



ALLIANCE FOR INTEGRITY IN MEDICARE

*Closing the Self-Referral Loophole and Preserving Medicare Integrity*

PARTNERS IN THE COALITION



September 20, 2011

The Honorable Patty Murray, Co-Chair,  
*Joint Select Committee on Deficit Reduction*

The Honorable Jeb Hensarling, Co-Chair,  
*Joint Select Committee on Deficit Reduction*

Dear Chairwoman Murray and Chairman Hensarling:

On behalf of the Alliance for Integrity in Medicare (AIM), a coalition committed to ending the practice of inappropriate physician self-referral in Medicare, we recognize the challenges you face in making significant reductions in government spending. As the Joint Select Committee on Deficit Reduction identifies ways to reach the benchmarks set forth by the Budget Control Act of 2011, we urge you to explore the savings that could be generated from closing the Medicare physician self-referral loophole.

The undersigned organizations, representing thousands of health professionals in the fields of advanced diagnostic imaging, anatomic pathology, physical therapy, and radiation therapy, are extremely concerned that misapplication of the in-office ancillary services (IOAS) exception to the physician self-referral law results in increased spending, unnecessary overutilization of services, and could also lead to compromised patient choice and care.

AIM strongly supports efforts to rein in inappropriate spending in the Medicare program to sustain the program for current and future beneficiaries. We are confident that closing the self-referral loophole for the services noted above, while preserving the ability for truly integrated multi-specialty practices to continue providing services through the exception, will create savings for the Medicare program. More specifically, the savings are achieved through a reduction in inappropriate utilization of diagnostic tests, and in some cases, follow-up treatments. We believe a legislative remedy is needed and enclose draft language for your review.

We would appreciate the opportunity to discuss this issue and its potential savings in greater detail. For further information, please contact Dave Adler, ASTRO's director of government relations, at (703) 839-7362.

Thank you in advance for your consideration.

Sincerely,

**The Alliance for Integrity in Medicare**

*American Clinical Laboratory Association*

*American College of Radiology*

*American Physical Therapy Association*

*American Society for Clinical Pathology*

*American Society for Radiation Oncology*

*Association for Quality Imaging*

*College of American Pathologists*

*Radiology Business Management Association*

cc:

Senate Majority Leader Harry Reid, Senate Minority Leader Mitch McConnell, Speaker of the House John Boehner, House Majority Leader Eric Cantor, House Minority Leader Nancy Pelosi

## **SECTION-BY-SECTION SUMMARY OF THE PROMOTING INTEGRITY IN MEDICARE ACT OF 2011**

**SEC. 1 PURPOSE:** This Act will amend Section 1877 of the Social Security Act, which prohibits physician self-referral, to exclude certain services from the in-office ancillary services (IOAS) exception and the physician services exception. As a result, these “excluded services” would continue to be subject to the prohibition on self-referral and would not be subject to these exceptions, which have been used to protect inappropriate arrangements between various entities and referring physicians. Section 1877 prohibits a physician (or an immediate family member) who has a financial arrangement with an entity from referring patients to the entity, if Medicare (or Medicaid) would otherwise pay for those services, unless an exception applies. In recent years, several government studies have found that the IOAS and the physician services exception are being used to circumvent the purpose of the self-referral law. The Act does recognize that multispecialty groups, where physicians in various specialties act in an integrated manner to provide services and are not compensated based on their referrals for ancillary services, are unlikely to overutilize these services; thus, the Act creates a separate exception for such entities.

In addition, the Act will amend Section 1861 of the Social Security Act to require supervision of the technical component of anatomic pathology services, filling a current regulatory gap that effectively exempts such services from Medicare's anti-markup rule. Together, these provisions are intended to prevent abusive billing of ancillary services to the Medicare program.

**SEC. 2 FINDINGS:** Establishes that the purpose of the self-referral law was to limit situations where physicians referred Medicare patients to entities with which the physicians had an investment or compensation relationship. The IOAS exception to the physician self-referral law was to permit physicians to order ancillary services in their offices when those services would allow physicians to make diagnostic and treatment decisions while the patient was in their office for a visit. CMS and MedPAC have recently stated that services furnished under the auspices of the IOAS exception have expanded and do not meet the original intent of the provision. Other gaps in the law, such as the physician services exception, are also being misused in the same way.

**SEC. 3 AMENDMENT TO THE PHYSICIAN SERVICES EXCEPTION:** Would amend the physician services exception so that certain specified “excluded services,” defined below, would not be eligible for that exception; thus, this exception could not be used to protect arrangements involving these services.

**SEC. 4 AMENDMENT TO THE IOAS EXCEPTION:** Would amend current language of the IOAS exception so that certain specified “excluded services,” defined below, would not be eligible for that exception, thus, this exception could not be used to protect arrangements involving these services.

**SEC. 5 MULTI-SPECIALTY GROUP PRACTICES EXCEPTION:** Would establish a new exception to the physician self-referral law that would permit multi-specialty group practices, as defined in the law, to bill and be paid for excluded services without violating the self-referral law.

**Sec. 6 NEW DEFINITIONS:** Would establish the following new definitions under the Act –

*Excluded services:* Defines “excluded services” as covering anatomic pathology services, radiation therapy services and supplies, advanced diagnostic imaging services and physical therapy services.

*Multispecialty physician group practice:* Defines this term to include groups of at least 35 members in various specialties, including both general practice and other specialties, where the physicians furnish a substantial portion of their patient care services through the group. Physicians who practice in the group could not be compensated in a way that would reward them for their referrals of designated health services. The section establishes other standards that must be met for a group to qualify as a multispecialty physician group practice.

*Entity:* Clarifies current regulations and ensures that an entity that meets the requirements of CMS’ anti-markup rule (42 C.F.R. § 414.50) is still subject to the self-referral law where it is furnishing excluded services.

**SEC. 7 CLARIFICATION OF SUPERVISION OF TECHNICAL COMPONENT OF ANATOMIC**

**PATHOLOGY SERVICES:** Enacts a technical change in the regulations regarding the Technical Component of physician pathology services; fills the current gap in regulations that exempts these services from any physician supervision requirements, a situation that virtually exempts the services from Medicare’s anti-markup requirements. The clarification would make these services subject to the same supervision requirements as the Professional Component of these services.

**SEC. 8 EFFECTIVE DATE:** The Act would be effective six months after enactment.

# A BILL

To amend title XVIII of the Social Security Act to protect taxpayers, Medicare beneficiaries and the Medicare program from abusive self-referral arrangements.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

## SECTION 1. SHORT TITLE; PURPOSE

(a) **SHORT TITLE.**—This Act may be cited as the ‘Promoting Integrity in Medicare Act of 2011’ (the “Act”).

(b) **PURPOSE.**—It is the purpose of this Act to prevent abusive billing of ancillary services to the Medicare program.

## SEC. 2. FINDINGS

The Congress finds that—

- (1) According to the Medicare Payment Advisory Commission (MedPAC), many physicians have expanded their practices in recent years to provide additional designated health services in their offices pursuant to the in-office ancillary services (IOAS) exception to the physician self-referral law;
- (2) Noting that many of these services are furnished unnecessarily, MedPAC expressed concern about the rapid growth of services furnished in physician offices, the inappropriate incentives created that increase volume under Medicare’s current fee-for-service payment systems, and the rapid volume growth, which contributes to Medicare’s rising financial burden on taxpayers and beneficiaries;
- (3) According to a summary of the bill that became the physician self-referral law, the IOAS exception was only expected to apply to in-office laboratory tests or radiology services, that would be furnished where a quick turnaround time was necessary;
- (4) CMS has also noted that a key rationale for the IOAS exception was to permit physicians to provide ancillary services in their offices during patient visits to allow physicians to make diagnostic and treatment decisions while the patient was in the office for an office visit;
- (5) However, CMS has now indicated that services furnished under the auspices of the IOAS exception are typically “not as closely related to the physician practice” as was contemplated for this exception; and

(6) Many of the services provided currently under the IOAS exception and similar exceptions are virtually never performed, nor are the results available, during the patient's office visit and thus are not used by the physician during that visit, thereby making such services inappropriate for inclusion in the IOAS exception.

### **SEC. 3. AMENDMENT TO THE PHYSICIANS' SERVICES EXCEPTION**

Section 1877(b)(1) of Title XVIII of the Social Security Act is amended by

- (1) inserting before the final period of the section, "except for services that are excluded services, as defined in subsection (h), unless billed in compliance with paragraph (6) below."

### **SEC. 4. AMENDMENT TO THE IN-OFFICE ANCILLARY SERVICES EXCEPTION**

Section 1877(b)(2) of Title XVIII of the Social Security Act is amended by—

- (1) inserting a comma after "equipment (excluding infusion pumps)";
- (2) striking "and" before "parenteral and enteral nutrients"; and
- (3) inserting ", and excluded services, as defined in subsection (h), unless billed in compliance with paragraph 6 below" after "nutrients, equipment, and supplies" and before the closed parenthesis ")"

### **SEC. 5. NEW MULTISPECIALTY GROUP PRACTICES EXCEPTION.**

Section 1877(b) of Title XVIII of the Social Security Act is amended by inserting a new subparagraph (6) as follows:

"(6) SERVICES PERFORMED BY MULTISPECIALTY GROUP PRACTICES—In the case of excluded services as defined in subsection (h), if they are performed or supervised by a physician-member of, and billed by, a multispecialty physician group practice, as defined in subsection (h)."

### **SEC. 6. DEFINITIONS OF EXCLUDED SERVICES AND MULTISPECIALTY PHYSICIAN GROUP PRACTICE**

Section 1877(h) of Title XVIII of the Social Security Act is amended by adding at the end the following new paragraphs:

- (8) For purposes of this section, the term "excluded services" means any of the following:

(A) anatomic pathology services, as defined by the Secretary in accordance with guidance in effect on the date of enactment and as modified by her from time to time, and including the technical or professional component of the following: surgical pathology, cytopathology, hematology, blood banking, pathology consultation and clinical laboratory interpretation services;

(B) radiation therapy services and supplies, as the Secretary defines by regulation;

(C) advanced diagnostic imaging studies, as defined in section 1834 (e)(1)(B) [42 U.S.C. 1395(m)]; or

(D) physical therapy services (as described in subsection (6)(B)).

(9) For purposes of this section, the term “multispecialty physician group practice” means a group practice as defined in paragraph (4)—

(A) whose membership is comprised of at least 35 full-time physicians, provided that the group’s membership may fall below 35 full-time physicians for no more than 30 days during a calendar year;

(B) that includes one or more full time physicians certified in each of 10 or more medical specialties (other than the specialties included in subparagraph (C) below), defined as those specialties that are listed in the Directory of Graduate Medical Education Programs published by the American Medical Association or the Annual Report and Reference Handbook published by the American Board of Medical Specialties, provided that no such specialty may account for more than 10% of the total number of physicians in the practice;

(C) at least thirty (30) percent of whose membership shall include physicians, substantially all of whose practice is in—

- (i) general practice;
- (ii) family practice;
- (iii) internal medicine;
- (iv) OB/GYN; or
- (iv) pediatrics;

provided that this percentage may fall below thirty (30) for no more than 30 days during a calendar year;

(D) at least 75% of whose leadership and management body is comprised of full time physicians who are members of the group;

(E) through which at least 75% of the group's individual physicians furnish 90% or more of their patient care services;

(F) that has a compensation structure that distributes all revenue from designated health services without regard to the volume or value of such services ordered by any physician; and

(G) such other requirements as the Secretary may impose by regulation, as needed, to prevent patient and Program abuse and to encourage high quality, efficient, and safe care of the multispecialty physician group, including, but not limited to, adoption of health information technology, adherence to clinical guidelines and performance standards, and use of patient safety techniques.

(10) The Secretary may waive such requirements of the definition of "multispecialty physician group practice" as may be necessary to carry out the provisions of Sec. 1877 of the Social Security Act.

(11) For purposes of this section, "entity" does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test (other than a diagnostic test that is an excluded service, as defined in subsection (8)), when otherwise billed in compliance with Section 1842(n)(1), and the regulations and policies promulgated by the Secretary thereunder.

## **SEC. 7. CLARIFICATION OF SUPERVISION OF TECHNICAL COMPONENT OF ANATOMIC PATHOLOGY SERVICES**

Section 1861(s)(17) of Title XVIII of the Social Security Act is amended by

(1) striking "and" in subsection (A);

(2) inserting a new subsection (B) which states--

"with regard to the provision of the technical component of anatomic pathology services, meets the applicable supervision requirements for laboratories certified in the subspecialty of histopathology, pursuant to Section 353 of the Public Health Services Act, and the regulations promulgated by the Secretary, thereunder; and"

(3) In the next subsection, change "(B)" to "(C)".

## **SEC. 8. EFFECTIVE DATES**

Unless otherwise specified, the amendments made by this Act shall be effective six months after the date of enactment.