

## **MEDICARE-MEDICAID FRAUD AND ABUSE AND ANTI-KICKBACK PROVISIONS**

NOTE: Analysis of issues related to Medicare and Medicaid fraud and abuse, federal and state anti-kickback laws is generally quite complex and fact-specific. Most of the safe harbors related to the federal anti-kickback law contain multiple enumerated requirements which must be met in order to achieve safe harbor protection. Physicians are well-advised to seek legal advice on these matters.

### **What constitutes fraud under the Medicare-Medicaid laws?**

In general terms, for purposes of Medicare and Medicaid laws, “fraud” means an intentional deception or misrepresentation made for the purpose of obtaining payment or other benefit not otherwise due or made with the knowledge that the deception or misrepresentation could result in some unauthorized payment or benefit to oneself or to some other person.<sup>1</sup> Fraud, for purposes of Medicaid law, also includes any act that would constitute fraud under any applicable state or federal law.

Health care fraud may take one of several forms, including among others:

- Submission of false claims for payment of items or services which were not provided.<sup>2</sup>
- Submission of claims for payment for items or services more complicated (or more costly) than those which were actually provided.<sup>3</sup>
- Kickback arrangements between service providers and their suppliers or referral sources.<sup>4</sup>

With respect to fraudulently making false statements regarding a federal health care program, a person does not need to have actual knowledge of the wrongful act or have a specific intent to commit fraud.<sup>5</sup>

### **What constitutes abuse under the Medicare-Medicaid laws?**

“Abuse,” for purposes of Medicare and Medicaid laws, means those practices of providers, physicians, and other suppliers of health care items or services which are inconsistent with accepted sound medical, financial, or business practices, such that those practices result, directly or indirectly, in unnecessary costs to the Medicare or Medicaid programs.<sup>6</sup> Specifically, the standards CMS uses to determine abuse in in billing are whether the act was (i) reasonable and necessary, (ii) conformed to professionally recognized standards, and (iii) provided at a fair

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<sup>1</sup> 42 C.F.R. § 455.2.

<sup>2</sup> 42 U.S.C. § 1320a-7b(a)(1),(2).

<sup>3</sup> 42 U.S.C. § 1320a-7a(a)(1)(A).

<sup>4</sup> 42 U.S.C. § 1320a-7b(b)(1).

<sup>5</sup> 42 U.S.C. § 1320a-7b(h).

<sup>6</sup> 42 C.F.R. § 455.2.

price.<sup>7</sup> Abuse can involve, among other things, claims for items or services which were not medically necessary or for which there is no legal entitlement to payment.<sup>8</sup> However, to constitute abuse, unlike fraud, no intentional deception or misrepresentation is required.<sup>9</sup>

### **What constitutes an illegal kickback under the Medicare and Medicaid programs?**

The Medicare-Medicaid anti-kickback statute<sup>10</sup> makes it a felony to knowingly and willfully offer, pay, solicit or receive any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for:

- Referring an individual to a person for the furnishing or arranging for the furnishing of any item or service payable in whole or in part under Medicare or Medicaid.
- Purchasing, leasing, ordering or arranging for or recommending purchasing, leasing or ordering any good, facility, service or item payable in whole or in part under Medicare or Medicaid.

Thus, the Medicare-Medicaid anti-kickback statute prohibits a physician from knowingly and willfully soliciting or receiving any kind of remuneration in any form in return for referring a patient for Medicare or Medicaid services. But a physician or other defendant does not have to have actual knowledge or a specific intent to commit a violation of the anti-kickback statute.<sup>11</sup> Further, some courts have held that, even where there are legitimate purposes for a payment, if one purpose of a payment is to induce referrals then the Medicare-Medicaid anti-kickback law has been violated.<sup>12</sup>

### **What are the penalties for violating the Medicare-Medicaid anti-kickback law?**

Violation of the Medicare-Medicaid anti-kickback law constitutes a felony punishable, upon conviction, by a fine of up to \$25,000 and/or imprisonment for up to five years.<sup>13</sup> Violations of the anti-kickback law may also result in the imposition of substantial civil money penalties and exclusion from participation in the Medicare and Medicaid programs.<sup>14</sup>

### **Are there any statutory exceptions to the Medicare-Medicaid anti-kickback law prohibitions?**

Yes. There are several statutory exceptions to the Medicare-Medicaid anti-kickback law prohibitions, which include:

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<sup>7</sup> Medicare General Information, Eligibility, and Entitlement, 20.3.2, available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ge101c01.pdf>.

<sup>8</sup> 42 U.S.C. § 1320a-7a(a)(1)(E).

<sup>9</sup> Medicare General Information, *supra*, at 20.3.2.

<sup>10</sup> 42 U.S.C. § 1320a-7b(b).

<sup>11</sup> 42 U.S.C. 1320a-7b(h).

<sup>12</sup> *United States v. Greber*, 760 F.2d 68 (3<sup>rd</sup> Cir., 1985); *United States v. Lahue*, 261 F.3d 993 (10<sup>th</sup> Cir., 2001).

<sup>13</sup> 42 U.S.C. § 1320a-7b(b).

<sup>14</sup> 42 U.S.C. § 1320a-7a(a).

- Discounts or price reductions obtained by a provider of services, if the discount or price reduction is properly disclosed and is passed along to Medicare and Medicaid.<sup>15</sup>
- Amounts paid by an employer to an employee who has a true employment relationship with the employer, for employment in the provision of items or services covered under Medicare or Medicaid.<sup>16</sup>
- Payments to certain group purchasing arrangements.<sup>17</sup>
- Waivers of Part B Medicare coinsurance by a federally qualified health care center with respect to an individual who qualifies for subsidized services under the Public Health Service Act.<sup>18</sup>
- Other payment practices, known as “safe harbors,” which have been specified in regulations promulgated by the Department of Health and Human Services (DHHS).<sup>19</sup>
- Certain remuneration between health maintenance organizations or competitive medical plans and individuals or entities providing items or services pursuant to written agreements, including through a risk-sharing arrangement that places the individual or entity at substantial financial risk for the cost or utilization of the items or services the individual or entity is to provide.<sup>20</sup>
- Certain waivers or deductions by pharmacies of cost-sharing.<sup>21</sup>
- Certain remuneration between certain federally qualified health centers (or entities controlled by such health centers) and a Medicare Advantage (MA) pursuant to a written agreement as described by law.<sup>22</sup>
- Certain remuneration between certain federally qualified health centers and individuals or entities providing goods, items, services, donations, loans, or a combination thereof to such health centers pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center.<sup>23</sup>

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<sup>15</sup> 42 U.S.C. § 1320a-7b(b)(3)(A).

<sup>16</sup> 42 U.S.C. § 1320a-7b(b)(3)(B).

<sup>17</sup> 42 U.S.C. § 1320a-7b(b)(3)(C).

<sup>18</sup> 42 U.S.C. § 1320a-7b(b)(3)(D).

<sup>19</sup> 42 U.S.C. § 1320a-7b(b)(3)(E).

<sup>20</sup> 42 U.S.C. § 1320a-7b(b)(3)(F).

<sup>21</sup> 42 U.S.C. § 1320a-7b(b)(3)(G).

<sup>22</sup> 42 U.S.C. § 1320a-7b(b)(3)(H).

<sup>23</sup> 42 U.S.C. § 1320a-7b(b)(3)(I).

- A discount in the price of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program (Medicare Part D).<sup>24</sup>

### **What are “safe harbor” regulations?**

Because the language of the anti-kickback statute is so broad that it could encompass many harmless, yet beneficial and efficient, commercial arrangements, Congress directed DHHS to promulgate regulations specifying those payment practices which, although potentially capable of inducing referrals of business under Medicare or Medicaid, would not be considered kickbacks for purposes of criminal prosecution or imposition of civil penalties under the anti-kickback law.<sup>25</sup>

DHHS has responded to that directive by promulgating 25 final safe harbors. Most of these safe harbors contain multiple enumerated requirements which must be met in order to achieve safe harbor protection. The enumerated requirements typically include, among other things, requirements that the amounts paid be consistent with fair market value and not be determined in a manner that takes into account, directly or indirectly, the volume or value of referrals.

If a remuneration arrangement fully complies with all of the enumerated requirements of a specific final safe harbor, the remuneration arrangement will not be subject to criminal prosecution or imposition of civil penalties under the Medicare-Medicaid anti-kickback statute.<sup>26</sup>

### **What happens if a remuneration arrangement does not fit entirely within a safe harbor?**

If a remuneration arrangement fails to fully comply with all of the enumerated requirements of a specific final safe harbor, there is no absolute protection from criminal or civil anti-kickback statute enforcement actions.<sup>27</sup> That does not mean, however, that all remuneration arrangements which do not fit squarely within the confines of a specific final safe harbor necessarily will be deemed criminal offenses or will be prosecuted under the anti-kickback law. It means simply that, where individuals and entities have entered into arrangements covered by the statute, but have failed to fully comply with an applicable final safe harbor or exception, they risk scrutiny and may be subject to civil or criminal enforcement action. The degree of risk depends on an evaluation of many which are the basis of the decision making process to select cases for investigation and prosecution.<sup>28</sup>

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<sup>24</sup> 42 U.S.C. § 1320a-7b(b)(3)(J).

<sup>25</sup> Section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93.

<sup>26</sup> 57 Fed. Reg. 52723.

<sup>27</sup> 65 Fed. Reg. 59441.

<sup>28</sup> 56 Fed. Reg. 35952.

## What areas are covered by the safe harbors?

DHHS has promulgated the safe harbors for:

- Payments that are returns on certain investment interests.<sup>29</sup>
- Payments made for certain space rentals.<sup>30</sup>
- Payments made for certain equipment rentals.<sup>31</sup>
- Payments made for services provided under certain personal services and management contracts.<sup>32</sup>
- Payments made for certain sales of practices by one practitioner to another practitioner.<sup>33</sup>
- Payments made in connection with certain referral services.<sup>34</sup>
- Payments made under certain warranties provided by a manufacturer or supplier.<sup>35</sup>
- Certain discounts on goods and services received by a buyer.<sup>36</sup>
- Amounts paid by an employer to an employee who has a true employment relationship with the employer.<sup>37</sup>
- Certain payments made by a vendor of goods and services to certain group purchasing organizations.<sup>38</sup>
- Certain waivers of beneficiary co-insurance and deductibles by hospitals for inpatient hospital services, as well as waivers of Part B co-insurance and deductibles by federally qualified health care centers or other health care facilities for individuals who qualify for subsidized services under the Public Health Services Act.<sup>39</sup>
- Certain incentives (such as increased coverage, reduced cost-sharing amounts or reduced premium amounts) which health maintenance organizations (HMOs), preferred provider organization (PPO), competitive medical plans (CMPs), pre-paid health plans (PHPs), or

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<sup>29</sup> 42 C.F.R. § 1001.952(a).

<sup>30</sup> 42 C.F.R. § 1001.952(b).

<sup>31</sup> 42 C.F.R. § 1001.952(c).

<sup>32</sup> 42 C.F.R. § 1001.952(d).

<sup>33</sup> 42 C.F.R. § 1001.952(e).

<sup>34</sup> 42 C.F.R. § 1001.952(f).

<sup>35</sup> 42 C.F.R. § 1001.952(g).

<sup>36</sup> 42 C.F.R. § 1001.952(h).

<sup>37</sup> 42 C.F.R. § 1001.952(i).

<sup>38</sup> 42 C.F.R. § 1001.952(j).

<sup>39</sup> 42 C.F.R. § 1001.952(k).

other health plans under contract with the Centers for Medicare and Medicaid Services (CMS)), or a state health care program provided to enrollees.<sup>40</sup>

- Certain price reductions offered to health plans.<sup>41</sup>
- Certain payments made to recruit practitioners to rural areas.<sup>42</sup>
- Certain obstetrical malpractice insurance subsidies in health professional shortage areas.<sup>43</sup>
- Payments that are returns on certain investment interests in group practices composed exclusively of active investors.<sup>44</sup>
- Certain payments made between a cooperative hospital service organization and its patron hospital.<sup>45</sup>
- Payments that are returns on certain investment interests in ambulatory surgical centers.<sup>46</sup>
- Certain referral agreements for specialty services.<sup>47</sup>
- Certain price reductions offered to eligible managed care organizations.<sup>48</sup>
- Certain price reductions offered by contracts with substantial financial risk to managed care organizations.<sup>49</sup>
- Replenishing of ambulance drugs or medical supplies.<sup>50</sup>
- Certain transfers of goods, items, services, donations, loans, or combinations thereof from an individual or entity to a federally qualified health center.<sup>51</sup>
- The provision of nonmonetary remuneration (consisting of hardware, software or information technology and training services) to transmit or receive electronic prescription information.<sup>52</sup>

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<sup>40</sup> 42 C.F.R. § 1001.952(l).

<sup>41</sup> 42 C.F.R. § 1001.952(m).

<sup>42</sup> 42 C.F.R. § 1001.952(n).

<sup>43</sup> 42 C.F.R. § 1001.952(o).

<sup>44</sup> 42 C.F.R. § 1001.952(p).

<sup>45</sup> 42 C.F.R. § 1001.952(q).

<sup>46</sup> 42 C.F.R. § 1001.952(r).

<sup>47</sup> 42 C.F.R. § 1001.952(s).

<sup>48</sup> 42 C.F.R. § 1001.952(t).

<sup>49</sup> 42 C.F.R. § 1001.952(u).

<sup>50</sup> 42 C.F.R. § 1001.952(v).

<sup>51</sup> 42 C.F.R. § 1001.952(w).

<sup>52</sup> 42 C.F.R. § 1001.952(x).

- The provision of nonmonetary remuneration (consisting of hardware, software or information technology and training services) to transmit or receive electronic health records.<sup>53</sup>

NOTE: Because most of the safe harbors contain multiple enumerated requirements which must be met in order to achieve safe harbor protection, physicians are well-advised to seek legal advice before assuming that their remuneration arrangements do not violate the anti-kickback law.

**Are there any “Fraud Alerts” which describe particular payment practices targeted by the agencies charged with the enforcement of the Medicare-Medicaid fraud and abuse and anti-kickback laws?**

Yes. The Office of Inspector General (OIG) has published a number of “Fraud Alerts” concerning certain kinds of remuneration arrangements, not protected by existing final safe harbors, which may be violative of the Medicare-Medicaid anti-kickback statute. The topics addressed by these Fraud Alerts are too numerous to list, but include:<sup>54</sup>

- Joint venture arrangements.
- Routine waiver of co-payments or deductibles under Medicare.
- Financial arrangements between hospitals and hospital-based physicians.<sup>55</sup>
- Hospital incentives to referring physicians.
- Prescription drug marketing schemes.
- Arrangements for provision of clinical laboratory services.
- Home health fraud.
- Medical supplies to nursing facilities.
- Provision of services in nursing facilities.
- Nursing home arrangement with hospice.
- Physician liability for certification in the provision of medical equipment and supplies and home health services.

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<sup>53</sup> 42 C.F.R. § 1001.952(y).

<sup>54</sup> Available at: <https://oig.hhs.gov/compliance/alerts/index.asp>.

<sup>55</sup> See: Department of Health and Human Services Office of Inspector General, *Financial Arrangements Between Hospitals and Hospital-based Physicians*, Available at: <http://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf>; See also: 63 Fed. Reg. 8990.

- Rental of space in physician offices by persons or entities to whom the physicians refer.
- Telemarketing by durable medical equipment suppliers

### **Where can a physician obtain copies of Fraud Alerts?**

Physicians can obtain copies of Fraud Alerts from the Office of the Inspector General, Department of Health and Human Services, 200 Independence Avenue S.W., Washington, D.C. 20201, telephone number 1-800-368-5779. Information related to fraud alerts may also be found at <http://oig.hhs.gov/compliance/alerts/index.asp>.

The homepage for the Office of the Attorney General is: <http://oig.hhs.gov/>.

### **Does Washington also have an anti-kickback law?**

Yes. See **REBATES**.

### **Does compliance with the Medicare-Medicaid anti-kickback law ensure compliance with Washington's anti-rebate law?**

No, not necessarily. See **REBATES**.

### **Are there any physician self-referral prohibitions under the Medicare-Medicaid laws?**

Yes. See **MEDICARE-MEDICAID PHYSICIAN SELF-REFERRAL PROHIBITIONS (STARK LAWS)**.

### **Does compliance with the Medicare-Medicaid anti-kickback law ensure compliance with the STARK laws?**

No. The Medicare-Medicaid anti-kickback law and the STARK laws address different evils and contain different prohibitions and exceptions. Physicians need to examine their financial relationships with other health care providers and entities separately under each of these laws. Physicians are well-advised to seek legal advice concerning any financial relationships they have with referral sources.