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Stark & Anti-Kickback Revisions Finalized: Changes to Stark's Big Three Provisions

On November 20, 2020, the *Centers for Medicare & Medicaid Services* (CMS) and the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) issued two final rules to modernize and clarify the *Stark Law* and the *Anti-Kickback Statute* (AKS).[1] The rule changes are part of the larger effort by HHS (of which CMS is part) to modernize and clarify fraud and abuse laws as part of the *Regulatory Sprint to Coordinated Care* initiative and CMS's *Patients over Paperwork* initiative, which are aimed at reducing regulatory barriers and accelerating the transformation of the healthcare system into one that better pays for value and promotes care coordination.[2] Recognizing the rapidly changing healthcare system, CMS and OIG established new rules, and rule changes, that are more consistent with emerging value-based healthcare delivery and payment models, and which may allow for better coordination of care.

This is the first installment in a *Health Capital Topics* series that will examine these final rules and discuss their impact on healthcare valuation going forward. This initial article will summarize the Stark Law final rule as relates to "The Big Three" Requirements – Commercial Reasonableness, the Volume or Value Standard and the Other Business Generated Standard, and Fair Market Value.

Overview of the Stark Law

The Stark Law governs those physicians (or their immediate family members) who have a financial relationship (i.e., an ownership investment interest or a compensation arrangement) with an entity, and prohibits those individuals from making Medicare referrals to those entities for the provision of *designated health services* (DHS).[3] Notably, the law contains a large number of *exceptions*, which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[4]

Goals of Definitional Revisions

Many of the exceptions to the Stark Law require that one or more of the following requirements be met: that the compensation arrangement be commercially reasonable, that the compensation methodology not be determined in a manner that takes into account the volume or value of referrals (or other business generated between the parties), and that the amount of compensation paid be *fair market value*.[5] Due to their pervasiveness, these requirements are often referred to as "The Big Three."

In its final rule, CMS explained its reasons for making changes to the definitions of these three terms, principally "*to establish bright-line, objective regulations for each of these fundamental requirements …*"[6]

Each of these requirements will be discussed in turn below.

Commercial Reasonableness

In its October 2019 proposed rule, CMS recognized that it has only addressed the concept once, in a 1998 proposed rule, interpreting the term "*commercially reasonable*" to mean an arrangement that appears to be:

> "*...a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals*."[7]

In an effort to finally define the term, CMS's proposed rule suggested two alternative proposed definitions for the term *commercially reasonable*:

(1) "*the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements*" [emphasis added]; or,

(2) "*the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty*."[8] [Emphasis added.]

CMS unequivocally noted that, no matter which of the alternative definitions were finalized, an arrangement would be *commercially reasonable* "*even if it does not result in profit for one or more of the parties*."[9] [Emphasis added.]

Based on the comments received as to these two alternative definitions, CMS ultimately chose to incorporate aspects of each of the proposed alternative definitions in its final definition:

> "*Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement*

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> *and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties*."[10] [Emphasis added.]

In explaining its selection of the above definition, CMS acknowledged that if the agency had finalized the first alternative proposed definition, the regulation would have included "*the limitation that the arrangement [be] on similar terms and conditions as like arrangements*."[11] [Emphasis added.] Commenters expressed concern "*that parties to an arrangement would not have access to data to identify 'like arrangements' or be aware of their terms and conditions*" or that "*parties may enter into a novel compensation arrangement that bears minimal, if any, resemblance to existing arrangements against which it could be compared for 'similar terms*.'"[12] CMS ultimately agreed with Commenters that

> "*requiring a compensation arrangement to be on similar terms as like arrangements in order to be commercially reasonable does not provide for the clarity that we and stakeholders seek and, in fact, could increase the burden on parties that must seek the expertise of outside organizations to ensure compliance with the requirement that their arrangement is commercially reasonable*."[13]

Further, CMS pointed out, the finalized definition "*is consistent with the guidance we provided in the 1998 proposed rule* [set forth above]*, appropriately considers the characteristics of the parties to the actual arrangement being assessed for its commercial reasonableness, and will adequately ensure that parties cannot protect abusive arrangements under the guise of 'commercial reasonableness*.'"[14]

Commenters raised a number of questions and comments related to the phrase "*furthers a legitimate business purpose of the parties*" in the definition of *commercial reasonableness*, and CMS dedicated a sizable portion of the final rule to the discussion of this phrase.

While CMS acknowledged that "*identifying the business purpose of an arrangement may entail an inquiry into the parties' intent for the arrangement*," the requirement that the arrangement *further* a legitimate business purpose of the parties "*would be considered only after the determination that there actually exists a legitimate business purpose for the arrangement*."[15] According to CMS, some of the purposes that could "*qualify as 'legitimate business purposes' of the parties to an arrangement, depending on the facts and circumstances of the parties*," included:

(1) Addressing community need;

(2) Providing timely access to healthcare services;

(3) Fulfilling licensure or regulatory obligations, such as those under the *Emergency Medical Treatment and Labor Act* (EMTALA);

(4) Providing charity care; and,

(5) Improving quality and health outcomes.[16]

However, as CMS noted in its October 2019 proposed rule, "*arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements*."[17]

As to the link between Commercial Reasonableness and the Volume or Value standard, CMS made note that, although many of the Stark Law exceptions require that an arrangement be commercially reasonable "*even if no referrals were made between the parties*" or "*even if no referrals were made to the employer*," this language was not included in the final *commercial reasonableness* definition. Nevertheless, CMS asserted, the *Volume or Value* standard (or *Other Business Generated* standard) "*remains an important constraint when determining whether an arrangement satisfies the requirements of an applicable exception*."[18]

Volume or Value Standard and the Other Business Generated Standard

Many Stark Law exceptions require that the compensation arrangement at issue "*not [be] determined in a manner that takes into account the volume or value of referrals by the physician...[or be] determined in a manner that takes into account other business generated between the parties*."[19] In response to Commenter concerns, CMS proposed in its October 2019 proposed rule "*objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician*,"[20] including "*narrowly-defined circumstances under which [the agency] would consider fixed-rate compensation...to be determined in a manner that takes into account the volume or value of referrals or other business generated*."[21]

In its final rule, CMS finalized the objective tests for those payments that correlate with the volume or value of referrals or other business generated. However, the agency declined to finalize its proposed "*additional special rules outlining the circumstances under which we would consider fixed-rate compensation to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation*."[22] This decision was based upon CMS's agreement with Commenters who noted that "*fixed rate compensation (for example, $200,000 per year) qualifies as unit-based compensation*," which means that the proposed special rules regarding fixed-rate compensation would be effectively nullified by the unit-based compensation special rule.[23]

Perhaps the most significant statement made by CMS in this section was the finalization of its discussion in the October 2019 proposed rule regarding the Volume or Value standard and the Other Business Generated standard in light of fraud and abuse cases, such as *United States ex rel. Drakeford v. Tuomey*, which have held that, within the context of inpatient and outpatient hospital services, any *ancillary service and technical component* (associated with a physician's professional services, i.e.,

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a "*facility fee*") services performed in connection with personally performed services constituted an impermissible referral.[24] In the proposed rule, CMS reaffirmed its previous position that "*[w]ith respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services...are billed each time the employed physician personally performs a service*."[25] Subsequently, in response to Commenter questions, CMS reiterated in the final rule that "*the fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement)*."[26] CMS reaffirmed the position it took in the Stark Phase II regulation, stating that "*with respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service*."[27] CMS also clarified that its guidance "*extends to compensation arrangements that do not rely on the exception for bona fide employment relationships [e.g., personal service arrangements]…and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions in the special rule [regarding unit-based compensation]*."[28]

Fair Market Value

Historically, the Stark Law has defined *fair market value* generally (with additional modifications of the definition as applies to equipment leases and office space leases[29]) as follows:

> "*the value in arm's-length transactions, consistent with the general market value....Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals*."[30]

In its October 2019 proposed rule, CMS proposed three separate *fair market value* definitions: (1) generally; (2) for the rental of equipment; and, (3) for the rental of office space.[31] However, the agency emphasized that "*the proposed structure of the definition merely reorganizes for clarity, but does not significantly differ from the [previous] statutory language*..."[32]

The three separate *fair market value* definitions were proposed as follows:

(1) **General**: The value in an arm's-length transaction –
   (a) With like parties and under like circumstances;
   (b) Of like assets or services; and,
   (c) Consistent with the general market value of the subject transaction.

(2) **Rental of Equipment**: With respect to the rental of equipment, the value in an arm's-length transaction –
   (a) With like parties and under like circumstances;
   (b) Of rental property for general commercial purposes (not taking into account its intended use); and,
   (c) Consistent with the general market value of the subject transaction.

(3) **Rental of Office Space**: With respect to the rental of equipment, the value in an arm's-length transaction –
   (a) With like parties and under like circumstances;
   (b) Of rental property for general commercial purposes (not taking into account its intended use);
   (c) Without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee; and,
   (d) Consistent with the general market value of the subject transaction.[33]

CMS finalized its proposed restructuring of the *fair market value* definitions, but revised the definitions for each:

(1) **General**: The value in an arm's-length transaction –
   (a) Consistent with the general market value of the subject transaction.

(2) **Rental of equipment**: With respect to the rental of equipment, the value in an arm's-length transaction –
   (a) Of rental property for general commercial purposes (not taking into account its intended use); and,
   (b) Consistent with the general market value of the subject transaction.

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(3) **Rental of office space**: With respect to the rental of office space, the value in an arm's-length transaction –

(a) Of rental property for general commercial purposes (not taking into account its intended use);

(b) Without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee; and,

(c) Consistent with the general market value of the subject transaction.[34]

As can be discerned from a reading of these above definitions, CMS ultimately chose not to finalize their proposed references in the definitions to "*like parties and under like circumstances*," but asserted that "*the structure of the final regulation merely reorganizes for clarity, but does not significantly differ from, the statutory language*"[35] of the Stark Law.[36]

Of note, the revised definition of *fair market value* (as well as the revised definition of *general market value*, discussed below) eliminates the connection to the *volume or value* standard, in line with the October 2019 proposed rule. CMS noted that "*a careful reading of the statute shows that the fair market value requirement is separate and distinct from the volume or value standard and the other business generated standard*," and thus there is no need to intertwine the discrete standards.[37]

Additionally, the Stark Law currently requires that *fair market value* "*be consistent with the general market value*," and defines the term as:

> "*...the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement*."[38]

In addition to the delineated definitions for *fair market value* set forth above, CMS suggested in the October 2019 proposed rule that *general market value* be defined separate and apart from *fair market value*.[39] Similar to *fair market value*, CMS delineated the definitions based on whether it applies *generally* or to *rental of equipment or office space*,[40] as follows:

(1) **General**: "*the price that assets or services would bring as the result of bona fide bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement*."[41] [Emphasis added.]

(2) **Rental of Equipment or Office Space**: "*the price that rental property would bring as the result of bona fide bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement*."[42] [Emphasis added.]

CMS finalized its proposal to define *general market value* separately from *fair market value*. However, the finalized definitions for *general market value* were further delineated, eschewing a "general" definition related to both assets and services (i.e., compensation) for specific definitions for each:

(1) **Assets**: "*the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other*." [Emphasis added.]

(2) **Compensation**: "*the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other*." [Emphasis added.]

(3) **Rental of Equipment or Office Space**: "*the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other*."[43] [Emphasis added.]

Interestingly, CMS largely reverted back to its original definition of *general market value* for the finalized definitions, choosing to reference "*well-informed parties*" rather than the parties to the subject transaction.

The October 2019 proposed rule discussed the equivalence of *general market value* and "*'market value,' the term uniformly used in the valuation industry*."[44] However, in the final rule, CMS admitted that "*[o]ur use of the term 'market value' in our preamble discussion, although not carried into the proposed definition of 'general market value,' may have been inaccurate*."[45] In response to those Commenters that pointed out that *general market value* does not equate to the market value of a transaction, such terminology is used in the valuation industry, CMS did not finalize their proposed statements equating *general market value* with market value, reasoning that, "*if finalized, [our proposals] could have had an unintended limiting effect on the regulated community, as well as the valuation community*."[46]

In the October 2019 proposed rule, CMS spent a significant amount of the *fair market value* section reconciling the terms *fair market value* and *general market value*, proposing clear guidance on the relationship, as well as the interplay, between the two terms. Specifically, CMS stated that it viewed *fair market value* as relating to "*the value of an asset or service to*

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hypothetical parties in a hypothetical transaction (that is, typical transactions for like assets or services, with like buyers and sellers, and under like circumstances)" [emphasis added], while *general market value* related to "*the value of an asset or service to the actual parties to a transaction...*"[47] CMS did not finalize its "*proposed analytical framework related to 'hypothetical' versus 'actual' transactions*" in its final rule, although the agency stated that it

> "*continue[s] to believe that the fair market value of a transaction—and particularly, compensation for physician services—may not always align with published valuation data compilations, such as salary surveys. In other words, the rate of compensation set forth in a salary survey may not always be identical to the worth of a particular physician's services*."[48]

In making its point, CMS reiterated the "*rock star*" physician scenario it set forth in the October 2019 proposed rule as an example of when "*extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other valuation data compilations that are not specific to the actual parties to the subject transaction*."[49]

CMS delved further into the topic of salary surveys, responding to a number of comments on the reliance on salary surveys and dispelling any misunderstandings as to CMS's policies on this matter:

- "*It appears from the comments that stakeholders may have been under the impression that it is CMS policy that reliance on salary surveys will result, in all cases, in a determination of fair market value for a physician's professional services. It is not CMS policy that salary surveys necessarily provide an accurate determination of fair market value in all cases… Consulting salary schedules or other hypothetical data is an appropriate starting point in the determination of fair market value, and in many cases, it may be all that is required*."[50]
- "*[W]e agree that a hospital may find it necessary to pay a physician above what is in the salary schedule, especially where there is a compelling need for the physician's services. For example, in an area that has two interventional cardiologists but no cardiothoracic surgeon who could perform surgery in the event of an emergency during a catheterization, a hospital may need to pay above the amount indicated at a particular percentile in a salary schedule to attract and employ a cardiothoracic surgeon*."[51]
- "*Parties do not necessarily fail to satisfy the fair market value requirement simply because the compensation exceeds a particular percentile in a salary schedule…We wish to be perfectly clear that nothing in our commentary was intended to imply that an independent valuation is required for all compensation arrangements*."[52]
- "*We are uncertain why the commenters believe that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate. The commenters are incorrect that this is CMS policy*."[53]

Interestingly, CMS also addressed the "*practice loss postulate*" (also known as the "*practice loss theory*").[54] In response to a Commenter who suggested that "*the definition of 'fair market value' should include a statement that organizations compensating individuals at an ongoing loss may create risk that the compensation is not representative of fair market value*," CMS agreed that, "*in some circumstances, an entity's compensation of a physician at an ongoing loss may present program integrity concerns, but see no need to include the language requested by the commenter in regulation*."[55] CMS asserted that including the phrase "*not in a position to generate business*" in the *general market value* definition should at least partly assuage the commenter's concern, because it "*requires that the nature or identity of the purchaser of the items or services…[be] irrelevant to a determination of 'general market value' and, thus, 'fair market value.'*"[56] CMS did, however, specifically note its disagreement with the Commenter's assertion that "*two hypothetical parties (that cannot consider the fact that one party can generate business for the other) would never enter into a situation in which the physician's compensation and benefits exceeded direct revenue*"[57] [emphasis added], noting that "*there are many valid reasons and legitimate business purposes for entering into an arrangement that will not result in profit for one or more of the parties to the arrangement*," as set forth in the commercial reasonableness definition and related guidance.[58]

Despite the revised definition and guidance, CMS reiterated its statements in prior rulemakings that in establishing

> "*the fair market value (and general market value) of a transaction that involves compensation paid for assets or services, we intend to accept any method that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions that are not in a position to refer to one another….Rather, as stated in Phase II and reiterated in Phase III, we will consider a range of methods of determining fair market value and that the appropriate method will depend on the nature of the transaction, its location, and other factors…*"[59]

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Conclusion

While various definitions were changed from their proposed versions, the overall intent behind CMS's revisions remained the same. As with the October 2019 proposed rule, the most significant takeaways stem from CMS's acknowledgment that: not all physicians, or compensation arrangements, are the same; compensation arrangements may have qualitative benefits that outweigh quantitative costs, i.e., profitability; and, salary surveys are only a starting point in the valuation of a healthcare transaction.

The final revisions to the Stark Law's "Big Three" further demonstrate the need for valuation professionals in the healthcare industry who utilize an evidence-driven methodology that includes both *qualitative* and *quantitative* assessments of the specific facts and circumstances related to the transaction; document their consideration of these facts and circumstances; and, articulate their ultimate applicability to the transaction in support of their opinion.

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5 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" CMS-1720-F, Unpublished Version, https://public-inspection.federalregister.gov/2020-26140.pdf (Accessed 11/24/20), p. 123.
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7 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55799 (citing "Medicare and Medicaid Programs; Physician Referrals to Health Care Entities With Which They Have a Financial Relationship: Proposed rule" Federal Register Vol. 63, No. 6 (January 9, 1998), p. 1700).
8 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55790, 55840.
9 *Ibid*, p. 55790, 55840.
10 "Definitions" 42 C.F.R. § 411.351; "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" CMS-1720-F, Unpublished Version, https://public-inspection.federalregister.gov/2020-26140.pdf (Accessed 11/24/20), p. 128.
11 CMS-1720-F, Unpublished Version, p. 129.
12 *Ibid.*
13 *Ibid*, p. 130.
14 *Ibid.*
15 *Ibid*, p. 135.
16 These purposes were also listed and discussed in the October 2019 proposed rule. "CMS-1720-F, Unpublished Version, p. 136.
17 *Ibid*, p. 135.
18 *Ibid*, p. 128-129.
19 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55791.
20 *Ibid.*
21 *Ibid*, p. 55794.
22 CMS-1720-F, Unpublished Version, p. 167.
23 *Ibid*, p. 166.
24 "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc." Case No. 10-254 (4th Cir., September 20, 2010), Opposition of the United States of America to Petition by Tuomey Healthcare System, Inc. for Permission to Appeal Interlocutory Order, p. 8-9.
25 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55795.
26 CMS-1720-F, Unpublished Version, p. 154.
27 *Ibid.*
28 *See* "Financial relationship, compensation, and ownership or investment interest." 42 C.F.R. § 411.354(d)(2)
29 "Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55797.
30 "Definitions" 42 CFR § 411.351.
31 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55797.
32 *Ibid.*
33 *Ibid.*
34 CMS-1720-F, Unpublished Version, , p. 198.
35 *Ibid.*
36 The Stark Law defines *fair market value* as "*the value in arms length [sic] transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee*." Social Security Act § 1877(h)(3); 42 U.S.C. § 1395nn(h)(3).
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38 "Definitions" 42 CFR § 411.351.
39 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55840.
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41 *Ibid.*
42 *Ibid*, p. 55798, 55840.
43 CMS-1720-F, Unpublished Version, p. 539.
44 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55798.
45 CMS-1720-F, Unpublished Version, p. 201-202.
46 *Ibid*, p. 201-202.
47 Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55799.
48 CMS-1720-F, Unpublished Version, p. 202.
49 *Ibid.*
50 *Ibid*, p. 211.
51 *Ibid.*
52 *Ibid*, p. 211-212.
53 *Ibid*, p. 215.
54 For more information on this controversial concept, see "Practice Loss Postulate (PLP) Regulatory Trend Misapplies Economic Theory to Healthcare Integration" Health Capital Topics, Vol. 9, Issue 6 (June 2016), https://www.healthcapital.com/hcc/newsletter/06_16/HTML/PHP/9.6_hc_topics_june_16_plp_abstract_6.22.php (Accessed 11/24/20).
55 CMS-1720-F, Unpublished Version, p. 207-208.
56 *Ibid.*
57 Emphasis added to illustrate CMS's disagreement with the categorical statement, i.e., that such a situation would "never" happen. CMS-1720-F, Unpublished Version, p. 208.
58 *Ibid*, p. 207-208.
59 *Ibid*, p. 209-210.

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