

OIG NEWS

For Immediate Release June 23, 2004

Office of Inspector General 330 Independence Ave., SW Washington, D. C. 20201 Phone: 202/619-1343

OIG INITIATES KICKBACK CIVIL MONETARY PENALTY CASE AGAINST PHARMERICA

Demand Letter Seeks \$21.8 Million and Ten Year Exclusion

The Office of Inspector General disclosed today the issuance of a demand letter on June 17, 2004 to PharMerica Drug Systems, Inc., one of the nation's largest institutional pharmacies, based on alleged kickback violations. The demand letter initiates the formal administrative process seeking civil monetary penalties and damages totaling \$21.8 million and a ten-year exclusion from participation in Federal health care programs. This is the largest amount ever sought by the OIG in a civil monetary penalty case and represents a continuation of the OIG's active enforcement of its administrative remedies for kickbacks.

The OIG alleges that PharMerica agreed to purchase a small Virginia pharmacy for an excessive amount in return for a commitment from the sellers, who also owned 17 nursing homes and 8 assisted living facilities, to refer their Medicaid patient's pharmacy business to PharMerica for the next seven years. The purchase price for the pharmacy, Hollings Manor I in Roanoke, which had virtually no operating history, was \$7.2 million. The OIG charged that the agreement violated the anti-kickback statute's prohibition on the payment of remuneration to induce the referral of Federal health care patients or business.

In addition to the monetary payment sought in this case, PharMerica's exclusion would mean that for the next ten years, no Federal health care program (including Medicare and Medicaid) would pay anyone for any items or services furnished (including distributed or supplied) by PharMerica. The OIG may seek civil monetary penalties, assessments or damages, and exclusion for a wide variety of conduct, including the payment or receipt of kickbacks for Federal health care program business. Since 2001, the OIG has collected over \$3.2 million dollars in settlement of 30 civil monetary penalty cases alleging violations of the kickback statute and/or the physician self-referral ("Stark") statute.

The civil monetary penalty, damages, and exclusion set forth in the demand letter will automatically become effective 65 days after the date of the demand letter unless PharMerica submits a timely request for a hearing before an administrative law judge.

PharMerica, which is headquartered in Tampa, Florida, specializes in the provision of pharmacy supplies and services to long-term care institutions. According to its website, PharMerica has 83 regional pharmacies throughout the nation, serving 300,000 patients. PharMerica is a wholly owned subsidiary of AmerisourceBergen Corporation, a global supplier of pharmaceuticals, medical-surgical supplies, specialty healthcare products, and related services.



Washington, D.C. 20201

June 17, 2004

VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED

Charles J. Carpenter President and Chief Executive Officer PharMerica Drug Systems, Inc. 175 Kelsey Lane Tampa, Florida 33619

Dear Mr. Carpenter:

I am writing to inform you that pursuant to the authority delegated by the Secretary of Health and Human Services to the Office of Inspector General (OIG), I am proposing to impose a Civil Monetary Penalty (CMP), damages, and a period of exclusion from participating in Medicare, Medicaid, and all Federal health care programs under section 1128A(a)(7) of the Social Security Act (the Act), 42 U.S.C. § 1320a-7a(a)(7), and 42 C.F.R. § 1003.102(b)(11) against PharMerica Drug Systems, Inc. (PharMerica).

I am proposing to impose a CMP of \$200,000 and damages of \$21,600,000. I am also proposing to exclude PharMerica from participating in Medicare, Medicaid, and all Federal health care programs for a period of 10 years. These proposed sanctions are based on PharMerica's offer and payment of remuneration to the owners of Hollins Manor I, L.L.C. (HMI), an institutional pharmacy, to induce the referral of Federal health care business to PharMerica from nursing facilities also owned by HMI's owners.

The Statutory Basis for the Proposed CMP, Damages, and Exclusion

Section 1128B(b)(2) of the Act (the Anti-Kickback Statute) states as follows:

Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –

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(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program, or
(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

See 42 U.S.C. § 1320a-7b(b)(2).

In addition to this criminal penalty, under the Civil Monetary Penalties Law (CMPL), the OIG is authorized to impose a CMP of up to \$50,000 for each act in violation of the Anti-Kickback Statute, damages of not more than three times the total amount of remuneration offered or paid, and a period of exclusion from participation in Medicare, Medicaid, and all other Federal health care programs. See section 1128A(a)(7) of the Act, 42 U.S.C. § 1320a-7a(a)(7); see also 42 C.F.R. § 1003.102(b)(11). The CMPL specifies that a principal is liable for penalties, assessments, and exclusion under this section for the actions of the principal's agent acting within the scope of the agency. See section 1128a(l) of the Act, 42 U.S.C. § 1320a-7a(l).

I have determined that PharMerica knowingly and willfully offered and paid remuneration to HMI's owners to induce them to refer their nursing home patients to PharMerica for the furnishing, or to arrange for the furnishing, of pharmacy items and/or services payable by a Federal health care program, or to induce HMI's owners to arrange for, or recommend the purchasing and/or ordering of, such pharmacy goods, services, and/or items. This conduct violates sections 1128A(a)(7) and 1128B(b) of the Social Security Act, 42 U.S.C. §§ 1320a-7a(a)(7) and 1320a-7b(b).

The Factual Basis for the Proposed CMPs, Damages, and Exclusion

On December 8, 1997, PharMerica entered into a purchase agreement to buy HMI for \$7,200,000. HMI's owners also owned 17 nursing homes serving approximately 2,000 residents and eight assisted living facilities (ALFs) serving approximately 800 residents. PharMerica paid a substantial purchase price for this newly-constructed pharmacy, whose key asset was a Pharmacy Services Agreement (PSA) that contractually provided for the nursing homes and ALFs owned by HMI's owners to refer their residents to HMI for pharmaceutical items and services for a period of seven years. PharMerica paid that

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substantial purchase price to induce the sellers to refer their nursing facilities residents' Medicaid business to PharMerica, or to purchase, order, arrange for, or recommend purchasing or ordering such nursing facilities residents' Medicaid business from PharMerica. To a significant extent, the purchase price reflected the value of the future business generated by these referrals.

The payment schedule set forth in the purchase agreement was as follows: (1) \$250,000 to seller Keith Green on December 8, 1997; (2) \$4,950,000 to the remaining sellers, William C. Cranwell, Robert M. Cranwell, Richard W. Frizzell, and Charles B. Walker on December 8, 1997; (3) \$1,000,000 to William C. Cranwell, Robert M. Cranwell, Richard W. Frizzell, and Charles B. Walker on or before June 8, 1998, and (4) \$1,000,000 to William C. Cranwell, Robert M. Cranwell, Richard W. Frizzell, and Charles B. Walker on or before December 8, 1998. The payments of remuneration that form the basis for the imposition of CMPs, damages, and exclusion are these four payments that occurred between December 8, 1997 and December 8, 1998.

The Amount of CMPs, Damages, and Length of Exclusion

Because the OIG has determined that these payments violated the Anti-Kickback Statute, the OIG is authorized under section 1128A(a)(7) of the Act, 42 U.S.C. § 1320a-7a(a)(7), to seek a CMP of up to \$50,000 for each act, i.e., each offer or payment. The OIG is also authorized to seek damages of up to treble the amount of remuneration offered or paid, without regard to whether a portion of such remuneration was offered or paid for a lawful purpose. Finally, the OIG may seek exclusion from participation in Medicare, Medicaid, and all other Federal health care programs. Id.

I am proposing that PharMerica pay a CMP of \$200,000 and damages in the amount of \$21,600,000. Additionally, I am proposing to exclude PharMerica from participating in Medicare, Medicaid, and all Federal health care programs for a period of 10 years.

In determining the appropriate amount of penalty, damages, and period of exclusion to impose, I have considered the following circumstances set forth in 42 C.F.R. §§ 1003.106(a)(1) and (b); see also 42 C.F.R. § 1003.107:

• Nature and Circumstances of the Incident. PharMerica knew that HMI was a newly-constructed pharmacy with a limited operating history, and PharMerica knew of the legal risks associated with the purchase of such a pharmacy. PharMerica further knew that HMI's primary value lay in the potential future stream of Medicaid business from the nursing homes owned by the same people who owned HMI. PharMerica was also aware of the legal risks of purchasing a

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"captive" institutional pharmacy, whose value derived largely from future business to be referred from the seller, especially a pharmacy with little or no operating history. Prior to the closing of the sale, PharMerica actively negotiated terms of the PSA and knew or should have known that HMI backdated the PSA to a date 18 months earlier than the date it was actually signed. The backdating of the PSA obscured the fact that the PSA was actually executed only a few weeks before the sale of HMI. The PSA provided for seven years of referrals of business from 2,000 nursing home residents, the large majority of whom were Medicaid beneficiaries. In addition to this significant number of patient referrals over such a long period of time, the OIG also considered the large amount of remuneration offered and paid in this case.

The Effect of Program Exclusion

The exclusion described in this letter would affect PharMerica's participation in Medicare, Medicaid, and all Federal health care programs, as defined in section 1128B(f) of the Act, 42 U.S.C. § 1320a-7b(f). The exclusion would have national effect and apply to all federal procurement and non-procurement programs and activities. The effect of PharMerica's exclusion is that no payment may be made by the above-mentioned programs for any items or services furnished, ordered, or prescribed (either directly or indirectly) by PharMerica, except as provided at 42 C.F.R. § 1001.1901(c), during PharMerica's exclusion. This payment ban applies to all methods of Federal program reimbursement, whether payment results from itemized claims, cost reports, fee schedules, or a prospective payment system (PPS). This payment prohibition applies when the Federal payment itself is made to another provider, practitioner or supplier that is not excluded for items or services manufactured, distributed, or otherwise supplied by PharMerica.

PharMerica cannot submit claims or cause claims to be submitted for payment under any Federal health care program for items or services furnished, ordered, or prescribed by PharMerica, during the period of exclusion. Violations of the terms and conditions of the exclusion may subject PharMerica to the imposition of civil monetary penalties as set forth at section 1128A of the Act, 42 U.S.C. § 1320a-7a, and/or criminal prosecution under section 1128B of the Act, 42 U.S.C. § 1320a-7b. Submitting claims or causing claims to be submitted to the programs for items or services PharMerica furnishes, orders, or prescribes, including management services or salary, can also serve as the basis for denying PharMerica reinstatement to the programs. 42 C.F.R. § 1001.3002(a)(2).

The Requirements and Procedures for Reinstatement

At the expiration of the period of exclusion, the reinstatement of PharMerica's participation in the Federal health care programs is not automatic. PharMerica must apply for reinstatement to Medicare, Medicaid, and all Federal health care programs under the provisions in 42 C.F.R. §§ 1001.3001-.3005. To apply for reinstatement to these programs, PharMerica must submit a written request to the OIG no earlier than 90 days prior to the expiration of the period of exclusion. At that time, PharMerica will be notified of the information and documentation required for the OIG to reach a decision regarding reinstatement.

Appeal Rights

The CMP, damages, and exclusion authorized by section 1128A(a) of the Act, 42 U.S.C. § 1320a-7a(a), and as set forth in this notice, will automatically become effective 65 days after the date of this letter unless PharMerica submits a timely request for a hearing. To request a hearing, PharMerica must file a request under the procedures set forth at 42 C.F.R. Part 1005 within 60 days of your receipt of this letter. Such a request must: (1) contain a statement as to the specific issues or facts and legal conclusions in the notice with which PharMerica disagrees; and (2) state the bases for PharMerica's contention why such specific issues or statements and conclusions are incorrect. See 42 C.F.R. § 1005.2(d). If PharMerica wishes to request a hearing, it must submit its request to:

Jacqueline Williams
Chief, Civil Remedies Division
Departmental Appeals Board, MS 6132
U.S. Department of Health and Human Services
330 Independence Ave, S.W.
Cohen Building, Room G-644
Washington, DC 20201
Telephone: (202) 565-0110

Due to delivery delays created by the irradiation process now in place for all Federal mail in Washington, DC, we recommend that PharMerica also send a copy of any request for hearing to Ms. Williams at the Departmental Appeals Board via facsimile at (202) 656-0226.

If PharMerica chooses not to contest the proposed penalties, damages, and exclusion, PharMerica should submit a written statement accepting their imposition within 60 days

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of receipt of this notice. Please have PharMerica's attorney contact Andrew S. Penn at (202) 205-9505 if you have any questions.

Sincerely,

Larry J. Goldberg

Assistant Inspector General for Legal Affairs

cc: Richard Beckler, Esq.