dangers

Further Investigation: The Centers for Medicare and Medicaid Services makes it clear that not only may it refer a disclosure to the Office of the Inspector General and the Department of Justice for investigation, but also, that if it uncovers matters during its verification process that are outside the scope of the matter disclosed, CMS may treat them as new matters outside the SRDP, subject to separate investigation by the appropriate authorities.

Period of Disallowance: Self-Referral Disclosure Protocol submissions must include the disclosing party's financial analysis of its Stark liabilities, which sets forth the total amount, itemized by year, that is actually or potentially "due or owing." Generally, this calculation will include all Medicare payments for designated health services received by the disclosing party that were made as a result of referrals generated while the relationship was not Stark compliant. The calculation must cover the entire time period "during which the disclosing party may not have been in compliance with the physician self-referral law." When the disclosure involves longstanding arrangements, this period could cover many years and even go further back than the general four-year period in which CMS may re-open claims for good cause. Providing a financial analysis for that entire time period may prove challenging for some providers and may also make it difficult for providers to negotiate smaller settlements.

Forfeiture of Right to Appeal: As a condition of disclosing a matter pursuant to the SRDP, the disclosing party must agree that no appeal rights attach to claims relating to the conduct disclosed if resolved through a settlement agreement.

Cooperation: Providers must be extremely meticulous in ensuring that all submissions are 100 percent accurate and honest and must be prepared to cooperate fully with requests for additional information. A perceived lack of cooperation could result in CMS' removal of the case from the SRDP and referral to other government authorities.

Conclusion

The considerations listed here are only a sampling of those that should be evaluated when making the complex decision of entering the Self-Referral Disclosure Protocol. In cases where a provider is aware of an overpayment due to Stark noncompliance and where no other laws are implicated, the SRDP may be an attractive option because it may result in reduction of the overpayment even while potentially exposing the provider to other liability.

Although proceeding with the Self-Referral Disclosure Protocol has inherent dangers, failing to disclose potential Stark liability may put a provider in significant jeopardy as well. As such, many providers facing the decision to disclose under the SRDP may feel stuck in a "damned if you do, dammed if you don't" quagmire. As more information, particularly about specific SRDP settlements, is released, providers may feel more comfortable taking advantage of the SRDP's benefits. In the meantime, providers should carefully analyze the risks and benefits involved before proceeding. ■

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