

rule at § 411.354(d)(4). In making this proposal, we are relying on the authority granted to the Secretary under sections 1877(b)(4), (e)(2)(D), (e)(3)(A)(vii), (e)(3)(B)(i)(II), and (e)(7)(vii) of the Act. We solicit comment as to whether, given the nature of academic medical centers, the proposed requirement at revised § 411.354(d)(4) is necessary.

We are also proposing to revise § 411.354(d)(4) to eliminate certain language regarding: (1) Whether the “set in advance” and “fair market value” conditions of the special rule apply to the compensation arrangement (as stated in the regulation) or to the compensation itself; and (2) when compensation is considered fair market value. Under proposed § 411.354(d)(4), we are clarifying that the physician’s compensation must be set in advance. Any changes to the compensation (or the formula for determining the compensation) must also be set in advance (that is, made prospectively). We are also clarifying that the physician’s compensation must be consistent with the fair market value of the services performed. In addition, we are proposing to eliminate the parenthetical language in existing § 411.354(d)(4) as it conflates the concept of fair market value and the volume or value standard. As noted previously, these are separate standards, and compliance with one is not contingent on compliance with the other. We are taking the opportunity to also propose nonsubstantive revisions for clarity. Although, as proposed, revised § 411.354(d)(4) sets forth protections that apply to both the compensation arrangement that includes a directed referral requirement and also specifically to the compensation itself, for continuity in the application of the protections of the regulation, we are proposing to leave the regulation in § 411.354(d) (special rules on compensation) rather than include it in § 411.354(e), which includes special rules for compensation arrangements. We seek comment on this approach.

5. Fair Market Value (§ 411.351)

The term “fair market value,” as it is defined at section 1877(h)(3) of the Act, consists of three basic components. Fair market value is defined generally as “the value in arms length [sic] transactions, consistent with the general market value.” The statutory definition includes additional qualifications for leases generally, providing that fair market value with respect to rentals or leases also means “the value of rental property for general commercial purposes (not taking into account its

intended use).” Finally, with respect to the lease of office space, in particular, the statutory definition further stipulates that fair market value also means that that value of the rental property is “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.” Most of the statutory exceptions at section 1877(e) of the Act relating to compensation arrangements include requirements pertaining to fair market value compensation, including the exceptions for the rental of office space, the rental of equipment, *bona fide* employment relationships, personal service arrangements, isolated transactions, and payments by a physician. Many of the regulatory exceptions created using the Secretary’s authority under section 1877(b)(4) of the Act also include requirements pertaining to fair market value compensation, including the exceptions for academic medical centers, fair market value compensation, indirect compensation arrangements, EHR items and services, and assistance to compensate a nonphysician practitioner.

The term “fair market value” is defined in our regulations in § 411.351. In the 1992 proposed rule (57 FR 8602) and the 1995 final rule (60 FR 41978), we incorporated the statutory definition of “fair market value” into our regulations without modification. In the 1998 proposed rule (63 FR 1686), we proposed to include in our definition of “fair market value” a definition of “general market value,” to explain what it means for a value to be “consistent with the general market value.” In an attempt to ensure consistency across our regulations, we proposed to adopt the definition of “general market value” from part 413 of our regulations, which pertains to reasonable cost reimbursement for end stage renal disease services. In the context of determining the cost incurred by a present owner in acquiring an asset, § 413.134(b)(2) defined “fair market value” as “the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.” We modified the definition drawn from § 413.134(b)(2) to include analogous provisions for determining the fair market value of any

items or services, including personal services, employment relationships, and rental arrangements. As proposed in the 1998 proposed rule, “general market value” would mean:

The price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers, 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, on the date of acquisition of the asset or at the time of the service agreement. 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.

The proposed definition of “fair market value” in the 1998 proposed rule did not substantively modify the provisions of the fair market value definition pertaining to leases in general and office space leases in particular. In Phase I, we finalized the definition of “fair market value” from the 1998 proposed rule with one modification (66 FR 944 through 945). The definition of “fair market” value finalized in Phase I clarified that a rental payment “does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.” In Phase I we also responded to commenters who requested guidance on how to determine fair market value in a variety of circumstances. We stated that we would accept any commercially reasonable method for determining fair market value. However, we noted that, in most exceptions, the fair market value requirement is further modified by language that precludes taking into account the volume or value of referrals, and, in some cases, other business generated by the referring physician. We concluded that, in determining whether compensation is fair market value, requirements pertaining to the volume or value of referrals and other business generated may preclude reliance on comparables that involve entities and physicians in a position to refer or generate business (66 FR 944). Elsewhere in Phase I, we suggested a similar underlying connection between the fair market value requirement and requirements pertaining to the volume or value of a physician’s referrals and other business generated (66 FR 877). In a discussion of the requirement that compensation not take into account other business generated, we stated that—

[T]he additional limiting phrase ‘not taking into account * * * other business generated between the parties’ means simply that the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid [designated health services] or any other business generated by the referring physician, including other Federal and private pay business. Simply stated, section 1877 of the Act establishes a straightforward test that compensation arrangements should be at fair market value for the work or service performed or the equipment or space leased—not inflated to compensate for the physician’s ability to generate other revenues.

Despite our intimation in Phase I that the concepts of fair market value and the volume and value of referrals or other business generated were fundamentally interrelated, the definition of fair market value finalized in Phase I did not include any reference to the volume or value of a physician’s referrals.

In Phase II, we made two significant modifications to the definition of “fair market value.” First, we proposed certain “safe harbors” for determining fair market value for hourly payments made to physicians for physician services (69 FR 16092 and 16107). (These safe harbors were not finalized.) Second, and more importantly, we incorporated into the definition of “fair market value” a reference to the volume or value standard found in many exceptions to the physician self-referral law. The Phase II definition of “fair market value” provided, in relevant part, that fair market value is usually 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. We explained our view that the determination of fair market value under the physician self-referral law differs in significant respects from standard valuation techniques and methodologies. In particular, we noted that the methodology must exclude valuations where the parties to the transactions are at arm’s length but in a position to refer to one another. We made no substantive changes to the definition of “fair market value” in Phase III or in any of our subsequent rulemaking.

In the CMS RFI, we solicited specific comments regarding possible approaches to modifying the definition of “fair market value” consistent with

the statute and in the context of the exceptions to the physician self-referral law (83 FR 29526). CMS RFI commenters from within and outside the health care provider community, including independent valuers, submitted comments explaining a variety of concerns and challenges with applying the definition of “fair market value” in our current regulations at § 411.351. After carefully reviewing the CMS RFI comments and the statements in our prior rules, we undertook a fresh review of the statutory definition of “fair market value” and the structure of the exceptions for various types of compensation arrangements at section 1877(e) of the Act and in our regulations in §§ 411.355 and 411.357.

As a preliminary matter and as described previously in section II.B.1. of this proposed rule, 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. (See section II.B.3. of this proposed rule for a detailed discussion of the volume or value standard and the other business generated standard.) The volume or value and other business generated standards do not merely serve as “limiting phrases” to modify the fair market value requirement. In order to satisfy the requirements of the exceptions in which these concepts appear, compensation must both: (1) Be fair market value for items or services provided; and (2) not take into account the volume or value of referrals (or the volume or value of other business generated by the physician, where such standard appears). We believe that the appropriate reading of the statute is that the requirement that compensation does not take into account the volume or value of referrals—which is plainly set out as an independent requirement of the relevant exceptions—is not also part of the definition of “fair market value.” We note that the statutory definition of “fair market value” at section 1877(h)(3) of the Act includes no reference to the volume or value of referrals (or other business generated between the parties). For these reasons, we are proposing to revise the definition of “fair market value” to eliminate the connection to the volume or value standard.

In proposing revisions to the definition of “fair market value” at § 411.351, we undertook to establish regulations that give meaning to the statutory language at section 1877(h)(3) of the Act. As described previously, the statute states a general definition of “fair market value” and then modifies that definition for application to leases of

equipment and office space. One of the modifications applies to leases of both equipment and office space; the other applies only to the lease of office space. To illustrate this more clearly in our regulations, we are proposing to modify the definition of “fair market value” to provide for a definition of general application, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space. (We are proposing to use the terms “rental” of equipment and “rental” of office space as those are the titles of the statutory exceptions at section 1877(e)(1)(A) and (B) of the Act and our regulatory exceptions at § 411.357(a) and (b).) We believe that this approach provides parties with ready access to the definition of “fair market value,” with the attendant modifiers, that is applicable to the specific type of compensation arrangement at issue. Therefore, we are proposing that, generally, fair market value means the value in an arm’s-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction. We are also proposing that, with respect to the rental of equipment, fair market value means the value, in an arm’s-length transaction with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction. And, with respect to the rental of office space, we are proposing that fair market value means the value in an arm’s length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), 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 consistent with the general market value of the subject transaction. We note that the proposed structure of the definition merely reorganizes for clarity, but does not significantly differ from, the statutory language at section 1877(h)(3) of the Act. We seek comment on our approach.

Second, we are proposing changes to the definition of “general market value,” currently included within the definition of fair market value at § 411.351. The current definition of “fair market value” states the following, some of which relates to fair market value and some of which relates to the included term,

“general market value.” Numerical references are added here for ease but do not appear in our current regulations:

(1) Fair market value means the value in arm’s-length transactions, consistent with the general market value.

(2) General market value means 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.

(3) 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.

(4) With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), “fair market value” means the value of rental property for general commercial purposes (not taking into account its intended use).

(5) In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.

(6) For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

Items one, four, and five essentially restate the language at section 1877(h)(3) of the Act, albeit with the intervening language in items two and three, and item six was added in Phase I in response to a comment for the purpose of interpreting the modifier “(not taking into account its intended use)” in item four and at section 1877(h)(3) of the Act. We stated in the 1998 proposed rule that items two and three were our attempt to give meaning to the statutory requirement that the fair market value of compensation must be

“consistent with the general market value.” In doing so, we relied on a regulation that relates to the circumstances under which an appropriate allowance for depreciation on buildings and equipment used in furnishing patient care can be an allowable cost. We see no benefit at this time to connect the definition of “general market value” to principles of reasonable cost reimbursement for end stage renal disease services in order to explain what it means for a value to be consistent with general market value, as required by the statute. Moreover, the definition at § 413.134(b)(2) upon which we relied states that *fair* market value (emphasis added) is defined as the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. The regulation goes on to state that, usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition. This definition more closely ties to the widely accepted IRS definition of “fair market value,”² not general market value. Therefore, we considered whether current § 411.351 includes an appropriate definition for “general market value.”

We see no indication in the legislative history or the statutory language itself that the Congress intended that the definition of “general market value” for purposes of the physician self-referral law should deviate from general concepts and principles in the valuation community. Yet, our current definition of “general market value” is unconnected to the recognized valuation principle of “market value” and itself may be the driver of valuation industry policy and procedure. After revisiting the legislative history of section 1877 of the Act and our prior preamble language related to the term “general market value,” we believe that the Congress used the term “general market value” to ensure that the fair market value of the remuneration (that is, as described below, the hypothetical value) is generally consistent with the valuation that would result using accepted market valuation principles. Therefore, we equate “general market value” as that term appears in the statute and our regulations with “market value,” the term uniformly used in the

² Fair Market Value is defined as “the price at which the property would change hands between a willing buyer and a willing seller when the former is not under any compulsion to buy and the latter is not under any compulsion to sell, both parties having reasonable knowledge of relevant facts.” (IRS Rev. Ruling 59-60).

valuation industry. Our own research indicates that, in the valuation industry, the term “market value” refers to the valuation of a planned transaction between two identified parties for identified assets or services, and intended to be consummated within a specified timeframe. Market value is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another. Thus, when parties to a potential personal service arrangement determine the (general) market value of the physician’s compensation, they must not consider that the physician could also refer patients to the entity when not acting as its medical director.

We are aware that our regulatory definition is likely at odds with general valuation principles, which do not use the term “general market value.” For this reason, we are proposing to establish a definition of “general market value” that is consistent with the recognized principle of “market” valuation to address this discrepancy and ease the burden on parties attempting to ensure compliance with the fair market value requirement in many of the compensation exceptions to the physician self-referral law. We are proposing to define “general market value” at § 411.351 to mean 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; or, in the case of the 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. We note that many CMS RFI commenters requested that we simply return to the statutory language. We disagree that would be the best approach. Generally, *in the absence of agency guidance*, a reasonable interpretation of a statutory or regulatory requirement of the physician self-referral law is satisfactory when asserting compliance with the requirement. We believe it is important to provide guidance with respect to the requirement that compensation is fair market value in order not to stymie our enforcement efforts (or those of our law enforcement partners). This guidance is also crucial to support the compliance efforts of the regulated industry.

It is our view that the concept of *fair* market value relates to the value of an asset or service to hypothetical parties in a hypothetical transaction (that is,

typical transactions for like assets or services, with like buyers and sellers, and under like circumstances), while *general* market value (or market value) relates to the value of an asset or service to the actual parties to a transaction that is set to occur within a specified timeframe. Some of the CMS RFI comments included similar information regarding the definition of general market value. Thus, under the statute, the hypothetical value of a transaction must be consistent with the value of the actual transaction transpiring between the particular buyer and seller. We are cognizant that the hypothetical value of a transaction may not always be identical to the market value of the actual transaction being considered. Extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject the transaction. By way of example, assume a hospital is engaged in negotiations to employ an orthopedic surgeon. Independent salary surveys indicate that compensation of \$450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the entire country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate. Thus, although the employee compensation of a hypothetical orthopedic surgeon may be \$450,000 per year, this particular physician commands a significantly higher salary and the general market value (or market value) of the transaction may, therefore, be well above \$450,000. The statute requires that the compensation is the value in an arm's length transaction, but that value must also be consistent with the general market value (or market value) of the subject transaction. In this example, compensation substantially above \$450,000 per year may be fair market value.

Some CMS RFI commenters pointed out that failure to consider the general market value (or market value) of a transaction, as we have proposed to define it here, results in hospitals and other entities paying more than they believe appropriate for physician services. By way of example, assume a hospital is engaged in negotiations to employ a family physician. Independent salary surveys indicate that compensation of \$250,000 per year would be appropriate for a family

physician nationally; no local salary surveys are available. However, the cost of living in the geographic location of the hospital is very low despite its proximity to good schools and desirable recreation opportunities. Yet, due to declining reimbursement rates and a somewhat poor payor mix, the hospital's economic position is tenuous. According to a CMS RFI commenter, the physician may request the \$250,000 that the hypothetical physician would earn, and the hospital may believe that it is compelled to pay the physician this amount, because our current definition of "fair market value" does not recognize the appropriate definition for the "general market value" (or market value) with which the physician's compensation must be consistent under the statute. In this example, the fair market value of the physician's compensation may be less than \$250,000 per year.

Finally, we are proposing to remove from the regulation text at § 411.351 in the definition of "fair market value" the existing statement that, for purposes of the definition of "fair market value," a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements. This language was added to the regulation text as a result of our response in Phase I to a commenter to the 1998 proposed rule, where we stated that a rental payment does not violate the requirement that the fair market value of rental property is the value of the property for general commercial purposes, not taking into account its intended use, merely because it reflects any costs that were incurred by the lessor in developing or upgrading the property, or maintaining the property or its improvements, regardless of why the improvements were added (66 FR 945). That is, the rental payment may reflect the value of any similar commercial property with improvements or amenities of a similar value, regardless of why the property was improved. We do not believe it is necessary to include this policy in regulation text. Moreover, based on some of the comments to the CMS RFI, this regulation text appears to have caused confusion among stakeholders. For this reason, we are proposing to remove the language from the definition of "fair market value" at § 411.351.

C. Group Practices (§ 411.352)

In the CMS RFI, we sought specific comments regarding whether and, if so, what barriers exist to qualifying as a "group practice" under the regulations

at 42 CFR 411.352 (83 FR 29526). In response, commenters identified several areas where policy clarification could enhance certainty of compliance with the rules for qualifying as a group practice, such as the definition of "single legal entity" at § 411.352(a), the "full range of care" and "substantially all" tests at § 411.352(c) and (d), respectively, and the special rules regarding the distribution of profits shares and productivity bonuses at § 411.352(i). Many commenters expressed frustration that certain methodologies that they viewed as equitable for distributing revenues earned through the participation of practice physicians in alternative payment models could prohibit a physician practice from qualifying as a group practice. Although we acknowledge the commenter's views that clarification of many parts of the group practice rules would be useful, we are limiting our proposals to those that relate to the main purposes of this proposed rule: (1) The proposed definitions and special rules for "commercially reasonable" compensation arrangements, "fair market value" compensation, and the volume or value standard applicable throughout the physician self-referral law and regulations; or (2) the transition from a volume-based to a value-based health care system. We may consider additional clarifications or revisions in a future rulemaking.

1. The "Volume or Value Standard" (§ 411.352(g))

In section II.B. of this proposed rule, we are proposing new special rules for compensation that would codify in regulation our interpretation regarding when compensation will be considered to take into account the volume or value of referrals or other business generated (the "volume or value standard"). In connection with those proposals, we reviewed the physician self-referral regulations to ensure that the volume or value standard is expressed using standardized terminology and identified several occurrences of inconsistent expression of the volume or value standard. Although section 1877 of the Act uses more than one phrase to describe the volume or value standard, which may be one reason for variations in the regulation text, we believe that the references are all to the same underlying prohibition on compensation that fluctuates with the volume or value of referrals or other business generated. Therefore, as noted previously, we are proposing to make certain conforming changes throughout our regulations to delineate the volume