

O&P Legislative/Policy Update

Editor's Note: In this issue we examine some of the changes in programs, policies, rules, and regulations coming from Congress, the Centers for Medicare and Medicaid (CMS), and state legislatures that affect the O&P industry, its practitioners, and its patients.

Specifically, John Latsko takes a closer look at a recent advisory from the Office of Inspector General of the Department of Health & Human Services examining two programs for the delivery of DMEPOS in the physician practice setting and the potential for violation of the federal anti-kickback statute. In addition, as several states pursue parity legislation, Sherry Metzger, MS, reviews the process the state of Colorado went through as the first state to achieve parity, and Tina Eichner previews the efforts toward licensure of practitioners in the state of New York.

For more information on recent policy actions, read online only coverage at www.oandp.com/edge



OIG QUESTIONS PROPOSED ARRANGEMENTS WITH MEDICAL GROUPS



► By John Latsko

On March 28, 2006, the Office of Inspector General (the "OIG") of the Department of Health and Human Services (the "DHHS") issued Advisory Opinion 06-02. The opinion examines two programs proposed by a manufacturer (the "Requestor") of durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS") for the delivery of DMEPOS in the physician practice setting. The OIG concluded that the programs could potentially generate prohibited remuneration under the federal anti-kickback statute (the "Anti-Kickback Law") and result in administrative and criminal sanctions.

Introduction of the Anti-Kickback Law

The Anti-Kickback Law makes it 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 a federal healthcare program ("FHCP"), such as Medicare or Medicaid. The Anti-Kickback Law has been broadly interpreted by courts to prohibit any payment, if one purpose of the payment is to induce the referral of FHCP items and services, irrespective of whether there are other legitimate business purposes for the payment. Violation of the statute constitutes

a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Medicare and Medicaid.

Recognizing that many common, non-abusive arrangements could constitute technical violations of the law, the OIG has promulgated regulations known as "safe harbors." If an arrangement satisfies all the elements of the applicable safe harbor(s), then payment under those arrangements will be protected from both criminal prosecution and civil penalties

under the Anti-Kickback Law. The absence of safe harbor protection does not make arrangements that implicate the Anti-Kickback Law necessarily illegal, but requires the OIG to evaluate the arrangements on a case-by-case basis.

The Proposed Programs

Pursuant to the proposed programs, the Requestor would offer physician practices (the “Practices”) the option of choosing between one of two programs. The first program “carves out” FHCP beneficiaries, and thus only involves the provision of DMEPOS items and services to patients who are not FHCP beneficiaries (the “First Program”). The second program includes both FHCP and non-FHCP patients (the “Second Program”).

The First Program (Non-FHCP Patients Only)

The first proposed program would involve the following six related components pursuant to a written agreement between the Requestor and the Practices:

- 1) The Practices would bill commercial plans and patients directly for the furnishing of DMEPOS products.
- 2) The Requestor would sell DMEPOS products to the Practices consistent with commercial practice and in compliance with the discount safe harbor. The Practices could profit by billing health plans and patients more for the products than the prices at which the Practices purchased the products.
- 3) The Requestor would rent continuous passive motion devices to the Practices on an as-needed basis at a per diem rate and the Practices would subsequently rent the devices to non-FHCP patients at a higher per diem rate than the Practices paid the Requestor. Although the rental arrangement would meet most of the requirements of the equipment rental safe harbor, the aggregate rental amount and the schedule and length of the rental would not be set in advance.
- 4) The Requestor would contract to supply the physician practice with various services provided by the Requestor’s employed technician including, but not limited to, fitting the non-FHCP patients for DMEPOS, complete in-home set-up of equipment, and instructing patients on the maintenance of the products. Payment to the Requestor for such services would satisfy the personal services and management contracts safe harbor.
- 5) The Requestor would provide coding, billing, and collection services to the Practices for a fixed monthly fee consistent with the personal services and management contracts safe harbor.
- 6) The Practices would not supply any DMEPOS items or services to FHCP patients. Rather, the Practices would prescribe such items and services for FHCP patients and instruct the patients to obtain them from any local supplier, including the Requestor.

The Second Proposed Program (FHCP and Non-FHCP Patients)

The second proposed program would involve the following four related components pursuant to a written agreement between the Requestor and the Practices:

- 1) The Requestor would supply and bill for the furnishing of the DMEPOS products under its Medicare supplier number.
- 2) The Requestor would rent a “consignment closet” from the Practices for a fixed monthly fee, and consign DMEPOS products to the practice to be stored in the space. The rent for the storage space would satisfy the space rental safe harbor.
- 3) The Requestor would pay the Practices a percentage of the revenues generated from the sale and rental of DMEPOS products to the Practice’s patients who are not FHCP patients in return for the Practice’s provision of inventory management and various other administrative services related to the consignment and storage of the products.
- 4) The Requestor would supply the Practices the services of a technician identical to those described in the First Program and consistent with the personal services and management contracts safe harbor, including the Practices’ payment at fair market value to the Requestor for the technician.

The OIG concluded that the proposed programs posed significant risk of fraud and abuse.

The First Program – Carve-Outs Do Not Necessarily Save a Contractual Joint Venture

The OIG characterized the First Program as closely resembling questionable “contractual joint ventures,” since certain factors were present that the OIG had previously deemed suspect in the

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WEBSITE PROVIDES HEALTHCARE POLICY OVERVIEW

In a new online tutorial from the Kaiser Family Foundation (www.kaiseredu.org), Jeff Crowley, MPH, of Georgetown University’s Health Policy Institute provides an overview of policy issues related to accessing healthcare for people with disabilities. The tutorial provides information on the types and prevalence of disabilities in the US, the major healthcare financing mechanisms, and the interaction of the Medicaid program with the Americans with Disabilities Act.

The website is designed to provide students, faculty, and others interested in learning about health policy easy access to the latest data, research, analysis, and developments in health policy. This site includes narrated slide tutorials, background reference libraries, and issue modules on current topics and policy debates.

To access the tutorial on accessing healthcare for people with disabilities, go to www.kaiseredu.org/tutorials_index.asp#Disabilities

OIG's Special Advisory Bulletin on "Contractual Joint Ventures" (68 Fed. Reg. 23148 (April 30, 2003)). Among these factors, the arrangement provided the Practices the opportunity to expand into the DMEPOS business and receive substantial profits with little or no business risk as the Requestor, a would-be competitor of the new physician practice supplier, would provide virtually all the key items and services necessary to the arrangement.

The OIG determined that the "carve-out" of FHCP business did not save the program, since the arrangement did not prohibit the participating physicians from ordering the Requestor's products for FHCP beneficiaries. According to the OIG, the arrangement may violate the Anti-Kickback Law by disguising remuneration for FHCP referrals through the payment of amounts purportedly related to non-FHCP business (a concept that the OIG has previously referred to as "swapping"). In addition, despite the Requestors' certification that most components of the First Program complied with a safe harbor, the OIG reiterated its controversial position in the Special Advisory Bulletin that safe harbor protection may not be available for a contractual joint venture.

The Second Program – Management Services Arrangements between DMEPOS Companies and Physician Practices are Subject to Close Scrutiny

Similar to the First Program, the OIG determined that the Second Program was problematic because the Practices would be offered a set of interrelated arrangements that appear designed to align the Practices with the Requestor's products. The OIG noted that the percentage of revenue payment to the Practices for inventory management and other administrative services did not meet the personal services safe harbor, since aggregate compensation was not set in advance, and was unwilling to accept at face value the Requestor's certifications that the payments relating to the use of the consignment closet and the leased technician complied with a safe harbor.

In conclusion, the OIG stressed that arrangements in which device manufacturers and suppliers furnish Practices with "management" or similar services related to the manufacturer's or supplier's products must be subject to close scrutiny under the fraud and abuse laws. According to the OIG, such ties only appear to exist so that the manufacturer or supplier could generate more business by influencing or rewarding referrals.

Restructuring the Programs to Minimize Risk of Fraud and Abuse

This Advisory Opinion demonstrates that the OIG continues to be skeptical of physician/DMEPOS company joint ventures designed to align the physician practices with the DMEPOS company's products through the DMEPOS company's provision of management and other administrative services.

Minimizing Risk under the First Program

The First Program clearly includes the characteristics of a contractual joint venture that the OIG previously deemed suspect in the Special Advisory Bulletin. The Requestor, however, attempted

to obtain a favorable advisory opinion by "carving out" FHCP patients and by claims that most of the component parts satisfied the requirements of safe harbors. Nonetheless, the OIG concluded that "carving out" FHCP patients does not save a contractual joint venture. Thus, the only way to restructure the First Program to minimize risk is by eliminating the characteristics of a suspect joint venture, while keeping in mind that Medicare anticipated that medical groups would become DMEPOS suppliers.

The OIG has stated that the following are indicia of a Suspect Contractual Joint Venture:


- A healthcare provider is expanding into a new line of business;
- The newly created business predominately or exclusively services the existing patient base;
- The arrangement results in little or no bona fide business risk to the healthcare provider;
- The supplier is an individual or entity that would normally be a competitor of the healthcare provider's new line of business but for the contractual relationship;
- The supplier provides all or many of the key services related to the operation of the business;
- The arrangement gives the healthcare provider the opportunity to bill for business otherwise provided by the supplier; and
- The arrangement is exclusive in nature.

To the extent the foregoing characteristics can be eliminated from the First Program, the risks of a violation of the Anti-Kickback Law could be manageable.

Minimizing Risk under the Second Program

Unlike the First Program, the OIG did not label the Second Program a contractual joint venture. Rather, the OIG determined that the Second Program presented substantial risks of fraud and abuse because the various components failed to meet safe harbors, or the OIG suspiciously was unwilling to accept the Requestor's representation that the components complied with the safe harbors. The Second Program, therefore, can presumably be restructured so that each component complies with the applicable safe harbor. The following components of the arrangement would need to be addressed:

- Rental of consignment closet;
- Percentage of revenue payment for inventory management and other administrative services;
- Specific responsibilities of the leased technician and fair market value of services;
- Medical group must assume reasonable business risks.

Although the OIG did not label the Second Program as a contractual joint venture, it made clear that any arrangement whereby a DMEPOS company will furnish physician practices with "management" or similar services will be subject to close scrutiny under the quality of care and services patients receive and the arrangement must be cost-effective. Anything less will be very risky.  QUICK FIND: EDPEAT0606

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