RECENT GUIDANCE FOR COMPLIANCE PROFESSIONALS: FROM DOJ TO OIG TO CMS

Health Ethics Trust Certification Course
February 2021

Barrett Law, PA
1. Compliance Guidance
   - Federal Sentencing Guidelines
   - Office of Inspector General (OIG)
     ▪ Compliance Guidance
   - Department of Justice (DOJ)
     ▪ A Brief Look at Prior DOJ Guidance
     ▪ A Brief Look at the 2019 Changes
     ▪ 2020 Changes

3. Department of Justice
   - FY 2020 FCA Recoveries
   - Inability-to-Pay Memo
   - Civil Division 2021 Enforcement Priorities
   - Open Payments Program
4. Office of Inspector General (OIG) Hot Topics
   - Advisory Opinions - General
   - 2020 OIG Advisory Opinions
   - Special Fraud Alert: Speaker Program
   - Certain OIG Work Plan Updates
   - COVID Frequently Asked Questions (FAQs)

6. HHS/CMS Hot Topics
   - HHS Advisory Opinion/Rules on the Use of Sub-regulatory Guidance
   - HHS FCA Working Group
   - Certain Physician Fee Schedule Changes
Compliance Guidance

Federal Sentencing Guidelines

Office of Inspector General

Department of Justice
# Federal Sentencing Guidelines

## SENTENCING TABLE
(In months of imprisonment)

<table>
<thead>
<tr>
<th>Offense Level</th>
<th>I (0-1)</th>
<th>II (2-3)</th>
<th>III (4, 5, 6)</th>
<th>IV (7-9, 10)</th>
<th>V (11, 13, 15)</th>
<th>VI (18 or more)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0-6</td>
<td>0-6</td>
<td>0-6</td>
<td>0-6</td>
<td>0-6</td>
<td>0-6</td>
</tr>
<tr>
<td>2</td>
<td>0-6</td>
<td>0-6</td>
<td>0-6</td>
<td>0-6</td>
<td>1-7</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0-6</td>
<td>0-6</td>
<td>0-6</td>
<td>2-4</td>
<td>3-9</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0-6</td>
<td>0-6</td>
<td>0-6</td>
<td>2-8</td>
<td>4-10</td>
<td>6-12</td>
</tr>
<tr>
<td>5</td>
<td>0-6</td>
<td>0-6</td>
<td>1-7</td>
<td>4-10</td>
<td>6-12</td>
<td>9-15</td>
</tr>
<tr>
<td>6</td>
<td>0-6</td>
<td>1-7</td>
<td>2-8</td>
<td>6-12</td>
<td>9-15</td>
<td>12-18</td>
</tr>
<tr>
<td>7</td>
<td>0-6</td>
<td>2-8</td>
<td>4-10</td>
<td>8-14</td>
<td>12-18</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>0-6</td>
<td>4-10</td>
<td>6-12</td>
<td>10-16</td>
<td>14-21</td>
<td>18-24</td>
</tr>
<tr>
<td>9</td>
<td>4-10</td>
<td>6-12</td>
<td>8-14</td>
<td>12-18</td>
<td>16-24</td>
<td>20-30</td>
</tr>
<tr>
<td>10</td>
<td>6-12</td>
<td>8-14</td>
<td>10-16</td>
<td>15-21</td>
<td>21-27</td>
<td>29-33</td>
</tr>
<tr>
<td>11</td>
<td>8-14</td>
<td>10-16</td>
<td>12-18</td>
<td>18-24</td>
<td>24-30</td>
<td>27-33</td>
</tr>
<tr>
<td>12</td>
<td>10-16</td>
<td>12-18</td>
<td>15-21</td>
<td>23-27</td>
<td>27-33</td>
<td>30-37</td>
</tr>
<tr>
<td>13</td>
<td>12-18</td>
<td>15-21</td>
<td>18-24</td>
<td>24-30</td>
<td>30-37</td>
<td>33-41</td>
</tr>
<tr>
<td>14</td>
<td>15-21</td>
<td>18-24</td>
<td>21-27</td>
<td>28-33</td>
<td>33-41</td>
<td>37-46</td>
</tr>
<tr>
<td>15</td>
<td>18-24</td>
<td>21-27</td>
<td>24-30</td>
<td>30-37</td>
<td>37-46</td>
<td>41-51</td>
</tr>
<tr>
<td>16</td>
<td>21-27</td>
<td>24-30</td>
<td>27-33</td>
<td>33-41</td>
<td>41-51</td>
<td>46-57</td>
</tr>
<tr>
<td>17</td>
<td>24-30</td>
<td>27-33</td>
<td>30-37</td>
<td>37-48</td>
<td>46-57</td>
<td>51-63</td>
</tr>
<tr>
<td>18</td>
<td>27-33</td>
<td>30-37</td>
<td>33-41</td>
<td>41-51</td>
<td>51-63</td>
<td>57-71</td>
</tr>
<tr>
<td>19</td>
<td>30-37</td>
<td>33-41</td>
<td>37-46</td>
<td>46-57</td>
<td>57-71</td>
<td>63-78</td>
</tr>
<tr>
<td>20</td>
<td>33-41</td>
<td>37-46</td>
<td>41-51</td>
<td>51-63</td>
<td>63-78</td>
<td>70-87</td>
</tr>
<tr>
<td>21</td>
<td>37-46</td>
<td>41-51</td>
<td>46-57</td>
<td>57-71</td>
<td>70-87</td>
<td>77-96</td>
</tr>
<tr>
<td>22</td>
<td>41-51</td>
<td>46-57</td>
<td>51-63</td>
<td>63-78</td>
<td>77-96</td>
<td>84-105</td>
</tr>
<tr>
<td>23</td>
<td>46-57</td>
<td>51-63</td>
<td>57-71</td>
<td>70-87</td>
<td>84-105</td>
<td>92-115</td>
</tr>
<tr>
<td>24</td>
<td>51-63</td>
<td>57-71</td>
<td>63-78</td>
<td>77-96</td>
<td>92-115</td>
<td>100-125</td>
</tr>
<tr>
<td>25</td>
<td>57-71</td>
<td>63-78</td>
<td>70-87</td>
<td>84-105</td>
<td>100-125</td>
<td>110-137</td>
</tr>
<tr>
<td>26</td>
<td>63-78</td>
<td>70-87</td>
<td>76-97</td>
<td>92-115</td>
<td>110-137</td>
<td>120-150</td>
</tr>
<tr>
<td>27</td>
<td>70-87</td>
<td>76-97</td>
<td>87-108</td>
<td>100-125</td>
<td>120-150</td>
<td>130-162</td>
</tr>
<tr>
<td>28</td>
<td>76-97</td>
<td>87-108</td>
<td>97-121</td>
<td>110-137</td>
<td>130-162</td>
<td>140-175</td>
</tr>
<tr>
<td>29</td>
<td>87-108</td>
<td>97-121</td>
<td>108-138</td>
<td>121-151</td>
<td>140-175</td>
<td>151-188</td>
</tr>
<tr>
<td>30</td>
<td>97-121</td>
<td>108-138</td>
<td>121-151</td>
<td>135-168</td>
<td>151-188</td>
<td>168-210</td>
</tr>
<tr>
<td>32</td>
<td>121-151</td>
<td>135-168</td>
<td>151-188</td>
<td>168-210</td>
<td>188-235</td>
<td>208-263</td>
</tr>
<tr>
<td>33</td>
<td>135-168</td>
<td>151-188</td>
<td>168-210</td>
<td>188-235</td>
<td>208-263</td>
<td>228-293</td>
</tr>
<tr>
<td>34</td>
<td>151-188</td>
<td>168-210</td>
<td>188-235</td>
<td>210-262</td>
<td>235-293</td>
<td>262-327</td>
</tr>
<tr>
<td>35</td>
<td>168-210</td>
<td>188-235</td>
<td>210-262</td>
<td>235-293</td>
<td>262-327</td>
<td>293-365</td>
</tr>
<tr>
<td>36</td>
<td>188-235</td>
<td>210-262</td>
<td>235-293</td>
<td>262-327</td>
<td>293-365</td>
<td>324-405</td>
</tr>
<tr>
<td>37</td>
<td>210-262</td>
<td>235-293</td>
<td>262-327</td>
<td>293-365</td>
<td>324-405</td>
<td>360-life</td>
</tr>
<tr>
<td>38</td>
<td>235-293</td>
<td>262-327</td>
<td>293-365</td>
<td>324-405</td>
<td>360-life</td>
<td>360-life</td>
</tr>
<tr>
<td>39</td>
<td>262-327</td>
<td>293-365</td>
<td>324-405</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
</tr>
<tr>
<td>40</td>
<td>292-365</td>
<td>324-405</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
</tr>
<tr>
<td>41</td>
<td>324-405</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
</tr>
<tr>
<td>42</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
<td>360-life</td>
</tr>
<tr>
<td>43</td>
<td>life</td>
<td>life</td>
<td>life</td>
<td>life</td>
<td>life</td>
<td>life</td>
</tr>
</tbody>
</table>

**Zone A**

**Zone B**

**Zone C**

**Zone D**

---

*Barrett Law, PA*
8B2.1. (a) To have an effective compliance and ethics program, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (b)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall—

(1) exercise due diligence to prevent and detect criminal conduct; and

(2) otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.

Such compliance and ethics program shall be reasonably designed, implemented, and enforced so that the program is generally effective in preventing and detecting criminal conduct. The failure to prevent or detect the instant offense does not necessarily mean that the program is not generally effective in preventing and detecting criminal conduct.

Available at: https://www.uscc.gov/guidelines
Office of Inspector General
OIG Compliance Guidance Documents


Available at: https://oig.hhs.gov/compliance/compliance-guidance/index.asp
<table>
<thead>
<tr>
<th>Date</th>
<th>Guidance Description</th>
<th>Federal Register</th>
<th>Date</th>
</tr>
</thead>
</table>
Department of Justice
A Brief Look at Prior DOJ Guidance

- 2017 – DOJ Fraud Section publishes Evaluation of Corporate Compliance Programs (ECCP) containing important topics and sample questions it uses when evaluating the effectiveness of corporate compliance programs.

- DOJ’s “Principles of Federal Prosecution of Business Organizations” include “Filip Factors”
  - One factor is the existence and effectiveness of the corporation’s pre-existing compliance program as well as remedial efforts to implement an effective corporate compliance program or to improve an existing one.
A Brief Look at Prior DOJ Guidance

- 11 Sections:
  1. Analysis and Remediation of Underlying Conduct
  2. Senior and Middle Management
  3. Autonomy and Resources
  4. Policies and Procedures
  5. Risk Assessment
  6. Training and Communications
  7. Confidential Reporting and Investigation
  8. Incentives and Disciplinary Measures
  9. Continuous Improvement, Periodic Testing and Review
  10. Third Party Management
  11. Mergers & Acquisitions
A Brief Look at the 2019 Changes

- Expands DOJ Guidance to beyond the Fraud Section to DOJ’s entire criminal division
- Focuses on 3 areas of corporate compliance:
  - Risk assessments – CCP must be proportionate to identified risks
  - Culture of compliance - Entities must demonstrate financial, practical and philosophical support for compliance
  - Continuous compliance program improvement – Entities should continually review, reassess and improve their CCP
- Effect on False Claims Act (FCA) Guidance
A Brief Look at the 2019 Changes

There are 3 Fundamental Questions prosecutors must ask when evaluating the effectiveness of a Corporate Compliance Program (CCP):

1. Is the compliance program well designed?
2. Is the compliance program being implemented effectively?
3. Does the compliance program work in practice?
The 2020 Changes

- Is the program being implemented effectively?

- Is the program adequately resourced and empowered to function effectively?
Some important questions that will be asked:

- Why did the entity set up the program the way it did and has it evolved over time?
- Are the risk assessments “snapshots” of the entity or based on continuous access to operational data which are periodically reviewed?
  - Have these periodic reviews resulted in updates to policies, procedures and controls?
  - Do the assessments incorporate “lessons learned”?
- Are the entity’s policies and procedures in a searchable format?
- Does the entity use technology for measuring the reporting and tracking of compliance hotline calls and other compliance complaints?
- Is there an evaluation of training effectiveness and can employees raise questions?
- Are third parties being used and why?
  - Is there oversight of third parties?
Additional Compliance Guidance

- Corporate Integrity Agreements
  - E.g., Novartis

- Government Take-Downs
  - E.g., “Operation Rubber Stamp”
  - $4.5 billion kickback scheme involving telemedicine & marketing schemes

- FIFA Bribery Scheme & Deferred Prosecution Agreement (DPA)
  - “breathtaking effort”
  - “Immediately took a cooperative tack”
  - “Model” compliance behavior

- DOJ Antitrust Division looking for “Gold Standard Compliance Program”
  - Strength of compliance program could lead to DPAs
  - Such a program has not yet been found
Department of Justice “Hot Topics”

FY 2020 False Claims Act (FCA) Recoveries

Inability-to-Pay Memo

Civil Division 2021 Enforcement Priorities

Open Payments Program
DOJ 2020 FCA Recoveries: Overview

<table>
<thead>
<tr>
<th>FY</th>
<th>NEW MATTERS(^a)</th>
<th>SETTLEMENTS AND JUDGMENTS(^b)</th>
<th>RELATOR SHARE AWARDS(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NON QUI TAM</td>
<td>QUI TAM</td>
<td>TOTAL</td>
</tr>
<tr>
<td>2006</td>
<td>70</td>
<td>385</td>
<td>1,712,459,257</td>
</tr>
<tr>
<td>2007</td>
<td>129</td>
<td>365</td>
<td>564,826,844</td>
</tr>
<tr>
<td>2008</td>
<td>160</td>
<td>379</td>
<td>312,193,480</td>
</tr>
<tr>
<td>2009</td>
<td>133</td>
<td>433</td>
<td>470,685,666</td>
</tr>
<tr>
<td>2011</td>
<td>125</td>
<td>634</td>
<td>241,365,995</td>
</tr>
<tr>
<td>2012</td>
<td>146</td>
<td>655</td>
<td>1,608,112,862</td>
</tr>
<tr>
<td>2013</td>
<td>101</td>
<td>757</td>
<td>188,376,772</td>
</tr>
<tr>
<td>2014</td>
<td>101</td>
<td>717</td>
<td>1,676,608,226</td>
</tr>
<tr>
<td>2015</td>
<td>117</td>
<td>640</td>
<td>738,442,487</td>
</tr>
<tr>
<td>2016</td>
<td>151</td>
<td>708</td>
<td>1,929,502,680</td>
</tr>
<tr>
<td>2017</td>
<td>148</td>
<td>681</td>
<td>280,097,308</td>
</tr>
<tr>
<td>2018</td>
<td>124</td>
<td>648</td>
<td>767,115,453</td>
</tr>
<tr>
<td>2019</td>
<td>148</td>
<td>638</td>
<td>844,282,697</td>
</tr>
<tr>
<td>2020</td>
<td>250</td>
<td>672</td>
<td>545,330,030</td>
</tr>
</tbody>
</table>

Available at: https://www.justice.gov/opa/press-release/file/1354316/download

Barrett Law, PA

20
## DOJ 2020 FCA Recoveries HHS

<table>
<thead>
<tr>
<th>FY</th>
<th>NEW MATTERS&lt;sup&gt;a&lt;/sup&gt;</th>
<th>SETTLEMENTS AND JUDGMENTS&lt;sup&gt;1&lt;/sup&gt;</th>
<th>RELATOR SHARE AWARDS&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NON QUI TAM</td>
<td>QUI TAM</td>
<td>TOTAL</td>
</tr>
<tr>
<td></td>
<td>NON&lt;sup&gt;3&lt;/sup&gt;</td>
<td>QUI TAM</td>
<td>TOTAL</td>
</tr>
<tr>
<td>2006</td>
<td>18</td>
<td>216</td>
<td>1,050,520,714</td>
</tr>
<tr>
<td>2007</td>
<td>25</td>
<td>199</td>
<td>465,052,993</td>
</tr>
<tr>
<td>2008</td>
<td>60</td>
<td>231</td>
<td>162,972,022</td>
</tr>
<tr>
<td>2009</td>
<td>35</td>
<td>279</td>
<td>240,061,424</td>
</tr>
<tr>
<td>2010</td>
<td>42</td>
<td>385</td>
<td>546,963,732</td>
</tr>
<tr>
<td>2011</td>
<td>38</td>
<td>417</td>
<td>178,287,545</td>
</tr>
<tr>
<td>2012</td>
<td>26</td>
<td>417</td>
<td>557,273,967</td>
</tr>
<tr>
<td>2014</td>
<td>32</td>
<td>471</td>
<td>88,054,490</td>
</tr>
<tr>
<td>2015</td>
<td>26</td>
<td>426</td>
<td>160,758,915</td>
</tr>
<tr>
<td>2016</td>
<td>71</td>
<td>504</td>
<td>97,354,415</td>
</tr>
<tr>
<td>2017</td>
<td>55</td>
<td>495</td>
<td>32,627,357</td>
</tr>
<tr>
<td>2018</td>
<td>60</td>
<td>447</td>
<td>568,069,015</td>
</tr>
<tr>
<td>2019</td>
<td>57</td>
<td>450</td>
<td>695,838,735</td>
</tr>
<tr>
<td>2020</td>
<td>117</td>
<td>456</td>
<td>400,572,626</td>
</tr>
</tbody>
</table>

Available at: https://www.justice.gov/opa/press-release/file/1354316/download

Barrett Law, PA
## DOJ 2020 FCA Recoveries HHS

<table>
<thead>
<tr>
<th>FY</th>
<th>NEW MATTERS*</th>
<th>SETTLEMENTS AND JUDGMENTS¹</th>
<th>RELATOR SHARE AWARDS²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NON QUI TAM</td>
<td>QUI TAM</td>
<td>TOTAL QUI TAM AND NON QUI TAM</td>
</tr>
<tr>
<td></td>
<td>NON³ QUI TAM</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,199</td>
<td>8,541</td>
<td>7,882,140,113</td>
</tr>
<tr>
<td></td>
<td>3,333</td>
<td>123</td>
<td>37,435,888</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td></td>
<td>81,255,439</td>
</tr>
</tbody>
</table>

Available at: https://www.justice.gov/opa/press-release/file/1354316/download
DOJ Civil Division Inability-to-Pay Memo

MEMORANDUM FOR ALL CIVIL DIVISION EMPLOYEES

FROM: ETHAN P. DAVIS
ACTING ASSISTANT ATTORNEY GENERAL
CIVIL DIVISION

SUBJECT: Assessing an Entity’s Assertion of an Inability to Pay

The Civil Division brings civil claims on behalf of the United States that provide for the recovery of money or property, including damages and penalties. Although the Division may litigate these claims to final judgment, the Division also may agree to resolve them, either before or after judgment is entered, through settlement. In seeking to resolve a claim for money, a party may assert that it is unable to satisfy the payment sought by the Division. This memorandum provides guidance and an analytical framework for the Division to assess an assertion of an inability to pay an otherwise appropriate amount to resolve potential civil liability.¹

I. General Policy Regarding Inability to Pay

The Assistant Attorney General is authorized to compromise claims for money when any entity, including an individual, corporation, limited liability company, partnership, sole proprietorship, or estate, offers the maximum it has the ability to pay. See 28 C.F.R.
DOJ Civil Division Enforcement Priorities
Acting Assistant Attorney General
Brian M. Boynton February 17, 2021

- Pandemic –Related Fraud
- Opioids
- Fraud Targeting Seniors
- Electronic Health Records
- Telehealth
- Cybersecurity
Open Payments Program

- Medtronic USA, Inc. (Oct 2020)
  - ✔ $9.2 million settlement
  - ✔ Allegations include kickbacks to neurosurgeon ($8.1 million) and Open Payments Program violations ($1.11 million)
  - ✔ Carnival Brazilian Grill

- Charlene Keller Fullmer (Feb 2021)
  - Reportedly stated that Open Payments Program violations may be included in global settlements and that DOJ may make more proactive use of Open Payments data
<table>
<thead>
<tr>
<th>Advisory Opinions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020 Advisory Opinions</td>
</tr>
<tr>
<td>Special Fraud Alert: Speaker Programs</td>
</tr>
<tr>
<td>AKS Final Rule PBMs</td>
</tr>
<tr>
<td>Certain 2021 OIG Work Plan Additions</td>
</tr>
<tr>
<td>OIG COVID FAQs</td>
</tr>
</tbody>
</table>
OIG’s Advisory Opinions

“In accordance with section 1128D(b) of the Social Security Act (42 U.S.C. 1320a-7d(b)) and 42 CFR part 1008, OIG issues advisory opinions about the application of OIG’s fraud and abuse authorities to the requesting party’s existing or proposed business arrangement. As required by the statute, these advisory opinions are being made available to the public through this OIG Web site.

One purpose of the advisory opinion process is to provide meaningful advice on the application of the anti-kickback statute and other OIG sanction statutes in specific factual situations. Please note, however, that advisory opinions are binding and may legally be relied upon only by the requestor. Since each opinion will apply legal standards to a set of facts involving certain known persons who provide specific statements about key factual issues, no third parties are bound nor may they legally rely on these advisory opinions.”

https://oig.hhs.gov/compliance/advisory-opinions/index.asp
AO 20-01 (01-13-2020) regarding a hospital's provision of discounted training to a specified fire department's personnel at the hospital's facility

AO 20-02 (01-22-2020) regarding financial assistance for travel, lodging, and other expenses provided by a pharmaceutical manufacturer to certain patients prescribed the manufacturer's drug

AO 20-03 (07-01-2020) regarding an arrangement under which a discount medical plan organization ("DMPO") pays chiropractors and chiropractic clinics a fee for each new DMPO member referred by the chiropractor or chiropractic clinic

AO 20-04 (07-24-2020) regarding a charitable organization's proposal to purchase or receive donations of unpaid medical debt owed by qualifying patients from certain types of health care providers and then forgive that debt

AO 20-05 (09-23-2020) regarding a pharmaceutical manufacturer's proposal to provide cost-sharing assistance directly to Medicare beneficiaries who are prescribed either of two formulations of its drug
AO 20-06 (12-23-2020) regarding a management company's provision of below fair market value Medicaid enrollment application assistance services to certain individuals and affiliated skilled nursing facilities' payments for those services in particular circumstances regarding a hospital's provision of discounted training to a specified fire department's personnel at the hospital's facility

AO 20-07 (12-28-2020) regarding a web-based platform where health care facilities and clinicians would, in particular circumstances, remit to patients and the patients' payors a portion of the claims for certain services for which payment may be made by the Medicare program as a secondary payor

AO 20-08 (12-30-2020) regarding a federally qualified health center’s proposal to offer gift cards to incentivize certain pediatric patients to attend rescheduled preventive and early intervention care appointments

AO 20-09 (12-32-2020) regarding a program where a pharmaceutical manufacturer provides financial assistance for travel, lodging, and other expenses to certain patients prescribed the manufacturer's drug
Special Fraud Alert: Speaker Programs

November 16, 2020

I. Introduction

This Special Fraud Alert highlights the fraud and abuse risks associated with the offer, payment, solicitation, or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. For purposes of this Special Fraud Alert, speaker programs are generally defined as company-sponsored events at which a physician or other health care professional (collectively, “HCP”) makes a speech or presentation to other HCPs about a drug or device product or a disease state on behalf of the company. The company generally pays the speaker HCP an honorarium, and often pays remuneration (for example, free meals) to the attendees. In the last three years, drug and device companies have reported paying nearly $2 billion to HCPs for speaker-related services.1

The Office of Inspector General (OIG) and Department of Justice (DOJ) have investigated and resolved numerous fraud cases involving allegations that remuneration offered and paid in connection with speaker programs violated the anti-kickback statute. The Federal government has pursued civil and criminal cases against companies and...
OIG Discount Safe Harbor Changes

- November 30, 2020 Final Rule

- Amends Discount Safe Harbor to eliminate protection for drug discounts and rebates offered by pharmaceutical manufacturers to pharmacy benefit managers (PBMs), Medicaid MCOs, and Medicare Part D sponsors

- Creates 2 new safe harbors:
  - Point-of Sale Safe Harbor
  - PBM Service Fees Safe Harbor
## Certain OIG Work Plan Items

<table>
<thead>
<tr>
<th>Month</th>
<th>Entity</th>
<th>Title</th>
<th>Responsible Office</th>
<th>Reference Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2021</td>
<td>Centers for Medicare and Medicaid Services</td>
<td><strong>Audits of Medicare Part B Laboratory Services During the COVID-19 Pandemic</strong></td>
<td>Office of Audit Services</td>
<td>W-00-21-35867</td>
</tr>
<tr>
<td>February 2021</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
<td><strong>Use of Telehealth to Provide Behavioral Health Services in Medicaid Managed Care</strong></td>
<td>Office of Evaluation and Inspections</td>
<td>OEI-02-19-00400; OEI-02-19-00401; OEI-02-19-00402</td>
</tr>
<tr>
<td>February 2021</td>
<td>Centers for Medicare and Medicaid Services</td>
<td><strong>Audit of Home Health Services Provided as Telehealth During the COVID-19 Public Health Emergency</strong></td>
<td>Office of Audit Services</td>
<td>W-00-21-35864</td>
</tr>
<tr>
<td>January 2021</td>
<td>ASA</td>
<td><strong>Audit of HHS Sole Source Contracts Awarded for COVID-19 Testing</strong></td>
<td>Office of Audit Services</td>
<td>W-00-21-59453</td>
</tr>
<tr>
<td>January 2021</td>
<td>OS</td>
<td><strong>Hospital Experiences Responding to the COVID-19 Pandemic: February 2021 Pulse Surveys</strong></td>
<td>Office of Evaluation and Inspections</td>
<td>OEI-09-21-00140</td>
</tr>
</tbody>
</table>
FAQs—Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Last Updated: 02-17-2021

The Office of Inspector General (OIG) recognizes that, in the current public health emergency resulting from the outbreak of the COVID-19, the health care industry must focus on delivering needed patient care. As part of OIG's mission to promote economy, efficiency, and effectiveness in HHS programs, we are committed to protecting patients by ensuring that health care providers have the regulatory flexibility necessary to adequately respond to COVID-19 concerns. Therefore, OIG is accepting inquiries from the health care community regarding the application of OIG's administrative enforcement authorities, including the Federal anti-kickback statute and civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP). If you have a question regarding how OIG would view an arrangement that is directly connected to the public health emergency and implicates these authorities, please submit your question to OIGComplianceSuggestions@oig.hhs.gov. In your submission, please provide sufficient facts to allow for an understanding of the key parties and terms of the arrangement at hand.
HHS & CMS “Hot Topics”

- HHS Rule Restricting Use of Sub-Regulatory Guidance
- HHS FCA Working Group
- Certain CMS Rule Changes
DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of the Secretary

Office of the General Counsel
Washington, D.C.  20201

ADVISORY OPINION 20-05 ON IMPLEMENTING ALLINA
DECEMBER 3, 2020

The Office of the General Counsel (“OGC”) has received questions regarding the steps the Department of Health and Human Services (“HHS” or “the Department”) is taking to comply with the Supreme Court’s decision in Azar v. Allina Health Services, 139 S. Ct. 1804 (2019) that the Department must use notice-and-comment rulemaking in certain circumstances where the Administrative Procedure Act (“APA”) does not require such rulemaking. In this Advisory Opinion, OGC clarifies what the public can expect the Center for Medicare to do in order to satisfy Allina’s requirements regarding notice-and-comment rulemaking.

This advisory opinion sets forth the current views of the Office of the General Counsel. It is not a final agency action or a final order. Nor does it bind HHS or the federal courts. It does not have the force or effect of law.

I. Meaning of “Substantive Legal Standard”
The Supreme Court in Allina held that under Social Security Act Section 1871, any Medicare issuance that establishes or changes a “substantive legal standard” governing the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities, or organizations to furnish services, must go through notice-and-comment rulemaking. See also Social Security Act § 1871(a)(2). The Court declined to define the term “substantive legal standard,” other than to conclude it is not coterminous with the APA term
HHS FCA Working Group

FOR IMMEDIATE RELEASE
December 4, 2020

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Announces False Claims Act Working Group to Enhance Efforts to Combat Fraud and Focus Resources on Bad Actors

Today, the Department of Health and Human Services (HHS) announced the creation of a False Claims Act Working Group (Working Group) that enhances its partnership with the Department of Justice (DOJ) and the HHS Office of Inspector General (OIG) to combat fraud and abuse by identifying and focusing resources on those who seek to defraud the American taxpayers. HHS regulates over a third of the United States economy. In 2020, HHS provided over $1.5 trillion in grants and other payments to public and private recipients, including for healthcare items and services. In addition, HHS is one of the largest government contractors, paying over $170 billion in 2020 to thousands of contractors. In combating COVID-19, HHS has administered unprecedented levels of taxpayer support for private individuals and organizations.

“Fraud on the federal government is not a victimless crime. Every dollar that goes to fraudsters is a dollar not being used for the important work that HHS programs do for the American people, including
Certain Provisions in CMS 2021 Final Physician Fee Schedule Rule

- **Non-Physician Practitioners**
  - Pharmacists may provide services on an incident-to basis
  - NPPs may supervise diagnostic tests
  - Physicians and NPPs may review and verify medical record notes

- **Telehealth**
  - Until 12/31/2021 or the end of the PHE, direct supervision can be provided using real-time, interactive audio-visual technology
  - Until 12/31/2021, certain audio-only assessments are permitted
  - Nursing facility subsequent care visits were reduced from once every 30 days to once every 14 days
  - New permanent telehealth services
Certain Provisions in CMS
2021 Final Physician Fee Schedule Rule

- **E/M Codes**
  - Coding based solely on medical decision making (MDM) or based solely on time
  - Changes apply to outpatient E/M office visits (99202 – 99215)
  - Changes do not apply to inpatient services
  - Documentation of histories and assessments should continue
Certain Enforcement Actions

Pharmaceutical Companies

Electronic Health Records

Marketing

Yates & Individual Accountability
Certain 2020 FCA Recoveries

- Certain recoveries include:
  - $591 million Novartis Pharmaceuticals Company – involves speakers bureaus
  - $148 million combined from Novartis & Gilead Sciences – involves patient copayments
  - $145 million from Practice Fusion - involves EHR software
  - $41.6 million from UTC Laboratories – involves genetic testing
  - $37 million from ResMed – involves DME
  - $13 combined from four foundations – involves patient assistance programs
Certain Enforcement Actions: Pharma

- **Novartis (July 2020) (2 actions)**
  - $678 combined million settlement
  - Allegations include that Novartis operated a sham speakers program pursuant to which it paid over $100 million to physicians to induce them to prescribe certain drugs

- **Gilead (Sept 2020)**
  - $97 million settlement
  - Allegations included that Gilead used CVC as a conduit to pay the copayments of thousands of Medicare patients taking Letairis
Certain Enforcement Actions: EHR

Practice Fusion (Jan 2020)
- $11.5 million civil settlement
- $26 million+ criminal fines
- Deferred prosecution
- Allegations included kickbacks from opioid and pharma companies
  - Misrepresenting software capabilities
  - Meaningful use payments

Athenahealth, Inc. (Jan 2021)
- $18.25 million settlement
- Allegations include the Athena provided lavish gifts and payments to increase sales
  - Concierge Event program
  - Client Lead Generation program
Certain Enforcement Actions: Marketing

- **Epsilon Data Management (Jan 2021)**
  - $150 million settlement to resolve criminal charge for selling millions of individuals’ information to perpetrators of elder fraud
  - Entered into a DPA and agreed to implement significant compliance measures to safeguard consumers’ data and prevent sales to those engaged in fraudulent or deceptive marketing

- **McKinsey & Company (Feb 2021)**
  - $573 million settlement
  - Global consulting firm
  - Relating to advice provided on opioid marketing and sales strategies
Certain Enforcement Actions: Yates

- **Owner of Texas Chain of Hospice Companies (Dec. 16, 2020)**
  - 20 year prison sentence & $120 million in restitution
  - Allegations included telling thousands of patients with long-term incurable illnesses that they had less than 6 months to live and enrolling them in hospice programs

- **Owner of Providence Home Health and Providence Hospice (Dec. 10, 2020)**
  - $1.05 million settlement; 5-year exclusion
  - Allegedly paid kickbacks for referrals of Medicare patients
    - Payments to medical director allegedly exceeded FMV
    - Allegedly identified a physician who was said to have been the attending physician – but he was incarcerated at the time

- **Owner of Brace Companies (Nov. 16, 2020)**
  - Pled guilty; $16.5 million pay-back
  - Faces up to 5 years in prison and up to $250,000 in fines
Any Questions/Thoughts/Comments
Lynn Barrett, Esq., CCP, CHE
Lynn@blhealthlaw.com