

## 2016 Stark Law Changes Issued

On November 16, 2015, the *Centers for Medicare and Medicaid Services* (CMS) published its final rule for the 2016 *Medicare Physician Fee Schedule* (MPFS) in the *Federal Register*, effective on January 1, 2016.<sup>1</sup> In addition to updating a number of policies, rates, and quality provisions for services covered under the MPFS,<sup>2</sup> the final rule modified various portions of the *physician self-referral law* (known as the *Stark Law*).<sup>3</sup> The 2016 MPFS final rule added two new exceptions to *Stark* – the “*assistance to compensate a nonphysician practitioner*” (NPP) exception, and the “*timeshare arrangements*” exception – as well as altered the requirements for physician-owned hospitals and clarified provisions involving holdover arrangements, writing requirements, and many others.<sup>4</sup> This Health Capital Topics article will discuss the 2016 MPFS final rule, detail the new *Stark Law* exceptions and alterations, and examine the potential impact of these modifications on the standards of *fair market value* and *commercial reasonableness*.

Generally, the *Stark Law* prohibits physicians from making *referrals for designated health services* (DHS) to an entity if the physician, or an immediate family member of the physician, has a *financial relationship* with that entity.<sup>5</sup> The *Ethics in Patient Referrals Act* (*Stark I*) was promulgated in 1989 and has since been modified to expand the scope of services and relationships covered under the law.<sup>6</sup> Originally covering only referrals to clinical laboratories, in 1993, *Stark I* was amended to expand the prohibition against *self-referrals* to 10 additional categories of DHS.<sup>7</sup> Currently, DHS consists of the following services:

- (1) Clinical laboratory services;
- (2) Physical therapy services;
- (3) Occupational therapy services;
- (4) Outpatient speech-language pathology services;
- (5) Radiology services;
- (6) Radiation therapy services and supplies;
- (7) Durable medical equipment and supplies;
- (8) Parenteral & enteral nutrients, equipment, & supplies;
- (9) Prosthetics, orthotics, & prosthetic devices & supplies;
- (10) Home health services;
- (11) Outpatient prescription drugs; and,
- (12) Inpatient & outpatient hospital services.

The very broad prohibition against physician *self-referrals* is limited by a number of *regulatory exceptions*, which Congress authorized to *promote practice integration* and to protect arrangements where there is little risk of abuse.<sup>8</sup> Before CMS promulgated the 2016 MPFS final rule, CMS had authorized 35 exceptions to the *Stark Law*, while retaining the authority to promulgate additional exceptions.<sup>9</sup> The 35 exceptions to the *Stark Law* are divided between exceptions that apply to: (1) *both ownership/investment interests and compensation arrangements*; (2) exceptions that apply *only to ownership/investment interests*; and, (3) exceptions that apply *only to compensation arrangements*.<sup>10</sup>

The 2016 MPFS final rule includes two new exceptions to the *Stark Law*, which are effective on January 1, 2016: (1) the “*assistance to compensate a nonphysician practitioner*” exception; and, (2) the “*timeshare arrangements*” exception.<sup>11</sup> The “*assistance to compensate a nonphysician practitioner*” exception permits “*remuneration provided by a hospital, FQHC [Federally Qualified Health Center], or RHC [Rural Health Clinic] to a physician to assist the physician with compensating an NPP to provide primary care services or mental health care services to patients of the physician’s practice.*”<sup>12</sup> The exception arises out of the need to increase access to primary care services, a central goal of the ACA, in light of recent projections of a shortage of primary care physicians.<sup>13</sup> To address this issue, CMS promulgated the “*assistance to compensate a nonphysician practitioner*” exception to allow NPPs to help increase access to primary care services.<sup>14</sup>

Among other requirements under the “*assistance to compensate a nonphysician practitioner*” exception, the total compensation and benefits paid to the NPP must “*not exceed fair market value for the patient care services furnished by the nonphysician practitioner to patients of the physician’s practice*” [emphasis added], nor may the arrangement violate the *Anti-Kickback Statute* (AKS).<sup>15</sup> This exception applies to the recruitment of physician assistants, nurse practitioners, clinical nurse specialists, clinical psychologists, clinical social workers, and certified nurse midwives, notably excluding certified registered nurse anesthetists.<sup>16</sup> In order to be eligible for the exception, “*substantially all of the services*” provided by the NPP receiving

compensation under this exception must be for “primary care services or mental health care services.”<sup>17</sup>

The second exception, the “timeshare arrangements” exception, permits “arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises.”<sup>18</sup> In order for an arrangement to be eligible under the new timeshare exception, the arrangement must be between: (1) either a hospital or physician organization; and, (2) a physician or the physician organization in which the physician is a member.<sup>19</sup> Any equipment a physician would like to have covered under the exception must be located and used within the office suite where the physician provides services, such as evaluation and management services.<sup>20</sup> Additionally, any services provided through the use of equipment subject to the “timeshare arrangements” exception must be to furnish DHS incidental to the evaluation.<sup>21</sup>

Similar to the “assistance to compensate a nonphysician practitioner” exception, the compensation paid to a physician under the “timeshare arrangements” exception must be “consistent with fair market value” (FMV) [emphasis added].<sup>22</sup> However, unlike the “assistance to compensate a nonphysician practitioner” exception, arrangements formed under the “timeshare arrangements” exception must also satisfy the requirement of commercial reasonableness.<sup>23</sup>

In addition to promulgating new *Stark Law* exceptions, the 2016 MPFS final rule clarifies *Stark Law* requirements relating to physician-owned hospitals, the writing requirement, holdover arrangements, and the “stand in the shoes” definition. First, physician-owned hospitals must “disclose the fact that the hospital is partially owned or invested in by physicians on any public Web site for the hospital and in any public advertising for the hospital.”<sup>24</sup> In the rule, CMS noted that social media platforms are not public websites for hospital disclosures, due in part to differences in types of information typically posted on social media platforms (e.g., “posting a video, or posting messages”) and information typically posted on a hospital’s main website (e.g., “the hospital’s history, leadership and governance structure, mission, and a list of staff physicians”).<sup>25</sup> In regard to advertising, the 2016 MPFS final rule defines *public advertising* for physician-owned hospitals under the *Stark Law* as “any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.”<sup>26</sup> While decisions of what constitutes *public advertising* for physician-owned hospitals under *Stark* will be decided on a case-by-case basis, the 2016 MPFS final rule stated that *public advertising* excludes communication regarding staff recruitment and community outreach.<sup>27</sup>

Additional alterations to the *Stark Law* include:

- (1) *Writing Requirement* – The 2016 MPFS final rule clarifies that “parties need not reduce the key

terms of an arrangement to a single formal contract to satisfy the writing requirement of the compensation exceptions at § 411.357 that require a writing.”<sup>28</sup>

- (2) *Holdover Arrangements* – The 2016 MPFS final rule altered the holdover requirements found in personal services arrangements and rental of office space exceptions to allow for *indefinite* holdovers, so long as the arrangements “continue on the same terms and conditions” as the original arrangement and comply with an exception.<sup>29</sup>
- (3) “*Stand in the Shoes*” Definition – The 2016 MPFS final rule clarifies that, in regard to the “stand in the shoes” provisions found in many compensation arrangement exceptions, “all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity.”<sup>30</sup>

In light of the incorporation of FMV and *commercial reasonableness* requirements in the new *Stark Law* exceptions, as well as the clarification of the need for a satisfactory writing, providers may be well-served to consult with competent healthcare legal counsel and certified valuation professionals that current and prospective arrangements are in compliance with new *Stark Law* requirements, including the thresholds of FMV and *commercial reasonableness*.

- 1 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” Federal Register, Vol. 80, No. 220 (November 16, 2015) p. 70886.
- 2 *Ibid*, p. 70888.
- 3 “Stark Relief? CMS Provides Proposals Could Ease Burden of Self-Referral Law” By Lisa Schencker, Modern Healthcare, July 10, 2015, <http://www.modernhealthcare.com/article/20150710/NEWS/150719991> (Accessed 11/13/15).
- 4 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” November 16, 2015, p. 71300-71341.
- 5 *Ibid*, p. 71300.
- 6 “Medicare Program; Physician Financial Relationships with, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements,” Federal Register Vol. 60, No. 156 (August 14, 1995), p. 41915.
- 7 *Ibid*.
- 8 “Medicare and State Health Care Programs: Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships; Final Rule,” Federal Register Vol. 66, No. 3 (January 4, 2001): 895.
- 9 “Limitations on Certain Physician Referrals” 42 U.S.C. § 1395nn(a)-(e) (2012).
- 10 *Ibid*.
- 11 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” November 16, 2015, p. 71376-71377.
- 12 *Ibid*, p. 71303.
- 13 *Ibid*, p. 71303; “Proposed Stark Law Changes – Welcomed Relaxation of Current Regulations” By Adrienne Dresevic, Clinton Mikel, and Aaron Berech, American Bar Association, Vol. 12, No. 2, October 2015, [http://www.americanbar.org/publications/aba\\_health\\_esource/2015-2016/october/starklaw.html](http://www.americanbar.org/publications/aba_health_esource/2015-2016/october/starklaw.html) (Accessed 11/12/15).
- 14 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY

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- 2016; Final Rule” November 16, 2015 p. 71301; Dresevic, Mikel, & Berech, October 2015.
- 15 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” November 16, 2015, p. 71377.
- 16 *Ibid*; “Proposed Stark Law Changes – Welcomed Relaxation of Current Regulations” Dresevic, Mikel, & Berech, October 2015.
- 17 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” November 16, 2015, p. 71377.
- 18 *Ibid*, p. 71327.
- 19 *Ibid*; Dresevic, Mikel, & Berech, October 2015.
- 20 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” November 16, 2015, p. 71377-78; Dresevic, Mikel, & Berech, October 2015.
- 21 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” November 16, 2015, p. 71326; Dresevic, Mikel, & Berech, October 2015.
- 22 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” November 16, 2015, p. 71326.
- 23 *Ibid*, p. 71326.
- 24 *Ibid*, p. 71334.
- 25 *Ibid*, p. 71335.
- 26 *Ibid*.
- 27 *Ibid*; Dresevic, Mikel, & Berech, October 2015.
- 28 “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule” November 16, 2015, p. 71315.
- 29 *Ibid*, p. 71318.
- 30 *Ibid*, p. 71322.



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