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MEMORANDUM

To: PPSV Clients
From: Mark R. Fitzgerald and Johanna Michaels Kreisel
Date: April 16, 2010
Re: Fraud and Abuse Provisions in the Patient Protection and Affordable Care Act

This memorandum provides a brief overview of the fraud and abuse provisions in the Patient Protection and Affordable Care Act (PPACA P.L. 111-148) which was enacted on March 23, 2010 and the Health Care and Education Reconciliation Act of 2010 (HEARA P.L. 111-152) which became effective on March 30, 2010. We focus on five areas that are relevant to PPSV clients including the 60-day reporting requirement for overpayments, changes to the beneficiary inducement prohibitions under the Civil Monetary Penalty (CMP) statute, new enforcement of physician-ordered durable medical equipment (DME), a new self-referral disclosure protocol and a new disclosure requirement for the provision of certain items under the in-office ancillary exception to the physician self-referral law.

1. Reporting and Returning Overpayments

Section 6402(a) of P.L. 111-148 requires any provider, supplier, Medicaid managed care organization, Medicare Advantage organization or PDP sponsor to report and return an overpayment from the Medicare or Medicaid program to the appropriate authority such as the Secretary, State, contractor or fiscal intermediary and provide written notification of the reason for the overpayment. An overpayment is defined as any funds received or retained after

appropriate reconciliation to which the entity or person is not entitled.¹ The overpayment must be paid within 60 days after it was identified or the date on which the corresponding cost report is due. The withholding of an overpayment past the 60-day deadline is classified as an “obligation” under the False Claims Act (FCA) and subjects the provider to potential FCA liability.² The new law also gives the OIG authority to impose civil monetary penalties against a person who withholds repayment beyond 60 days.³ There is no clarification as to when an overpayment should be considered to have been “identified,” and even the Assistant Inspector General for Legal Affairs at the Office of the Inspector General (OIG) acknowledged that this standard is “murky.”⁴ Therefore, providers will have to develop new compliance strategies to ensure that they are not in possession of overpayments beyond the 60-day window. These will include policies for deciding when the 60-day clock should begin to run on an overpayment issue, and responding to situations where the audit work required to identify the specific claims that have been overpaid and the overpayment amounts cannot be completed within the 60-day window. This requirement went into effect on March 23, 2010.

2. Beneficiary Inducement Provisions

PPACA significantly expands the exceptions to prohibited “remuneration” under the CMP statute. The law prohibits any offer or transfer of remuneration that a person knows or should know is likely to influence a Medicare or Medicaid beneficiary to order or receive services from a particular provider.⁵ PPACA changes the definition of remuneration to give providers greater flexibility to distribute charitable items and benefits to patients. Section 6402(d)(2)(B) creates four new exceptions to the definition of remuneration under the CMP.⁶ Most important to providers are the following three exceptions:

- 1) Remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs.
- 2) The offer or transfer of items or services for free or less than fair market value by a person *if the items or services consist of coupons, rebates, or other awards from a retailer*; the items or services are offered or transferred on equal terms to the general public, regardless of insurance status and the offer or transfer of the items or services are not tied to the provision of other items or services reimbursed by Medicare or Medicaid.
- 3) The offer or transfer of items or services for free or less than fair market value by a person if the items are not offered as part of any advertisement or solicitation; the items or services are not tied to the provision of other services reimbursed by Medicare or Medicaid; there is a reasonable connection between the items or services

¹ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 111th Congress §6402 (2010).

² *Id.* (Noting that “[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.”).

³ Pub. L. No. 111-148, §6402(d)(2).

⁴ This statement was made in the context of a presentation and does not represent the formal view of the OIG.

⁵ 42 U.S.C. §1320a-7a(a)(5).

⁶ Pub. L. No. 111-148, §6402(d)(2)(B).

and the medical care of the individual and the person provides the items or services after determining in good faith that the individual is in financial need.

While the first exception should cover many charitable activities of a provider, we recommend not relying solely on this provision until additional guidance is issued by the OIG. It is simply too unclear at this stage to determine when a gift will be deemed to promote access to care. Under the second exception, a provider may offer discounts and coupons *from retailers* so long as they are made available to *all patients*, and so long as the offer is not contingent on the patient receiving other items or services from the provider. The third option allows providers to set up charitable support programs based on *financial need* so long as the program is not tied to the provision of other services by the provider and is not marketed or advertised. The benefits provided under this exception must be connected to the patient's receipt of medical care. For example, offering financially needy patients free transportation to and from appointments should meet this test. These changes became effective on March 23, 2010.

3. Physician-Ordered Durable Medical Equipment

As part of Health and Human Services' (HHS) efforts to eliminate fraud and abuse in the durable medical equipment and home health suppliers' markets, section 6406 of PPACA grants the Secretary an additional enforcement tool to regulate the prescribing of durable medical equipment (DME) and home health services.⁷ This section authorizes the Secretary to revoke the Medicare enrollment of a physician or supplier for up to a year for the failure to maintain and upon request, provide documentation relating to written orders or requests of payment for DME and home health certifications. The statute authorizes the Secretary to apply this requirement to other items or services ordered by a physician or supplier. This provision adds another enforcement device to the Secretary's arsenal which is perhaps not as severe as pursuing a false claims action against a provider but clearly more significant than a simple disallowance of a claim.

In addition to the documentation requirement, the following section, §6407, requires a physician, physician assistant, nurse practitioner or clinical nurse specialist to certify that he/she has had a face-to-face encounter with the patient within six months of issuing an order for DME.⁸ The documentation requirement applies to orders, certifications or referrals made on or after January 1, 2010. The face-to-face requirement became effective on March 23, 2010.

4. Stark Self-Referral Disclosure Protocol

Section 6409 creates a process for disclosing violations and potential violations of the Medicare Physician Self-Referral Law ("Stark law") to the Secretary of HHS. This protocol must be developed within six months of enactment.⁹ It also creates a new authority in which the Secretary may reduce civil monetary penalties for violation of the Stark law by taking into consideration the timeliness of the disclosure, the physician's and/or DHS entity's cooperation, the nature and extent of the illegality or impropriety of the act and other factors deemed

⁷ Pub. L. No. 111-148, §6406.

⁸ Pub. L. No. 111-148, §6407.

⁹ Pub. L. No. 111-148, §6409.

necessary by the Secretary. Within 18 months of establishment, the Secretary is required to submit to Congress a report on the amount of money collected through the protocol as well as the number of disclosures made and the types of violations reported. It is unclear whether self-disclosure under this protocol will relieve a provider of its obligations to submit an overpayment within 60 days of identification. While additional clarification from OIG is necessary, we note that the OIG's self disclosure protocol for non-Stark issues discourages providers from making payment at the time of initial disclosure.

5. In-Office Ancillary Exception Disclosure Requirement

In addition to the disclosure requirement for Stark violations, section 6003 amends the Physician Self-Referral Law to require physician practices that rely on the Stark law's "in-office ancillary services exception" to provide patients with a list of alternative suppliers each time the following "in-office" imaging procedures are offered: MRI, CT and PET. CMS has the authority to extend this disclosure requirement to "other radiology" services that are "designated health services" for Stark purposes. This disclosure must be provided at the time the test is ordered, must be in writing and inform the patient that he or she may obtain the test from someone other than the referring physician or group. Additionally, the disclosure should include a list of other "suppliers" of imaging services in the area where the patient resides.

This provision raises a number of complicated implementation questions which will ultimately require guidance, probably through formal rule-making from CMS. Indeed, an argument can be made that the provision is not enforceable until regulations are promulgated, but since the provision explicitly provides an effective date of January 1, 2010, we recommend that practitioners move forward with good faith implementation efforts while awaiting guidance from the agency.

Conclusion

There a number of significant changes to fraud and abuse enforcement established through PPACA. As discussed above, many of these changes will require clarifying guidance from the Secretary of HHS or the OIG. We will keep you updated as these issues evolve. Please do not hesitate to contact us with additional questions.