May 14, 2009

BY ELECTRONIC MAIL

The Honorable Charles E. Grassley
Ranking Member, Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510-6200
Health_Reform@finance-dem.senate.gov

Re: Comments on the Physician Payments Sunshine Act of 2009, S. 301

Dear Senator Grassley:

This firm represents the Quality Implant Coalition (QuIC), a coalition of manufacturers of implantable medical devices formed to urge governmental action to preserve the quality and integrity of implantable medical devices.

QuIC appreciates the opportunity to provide comments on the Physician Payments Sunshine Act, and in particular to strongly endorse the inclusion of its payment transparency provisions in any future healthcare reform package. Our comments focus principally on self-referral to physician-owned implant and other medical device companies, entities commonly referred to as POCs. Physician investment in entities to which those physician-investors refer patients poses a significant conflict of interest, one which, at a minimum, must be disclosed publicly to allow informed decision-making on the part of patients and payors. Accordingly, our attached comments propose minor changes to S. 301 to ensure transparency of these unique financial relationships, as well as urging Congress to support other investigative and regulatory initiatives aimed at further restricting self-referral to POCs.

We appreciate your timely consideration of our comments, and we would be happy to meet with you or your staff to discuss these issues further.

Very truly yours,

Thomas N. Bulleit, Jr.

Enclosures

cc: The Honorable Max S. Baucus
The Honorable Herb Kohl

Quality Implant Coalition
Addressing Abuses Arising From
Physician Owned Implant and Other Medical Device Companies
May 2009

About QuIC: Protecting Patients and Payors. The Quality Implant Coalition (QuIC) is a coalition of manufacturers of medical devices that is concerned with the potential for harm to patients, payors, and the general health care system that inevitably arises when a physician's choice of the implantable medical devices s/he will use in treating his or her own patients is influenced by that physician's financial interests in those devices. QuIC's specific focus is on self-referral to physician-owned implant and other medical device companies, entities that CMS has denominated "POCs" (physician-owned companies), and others have called "POIs" (physician-owned intermediaries).

The POC Business Model: An Inherent Conflict of Interest. Since most implantable devices are physician preference items, a surgeon is in the unique position to direct the type of device, and device supplier, a hospital must purchase for that physician to use in connection with his or her procedures. Thus, physician ownership in a POC presents a uniquely problematic scenario, pitting a physician's own financial self-interest in selecting a POC-supplied device against a patient's best interest.

The POC Business Model: Three Variations on the Same Theme.

1. "Distributor" POCs: Most implantable medical devices are sold directly to hospitals. So-called "distributor" POCs use the leverage of their physician-investors to insert themselves into the supply chain where they either buy and resell, or solicit commissions for arranging for the sale, of certain implantable devices, and then share these proceeds with their physician-investors in the form of "profits," "investment dividends," or other payments or financial benefits.

2. "Manufacturer" POCs: Some POCs purport to operate as implant manufacturers; however, these entities appear in fact to be nothing more than distributors, outsourcing all key manufacturing functions. Thus, like POC "distributors," "manufacturer" POCs add no value other than their mark-up on the outsourced implant product.

3. "GPO" POCs: Some POCs organize themselves in an attempt to take advantage of the Antikickback Law safe harbor for group purchasing organizations (GPOs), which allows manufacturers to pay fees to a GPO in exchange for the GPO aggregating the purchasing power of a large number of hospital buyers for lower prices. The safe harbor should not be available for fees to a "GPO" POC, which typically lacks any significant membership that would allow it to aggregate purchasing power, and which in any event acts in the interests of its physician-owners in violation of the GPO's obligation to serve in the fiduciary capacity of a purchasing *agent* for its hospital members. In any event, the safe harbor does not protect the physicians' ownership interest, so that the "GPO fees" paid by participating manufacturers are nothing more than kickbacks to the physician-owners for ordering the manufacturer's implants.

OIG and CMS Concerns. Both CMS and the HHS Office of Inspector General have recognized the inherent conflict of interest and potential for harm presented by the self-referral of physician-investors to POCs, but to date insufficient regulatory and investigative effort has been expended to stem their proliferation.

- OIG has cautioned that "[g]iven the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers, we believe these entities should be closely scrutinized under the fraud and abuse laws."
- More recently, OIG stated that "physician ownership of medical device manufacturers and related businesses appears to be a growing trend in the medical device sector. These business ventures raise substantial concerns that a physician's return on investment from the venture may influence the physician's choice of device," in violation of the Antikickback Law, the False Claims Act, and/or OIG's Civil Monetary Penalty authority.
- In discussing the status of POCs under the Stark Law, CMS stated that "[w]e are concerned that some [POCs] may serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices . . . that the physician-investors use on their own patients."
- CMS has opined that "[i]n many instances, the [POC] arrangement would not satisfy the requirements of the exception for indirect compensation arrangements . . . and would, therefore, run afoul of the physician self-referral [Stark] statute."
- In the same publication, CMS analogized POCs to physician-owned "under arrangements" providers, which it noted are "contrary to the plain intent" of the Stark Law.

Congress Should Act to Stop POC Self-Referral Abuse. Small clarifications to the language of S. 301 would be a significant step in the right direction of making the patient and program abuse of self-referral to POCs more transparent, and Congressional support of existing OIG and CMS initiatives could in the longer term produce even more desirable protection for patients and payors.

Make the Financial Benefit Transparent. With minor changes to S. 301 *(attached)*, Congress can ensure that the hidden financial benefits to referring physicians of their POC ownership at least get the scrutiny they deserve, highlighting the inherent conflict of interest and allowing patients and payors to make informed decisions of whether to deal with such entities.

- Make S. 301apply to "Applicable Distributors." The Bill currently applies to "Applicable Manufacturers" and "Applicable Group Purchasing Organizations." Add a definition of "Applicable Distributors" as entities that buy and resell, or receive commissions for arranging for sale, of covered drugs or devices.
- Require Sunshine for "Applicable Distributors." Require "Applicable Distributors" to disclose their physician ownership and payment arrangements, including "sales commissions," just as the Bill currently does for "Applicable Manufacturers" and "Applicable Group Purchasing Organizations."

Support Prohibiting Self-Referral to POCs. Since at least "one purpose" of physician investment in POCs is to induce the physician-investor's referral of patients to hospitals that purchase implants through the POC, these entities already violate the Antikickback Law; however, while OIG has strongly cautioned against these arrangements, the need to establish criminal intent appears to have slowed significant enforcement action to date. Likewise, CMS has recognized that self-referral to POCs is likely to lead to Stark violations and program abuses, and has indicated the possibility of further regulatory clarifications that have not yet been issued. Stronger Congressional oversight of OIG's approach to POCs under the Antikickback Law, and of CMS's interpretation and implementation of the Stark Law in this area, would be of great benefit to patients and to the Medicare and Medicaid programs.

For more information, contact Tom Bulleit, Hogan & Hartson LLP (TNBulleit@hhlaw.com)

111th CONGRESS
1st Session
S. 301

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

IN THE SENATE OF THE UNITED STATES

January 22, 2009

Mr. GRASSLEY (for himself, Mr. KOHL, and Ms. KLOBUCHAR) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XI of the Social Security Act to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, biologicals, or medical supplies for which payment is made under Medicare, Medicaid, or SCHIP.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the `Physician Payments Sunshine Act of 2009'.

SEC. 2. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128F the following new section:

`SEC. 1128G. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

`(a) Transparency Reports-

`(1) PAYMENTS OR OTHER TRANSFERS OF VALUE-

`(A) IN GENERAL- Except as provided in subsection (e), on March 31, 2011, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

`(i) The name of the covered recipient.
`(ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and Medicare billing number of the covered recipient.
`(iii) The value of the payment or other transfer of value.
`(iv) The dates on which the payment or other transfer of value was provided to the covered recipient.
`(v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as--
`(I) cash or a cash equivalent;
`(II) in-kind items or services;
`(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or
`(IV) any other form of payment or other transfer of value (as defined by the Secretary).
`(vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as--
`(I) consulting fees;
`(II) compensation for services other than consulting;
`(III) honoraria;
`(IV) gift;
`(V) entertainment;
`(VI) food;
`(VII) travel;
`(VIII) education;
`(IX) research;
`(X) charitable contribution;
`(XI) royalty or license;
`(XII) current or prospective ownership or investment interest;
`(XIII) compensation for serving as faculty or as a speaker for a continuing medical education program;
`(XIV) grant; or
`(XV) any other nature of the payment or other transfer of value (as defined by the Secretary).
`(vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.
`(viii) Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.
`(B) AGGREGATE REPORTING- Information submitted by an applicable manufacturer under subparagraph (A) shall include the aggregate amount of all payments or other transfers of value provided by the applicable manufacturer to covered recipients (and to entities or individuals at the request of or designated on behalf of a covered recipient) during the preceding year.
`(C) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE- In the case where an applicable manufacturer

provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

`(2) PHYSICIAN OWNERSHIP- In addition to the requirement under paragraph (1)(A), on March 31, 2011, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer**,** ~~or~~ applicable group purchasing organization**,** ***OR APPLICABLE DISTRIBUTOR*** shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c)) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a))) in the applicable manufacturer**,** ~~or~~ applicable group purchasing organization***, OR APPLICABLE DISTRIBUTOR*** during the preceding year:

`(A) The dollar amount invested by each physician holding such an ownership or investment interest.

`(B) The value and terms of each such ownership or investment interest.

`(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (viii) of paragraph (1)(A), except that in applying such clauses, `physician' shall be substituted for `covered recipient' each place it appears.

`(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.

`(b) Penalties for Noncompliance-

`(1) FAILURE TO REPORT-

`(A) IN GENERAL- Subject to subparagraph (B), except as provided in paragraph (2), any applicable manufacturer**,** ~~or~~ applicable group purchasing organization***, OR APPLICABLE DISTRIBUTOR*** that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

`(B) LIMITATION- The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer**,** ~~or~~ applicable group purchasing organization***, OR APPLICABLE DISTRIBUTOR*** shall not exceed $150,000.

`(2) KNOWING FAILURE TO REPORT-

`(A) IN GENERAL- Subject to subparagraph (B), any applicable manufacturer**,** ~~or~~ applicable group purchasing organization***, OR APPLICABLE DISTRIBUTOR*** that knowingly fails to submit information

required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

`(B) LIMITATION- The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer**,** ~~or~~ applicable group purchasing organization***, OR APPLICABLE DISTRIBUTOR*** shall not exceed $1,000,000.

`(3) USE OF FUNDS- Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

`(c) Procedures for Submission of Information and Public Availability-

`(1) IN GENERAL-

`(A) ESTABLISHMENT- Not later than November 1, 2009, the Secretary shall establish procedures--

`(i) for applicable manufacturers**,** ~~and~~ applicable group purchasing organizations***, AND APPLICABLE DISTRIBUTORS*** to submit information to the Secretary under subsection (a); and

`(ii) for the Secretary to make such information submitted available to the public.

`(B) DEFINITION OF TERMS- The procedures established under subparagraph (A) shall provide for the definition of terms (other than those terms defined in subsection (g)), as appropriate, for purposes of this section.

`(C) PUBLIC AVAILABILITY- The procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2011, and on June 30 of each calendar year beginning thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that--

`(i) is searchable and is in a format that is clear and understandable;

`(ii) contains information that is presented by the name of the applicable manufacturer**,** ~~or~~ applicable group purchasing organization, ***OR APPLICABLE DISTRIBUTOR,*** the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply, as applicable;

`(iii) contains information that is able to be easily aggregated and downloaded;

`(iv) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year;

`(v) contains background information on industry-physician relationships;

`(vi) in the case of information submitted with respect to a payment or other transfer of value described in subsection (e), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;

`(vii) contains any other information the Secretary determines would be helpful to the average consumer; and

`(viii) provides the covered recipient an opportunity to submit corrections to the information made available to the public with respect to the covered recipient.

`(2) CONSULTATION- In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

`(d) Annual Reports and Relation to State Laws-

`(1) ANNUAL REPORT TO CONGRESS- Not later than April 1 of each year beginning with 2011, the Secretary shall submit to Congress a report that includes the following:

`(A) The information submitted under subsection (a) during the preceding year, aggregated for each applicable manufacturer**,** ~~and~~ applicable group purchasing organization***, AND APPLICABLE DISTRIBUTOR*** that submitted such information during such year.

`(B) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year.

`(2) ANNUAL REPORTS TO STATES- Not later than April 1 of each year beginning with 2011, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State.

`(3) RELATION TO STATE LAWS-

`(A) IN GENERAL- Effective on January 1, 2010, subject to subparagraph (B), the provisions of this section shall preempt any law or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as defined in subsection (g)) to disclose or report information (as described in subsection (a)) regarding a payment or other transfer of value provided by the applicable manufacturer to a covered recipient (as so described).

`(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS- Subparagraph (A) shall not preempt any law or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information not required to be disclosed or reported under this section.

`(e) Delayed Reporting for Payments Made Pursuant to Product Development Agreements and Clinical Investigations- In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product development agreement for services furnished in connection with the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation, the applicable manufacturer may report the value of such payment or other transfer of value in the first reporting period under subsection (a) after the earlier of the following:

`(1) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

`(2) Two calendar years after the date such payment or other transfer of value was made.

`(f) Implementation-

`(1) CONSULTATION- The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

`(2) LIMITATION ON REVIEW- There shall be no judicial review of the implementation of this section.

`(g) Definitions- In this section:

‘ (1) ***APPLICABLE DISTRIBUTOR. – THE TERM ‘APPLICABLE DISTRIBUTOR’ MEANS AN ENTITY, OTHER THAN AN APPLICABLE GROUP PURCHASING ORGANIZATION, THAT BUYS AND RESELLS, OR RECEIVES A COMMISSION OR OTHER SIMILAR FORM OF PAYMENT, FROM ANOTHER SELLER, FOR SELLING OR ARRANGING FOR THE SALE OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.***

`(~~1~~*2*) APPLICABLE GROUP PURCHASING ORGANIZATION- The term `applicable group purchasing organization' means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply.

`(~~2~~*3*) APPLICABLE MANUFACTURER- The term `applicable manufacturer' means a manufacturer of a covered drug, device, biological, or medical supply.

`(~~3~~*4*) CLINICAL INVESTIGATION- The term `clinical investigation' means any experiment involving 1 or more human subjects in which a drug or device is administered, dispensed, or used.

`(~~4~~*5*) COVERED DEVICE- The term `covered device' means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

`(~~5~~*6*) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY- The term `covered drug, device, biological, or medical supply' means any drug, biological product, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

`(~~6~~*7*) COVERED RECIPIENT- The term `covered recipient' means the following:

`(A) A physician.

`(B) A physician medical practice.

`(C) A physician group practice.

`(~~7~~*8*) EMPLOYEE- The term `employee' has the meaning given such term in section 1877(h)(2).

`(~~8~~***9***) KNOWINGLY- The term `knowingly' has the meaning given such term in section 3729(b) of title 31, United States Code.

`(~~9~~***10***) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY- The term `manufacturer of a covered drug, device, biological, or medical supply' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, processing, marketing, or distribution of a covered drug, device, biological, or medical supply (or any subsidiary of or entity affiliated with such entity).

`(~~10~~***11***) PAYMENT OR OTHER TRANSFER OF VALUE-

`(A) IN GENERAL- The term `payment or other transfer of value' means a transfer of anything of value and includes, subject to subparagraph (B), without limitation, any compensation, gift, honorarium, speaking fee, consulting fee, travel, services, dividend, profit distribution, stock or stock option grant, or ownership or investment interest.

`(B) EXCLUSIONS- An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

`(i) Any payment or other transfer of value provided by an applicable manufacturer to a covered recipient where the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient does not exceed $100 during the calendar year. Such aggregate amount shall be determined without taking into account any payment or other transfer of value described in clauses (ii) through (ix).

`(ii) Product samples that are not intended to be sold and are intended for patient use.

`(iii) Educational materials that directly benefit patients or are intended for patient use.

`(iv) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

`(v) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

`(vi) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

`(vii) Discounts (including rebates).

`(viii) In-kind items used for the provision of charity care.

`(ix) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

`(~~11~~***12***) PHYSICIAN- The term `physician' has the meaning given that term in section 1861(r). For purposes of this section, such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).'.