# Stark Law Regulations – Comparison Chart of Selected Provisions of Current Regulations and Proposed Rule

| Reference | Current Regulations | Proposed Rule | Change / Comments |
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| **Definitions** | | | |
| **§ 411.351 – Commercially Reasonable** | *N/A* | *Commercially reasonable* means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties. | CMS proposes to add a definition for "Commercially Reasonable." |
| **§ 411.351 – Cybersecurity** | *N/A* | *Cybersecurity* means the process of protecting information by preventing, detecting, and responding to cyberattacks. | CMS proposes to add a definition for "Cybersecurity." |
| **§ 411.351 – DHS** | (2) Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at § 416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). | (2) Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). | CMS proposes to revise paragraph (2) of "Designated health services (DHS)" to clarify that a service provided by a hospital to an inpatient does not constitute a designated health service payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). |
| **§ 411.351 – Does not violate the anti-kickback statute** | *Does not violate the anti-kickback statute*, as used in this subpart only, means that the particular arrangement— | Deleted | CMS proposes to delete the definition of "does not violate the anti-kickback statute" in an effort to decouple the Stark Law from the AKS. |

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| | (1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at §1001.952 of this title, "Exceptions";<br>(ii) Has been specifically approved by the OIG in a favorable advisory opinion issued to a party to the particular arrangement (for example, the entity furnishing DHS) with respect to the particular arrangement (and not a similar arrangement), provided that the arrangement is conducted in accordance with the facts certified by the requesting party and the opinion is otherwise issued in accordance with part 1008 of this title, "Advisory Opinions by the OIG"; or<br>(iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act.<br>(2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—<br>(i) The party's specific arrangement does not implicate the anti-kickback statute, does not constitute prohibited remuneration, or fits in a safe harbor under §1001.952 of this title; or<br>(ii) The party will not be subject to any OIG sanctions arising under the anti-kickback statute (for example, under sections 1128A(a)(7) and 1128(b)(7) of the Act) in connection with the party's specific arrangement. | | |
| **§ 411.351 – Electronic Health Record** | *Electronic health record* means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions. | *Electronic health record* means a repository that includes electronic health information that—<br><br>(1) Is transmitted by or maintained in electronic media; and<br><br>(2) Relates to the past, present, or future health or condition of an individual or the provision of health care to an individual. | CMS proposes to revise the definition of "electronic health record" to ensure consistency with the 21st Century Cures Act. |

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| **§ 411.351 – Fair Market Value** | *Fair market value* means the value in arm's-length transactions, consistent with the general market value. "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. 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. 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). 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. 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. | *Fair market value* means—<br>(1) *General.* The value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction.<br><br>(2) *Rental of equipment.* With respect to the rental of equipment, 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.<br><br>(3) *Rental of office space*. With respect to the rental of office space, 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. | CMS proposes 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. |

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| **§ 411.351 – General market value** | Incorporated into definition of "fair market value." | *General market value* means—<br><br>(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.<br><br>(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. | CMS is proposing to establish a definition of "general market value" that is consistent with the term "market value" as used in the valuation industry. |
| **§ 411.351 – Interoperable** | *Interoperable* means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered. | *Interoperable* means—<br><br>(1) Able to securely exchange data with and use data from other health information technology without special effort on the part of the user;<br><br>(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and<br><br>(3) Does not constitute information blocking as defined in section 3022 of the Public Health Service Act. | CMS proposes to revise the definition of "interoperable" to ensure consistency with the 21st Century Cures Act. |
| **§ 411.351 – Isolated financial transaction** | *N/A* | *Isolated financial transaction*—(1) Isolated financial transaction means a transaction involving a single payment between two or more persons or a transaction that involves integrally related installment payments, provided that—<br><br>(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of | CMS is proposing to establish a definition of "isolated financial transaction" that is independent of the definition of "transaction" and clarify that an "isolated financial transaction" does not include payment for multiple services provided over an extended period, even if |

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| | | referrals or other business generated by the physician; and<br>(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.<br><br>(2) An isolated financial transaction includes a one-time sale of property or a practice, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated). | there is only one payment for such services. |
| **§ 411.351 – Physician** | *Physician* means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart. | *Physician* has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart. | CMS proposes to revise the definition of "physician" to provide uniformity with regard to the definition of a "physician" as set forth in Section 1861(r) of the Social Security Act. |
| **§ 411.351 – Referral** | *Referral*—<br>(1) Means either of the following:<br><br>(i) Except as provided in paragraph (2) of this definition, the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service for which payment may be made under Medicare Part B, including a request for a consultation with another physician and any test or procedure ordered by or to be performed by (or under the supervision of) that other physician, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or | The following paragraph is added:<br><br>(4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart. | CMS proposed to modify the definition of "referral" to add paragraph (4) in order to explicitly state that a referral is not an item or service for purposes of Section 1877 of the Social Security Act and the physician self-referral regulations. |

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| | provided by the referring physician if it is performed or provided by any other person, including, but not limited to, the referring physician's employees, independent contractors, or group practice members.<br><br>(ii) Except as provided in paragraph (2) of this definition, a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the referring physician. A designated health service is not personally performed or provided by the referring physician if it is performed or provided by any other person including, but not limited to, the referring physician's employees, independent contractors, or group practice members.<br><br>(2) Does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy, if—<br><br>(i) The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and<br><br>(ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or | | |

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| | radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.<br>(3) Can be in any form, including, but not limited to, written, oral, or electronic. | | |
| **§ 411.351 – Remuneration** | *Remuneration* means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, except that the following are not considered remuneration for purposes of this section:<br><br>(1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.<br><br>(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely for one or more of the following purposes:<br><br>(i) Collecting specimens for the entity furnishing the items, devices or supplies;<br><br>(ii) Transporting specimens for the entity furnishing the items, devices or supplies;<br><br>(iii) Processing specimens for the entity furnishing the items, devices or supplies;<br><br>(iv) Storing specimens for the entity furnishing the items, devices or supplies;<br><br>(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or | (2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes:<br><br>(3)<br><br>(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in any manner that takes into account the volume or value of any referrals. | CMS proposes changes to paragraphs (2) and (3) (iii) to remove the parenthetical in the current definition of "remuneration," which stipulates that the carve-out to the definition of "remuneration" does not apply to surgical items, devices, or supplies and to remove the modifier "directly or indirectly" in connection with the volume or value standard. |

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| | (vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.<br><br>(3) A payment made by an insurer or a self-insured plan (or a subcontractor of the insurer or self-insured plan) to a physician to satisfy a claim, submitted on a fee-for-service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—<br><br>(i) The health services are not furnished, and the payment is not made, under a contract or other arrangement between the insurer or the self-insured plan (or a subcontractor of the insurer or self-insured plan) and the physician;<br><br>(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and<br><br>(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals. | | |
| **§ 411.351 – Target Patient Population** | *N/A* | *Target patient population* means an identified patient population selected by a value- based enterprise or its VBE participants based on legitimate and verifiable criteria that—<br><br>(1) Are set out in writing in advance of the commencement of the value-based arrangement; and<br><br>(2) Further the value-based enterprise's value-based purpose(s). | CMS proposes to add the definition of "target patient population" that is used in connection with the value based arrangement exceptions to the Stark Law. |

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| **§ 411.351 – Transaction** | *Transaction* means an instance or process of two or more persons or entities doing business. An isolated financial transaction means one involving a single payment between two or more persons or entities or a transaction that involves integrally related installment payments provided that –<br><br>(1) The total aggregate payment is fixed before the first payment is made and does not take into account, directly or indirectly, the volume or value of referrals or other business generated by the referring physician; and<br><br>(2) The payments are immediately negotiable or are guaranteed by a third party, or secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party. | *Transaction* means an instance or process of two or more persons or entities doing business. | CMS proposes to update the definition of "transaction" to remove the reference to "isolated financial transaction" |
| **§ 411.351 – Value-Based Activity** | *N/A* | *Value-based activity* – (1) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:<br><br>(i) The provision of an item or service;<br><br>(ii) The taking of an action; or<br><br>(iii) The refraining from taking an action.<br><br>(2) The making of a referral is not a value-based activity. | CMS proposes to add the definition of "value-based activity" that is used in connection with the value based arrangement exceptions to the Stark Law. |
| **§ 411.351 – Value-Based Arrangement** | *N/A* | *Value-based arrangement* means an arrangement for the provision of at least one value-based activity for a target patient population between or among—<br><br>(1) The value-based enterprise and one or more of its VBE participants; or | CMS proposes to add the definition of "value-based arrangement" that is used in connection with the value based arrangement exceptions to the Stark Law. |

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| | | (2) VBE participants in the same value-based enterprise. | |
| **§ 411.351 – Value-Based Enterprise** | *N/A* | *Value-based enterprise* (VBE) means two or more VBE participants—<br><br>(1) Collaborating to achieve at least one value-based purpose;<br><br>(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;<br><br>(3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and<br><br>(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s). | CMS proposes to add the definition of "value-based enterprise" that is used in connection with the value based arrangement exceptions to the Stark Law. |
| **§ 411.351 –Value-Based Purpose** | *N/A* | *Value-based purpose* means—<br><br>(1) Coordinating and managing the care of a target patient population;<br><br>(2) Improving the quality of care for a target patient population;<br><br>(3) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or<br><br>(4) Transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and | CMS proposes to add the definition of "value-based purpose" that is used in connection with the value based arrangement exceptions to the Stark Law. |

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| | | control of costs of care for a target patient population. | |
| **§ 411.351 – VBE Participant** | *N/A* | *VBE participant* means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise. | CMS proposes to add the definition of "VBE participant" that is used in connection with the value based arrangement exceptions to the Stark Law. |
| **Group Practice** | | | |
| **§ 411.352(i)(1) – Special Rules for Profit Shares and Productivity Bonuses – Overall Profits** | (1) A physician in the group practice may be paid a share of overall profits of the group, provided that the share is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician. A physician in the group practice may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals of DHS by the physician (except that the bonus may directly relate to the volume or value of DHS referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).<br><br>(2) Overall profits means the group's entire profits derived from DHS payable by Medicare or Medicaid or the profits derived from DHS payable by Medicare or Medicaid of any component of the group practice that consists of at least five physicians. Overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met: | (1) *Overall profits.*<br><br>(i) Notwithstanding paragraph (g) of this section, a physician in the group practice may be paid a share of overall profits of the group that is indirectly related to the volume or value of the physician's referrals.<br><br>(ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.<br><br>(iii)Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:<br><br>(A) Overall profits are divided *per capita* (for example, per member of the group or per physician in the group).<br><br>(B) Overall profits derived from designated health services are distributed based on the distribution of the group's revenues attributed to | CMS is proposing to clarify its interpretation of the overall profits of a group that can be distributed to physicians in a group. |

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| | (i) The group's profits are divided per capita (for example, per member of the group or per physician in the group).<br><br>(ii) Revenues derived from DHS are distributed based on the distribution of the group practice's revenues attributed to services that are not DHS payable by any Federal health care program or private payer.<br><br>(iii) Revenues derived from DHS constitute less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 percent or less of his or her total compensation from the group. | services that are not designated health services and would not be considered designated health services if they were payable by Medicare.<br><br>(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group. | |
| **§ 411.352(i)(2) – Special Rules for Profit Shares and Productivity Bonuses – Productivity Bonuses** | (3) A productivity bonus must be calculated in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of DHS. A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS if one of the following conditions is met:<br><br>(i) The bonus is based on the physician's total patient encounters or relative value units (RVUs). (The methodology for establishing RVUs is set forth in § 414.22 of this chapter.)<br><br>(ii) The bonus is based on the allocation of the physician's compensation attributable to services that are not DHS payable by any Federal health care program or private payer.<br><br>(iii) Revenues derived from DHS are less than 5 percent of the group practice's total revenues, and the allocated portion of those revenues to each physician in the group practice constitutes 5 | (2) *Productivity bonuses.*<br><br>(i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, that is indirectly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).<br><br>(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:<br><br>(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally | CMS is proposing to renumber the regulation that lists the provisions related to the payment of productivity bonuses from §411.352(i)(3) to §411.352(i)(2) and is proposing minor changes to such provisions. |

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| | percent or less of his or her total compensation from the group practice. | performed by the physician. (The methodology for establishing RVUs is set forth in §414.22 of this chapter.)<br><br>(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.<br><br>(C) Revenues derived from designated health services are less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group. | |
| **§ 411.352(i)(3) – Special Rules for Profit Shares and Productivity Bonuses – Value-Based Enterprise Participation** | *N/A* | (3) *Value-based enterprise participation*. Profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined in §411.351, are distributed to the participating physician. | CMS is proposing to add a new §411.352(i)(3) to address downstream compensation that derives from payments made to a group practice, rather than directly to a physician in the group, that relate to the physician's participation in a value-based arrangement. |
| **§ 411.352(i)(4) – Special Rules for Profit Shares and Productivity Bonuses – Supporting Documentation** | (4) Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(2) and (i)(3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request. | (4) *Supporting documentation*. Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request. | CMS proposed a clarifying edit to reference a new proposed section. |
| **Prohibition on Certain Referrals by Physicians and Limitations on Billing** | | | |

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| **§ 411.353(c)(1) – Denial of Payment for Services Furnished Under a Prohibited Referral** | (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral. The period during which referrals are prohibited is the period of disallowance. For purposes of this section, with respect to the following types of noncompliance, the period of disallowance begins at the time the financial relationship fails to satisfy the requirements of an applicable exception and ends no later than –<br><br>(i) Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception;<br><br>(ii) Where the noncompliance is due to the payment of excess compensation, the date on which all excess compensation is returned by the party that received it to the party that paid it and the financial relationship satisfies all of the requirements of an applicable exception; or<br><br>(iii) Where the noncompliance is due to the payment of compensation that is of an amount insufficient to satisfy the requirements of an applicable exception, the date on which all additional required compensation is paid by the party that owes it to the party to which it is owed and the financial relationship satisfies all of the requirements of an applicable exception. | (1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral. | CMS is proposing to delete the rules on the period of disallowance at §411.353(c)(1) in their entirety. The "period of disallowance" is the period of time during which a physician may not make referrals for designated health services to an entity and the entity may not bill Medicare for the referred designated health services when a financial relationship between the parties failed to satisfy the requirements of any applicable exception. |
| **§ 411.353(f)(1)(i) – Exception for Certain Arrangements Involving Temporary Noncompliance** | (i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under § 411.355, § 411.356, or § 411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception; | (i) The financial relationship between the entity and the referring physician fully complied with an applicable exception under § 411.355, § 411.356, or § 411.357 for at least 180 consecutive calendar days immediately preceding the date on which the financial | CMS proposes to remove ";" and add in its place "; and" |

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| | | relationship became noncompliant with the exception; and | |
| **§ 411.353(f)(1)(ii) – Exception for Certain Arrangements Involving Temporary Noncompliance** | (ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; and | (ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance. | CMS proposes to remove "; and" and add in its place a period. |
| **§ 411.353(f)(1)(iii) – Exception for Certain Arrangements Involving Temporary Noncompliance** | (iii) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), and the claim or bill otherwise complies with all applicable Federal and State laws, rules, and regulations. | *N/A* | CMS has proposed to remove this section. |
| **§ 411.353(g) – Special Rule for Certain Arrangements Involving Temporary Noncompliance With Signature Requirements** | *Special rule for certain arrangements involving temporary noncompliance with signature requirements.*<br><br>(1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if –<br><br>(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the signature requirement of the exception; and<br><br>(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant and the compensation arrangement otherwise complies with all criteria of the applicable exception. | *N/A* | CMS has proposed to remove this section. |

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| | (2) [Reserved] | | |
| **Financial Relationship, compensation, and ownership or investment interest.** | | | |
| **§ 411.354(b)(3)(iv) – Ownership or Investment Interest** | (iv) An "under arrangements" contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS "under arrangements" with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section); or | (iv) An "under arrangements" contract between a hospital and an entity owned by one or more physicians (or a group of physicians) providing DHS "under arrangements" with the hospital (such a contract is a compensation arrangement as defined in paragraph (c) of this section); | CMS proposes to remove "; or" and add in its place ";" |
| **§ 411.354(b)(3)(v) – Ownership or Investment Interest** | (v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section). | (v) A security interest held by a physician in equipment sold by the physician to a hospital and financed through a loan from the physician to the hospital (such an interest is a compensation arrangement as defined in paragraph (c) of this section); | CMS proposes to remove a period and add in its place ";" |
| **§ 411.354(b)(3)(vi) – Ownership or Investment Interest** | *N/A* | (vi) A titular ownership or investment interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or | Under the proposed §411.354(b)(3)(vi), "ownership and investment interests" would not include titular ownership or investment interests. |
| **§ 411.354(b)(3)(vii) – Ownership or Investment Interest** | *N/A* | (vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a). | Under the proposed §411.354(b)(3)(vii), "ownership and investment interests" would not include an interest in an entity that arises through participation in an ESOP. |
| **§ 411.354(c)(2)(ii) – Compensation Arrangement – Indirect Compensation Arrangement** | (ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by | (ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that takes into account the volume or value of referrals or other business generated by the referring physician for | CMS proposes to update this section to remove references to "varies with, or." |

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| | the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and | the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); | |
| **§ 411.354(c)(4) – Compensation Arrangement – Exceptions Applicable to Indirect Compensation Arrangements** | *N/A* | (4) *Exceptions applicable to indirect compensation arrangements.*<br><br>(i) *General.* Except as provided in this paragraph (c)(4) of this section, only the exceptions at §§411.355 and 411.357(p) are applicable to indirect compensation arrangements.<br><br>(ii) *Special rule for indirect compensation arrangements involving value-based arrangements.* When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined | CMS proposes to set forth the exceptions that are applicable to the indirect compensation arrangement. |

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| | | in §411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party, only the exceptions at §§411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement. | |
| **§ 411.354(d)(2) – Special Rules on Compensation** | (2) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "the volume or value of referrals" if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS. | (2) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals. | CMS proposed to remove the reference to "of DHS." |
| **§ 411.354(d)(3) – Special Rules on Compensation** | (3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "other business generated between the parties," provided that the compensation is fair market value for items and services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the referring physician, which are not considered "other business generated" by the referring physician). | (3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account other business generated between the parties or other business generated by the referring physician if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the physician, which are not considered "other business generated" by the physician). | CMS proposes to specify that unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account other business generated between the parties or <u>other business generated by the referring physician</u> if certain conditions are met as set forth in the section. |
| **§ 411.354(d)(4) – Special Rules on Compensation** | (4) A physician's compensation from a *bona fide* employer or under a managed care contract or other arrangement for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement: | (4) If a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, all of the following conditions must be met.<br><br>(i) The compensation, or a formula for determining the compensation, is set in advance | CMS is 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 |

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| | (i) Is set in advance for the term of the arrangement.<br><br>(ii) Is consistent with fair market value for services performed (that is, the payment does not take into account the volume or value of anticipated or required referrals).<br><br>(iii) Otherwise complies with an applicable exception under § 411.355 or § 411.357.<br><br>(iv) Complies with both of the following conditions:<br><br>(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.<br><br>(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.<br><br>(v) The required referrals relate solely to the physician's services covered by the scope of the employment, the arrangement for personal services, or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, arrangement for personal services, or contract. | for the duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.<br><br>(ii) The compensation is consistent with the fair market value of the physician's services.<br><br>(iii) The compensation arrangement otherwise complies with an applicable exception at §§411.355 or 411.357.<br><br>(iv) The compensation arrangement complies with both of the following conditions:<br><br>(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.<br><br>(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.<br><br>(v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her | compensation itself; and (2) when compensation is considered fair market value. CMS proposes to clarify 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). CMS is also clarifying that the physician's compensation must be consistent with the fair market value of the services performed. In addition, CMS is 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 |

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| | | employment, personal service arrangement, or managed care contract. | |
| **§ 411.354(d)(5) – Special Rules on Compensation** | *N/A* | (5)<br><br>(i) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if—<br><br>(A) The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or<br><br>(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.<br><br>(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if—<br><br>(A) The formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the | CMS proposes to implement a special rule that creates a bright-line rule for determining whether compensation takes into account the volume or value of referrals or take into account other business generated between the parties. 411.354(d)(5) addresses situations involving compensation from an entity furnishing DHS to a physician. |

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| | | physician's generation of other business for the entity; or<br><br>(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.<br><br>(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.<br><br>(iv) This paragraph (d)(5) applies only to section 1877 of the Act. | |
| **§ 411.354(d)(6) – Special Rules on Compensation** | *N/A* | (6)<br><br>(i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if—<br><br>(A) The formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity; or<br><br>(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined. | CMS proposes to implement a special rule that creates a bright-line rule for determining whether compensation takes into account the volume or value of referrals or take into account other business generated between the parties. § 411.354(d)(6) addresses compensation from a physician to an entity furnishing DHS. |

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| | | (ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if—<br><br>(A) The formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity; or<br><br>(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.<br><br>(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable decreases as the other variable increases.<br><br>(iv) This paragraph (d)(6) applies only to section 1877 of the Act. | |
| **§ 411.354(e)(3) – Special Rule on Compensation Arrangements – Special Rule on Writing and** | *N/A* | (3) *Special rule on writing and signature requirements*. In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if— | CMS proposes a special rule for noncompliance with the writing and signature requirements. |

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| **Signature Requirements** | | (i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and<br><br>(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception. | |
| **General exceptions to the referral prohibition related to both ownership/investment and compensation.** | | | |
| **§ 411.355(b)(4)(v) – In-Office Ancillary Services** | (v) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(c)(5) – Services Furnished By An Organization To Enrollees** | (5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter. | (5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter. | CMS proposes to reference designated health services furnished by an organization (or its contractors or subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization. |
| **§ 411.355(e)(1)(ii)(C) – Academic Medical Centers** | (C) The total compensation paid by each academic medical center component is not determined in a manner that takes into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center. | (C) The total compensation paid by each academic medical center component is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician within the academic medical center. | CMS proposes to specify that payment is not determined in <u>any</u> manner that takes into account the volume or value of referrals or other business generated between the parties. |
| **§ 411.355(e)(1)(ii)(D) – Academic Medical Centers** | *N/A* | (D) If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4). | CMS is proposing to require §411.354(d)(4) compliance in connection with this exception. |

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| **§ 411.355(e)(1)(iv) – Academic Medical Centers** | (iv) The referring physician's compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(f)(3) – Implants Furnished by an ASC** | (3) The arrangement for the furnishing of the implant does not violate the anti-kickback statute (section 1128B(b) of the Act). | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(f)(4) – Implants Furnished by an ASC** | (4) All billing and claims submission for the implants does not violate any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(g)(2) – EPO and Other Dialysis-Related Drugs** | (2) The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute (section 1128B(b) of the Act). | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(g)(3) – EPO and Other Dialysis-Related Drugs** | (3) All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(h)(2) – Preventative Screening Tests, Immunizations, and Vaccines** | (2) The arrangement for the provision of the preventive screening tests, immunizations, and vaccines does not violate the anti-kickback statute (section 1128B(b) of the Act). | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(h)(3) – Preventative Screening Tests, Immunizations, and Vaccines** | (3) All billing and claims submission for the preventive screening tests, immunizations, and vaccines does not violate any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(i)(2) – Eyeglasses and Contact Lenses** | (2) The arrangement for the furnishing of the eyeglasses or contact lenses does not violate the anti-kickback statute (section 1128B(b) of the Act). | [Reserved] | CMS proposes to remove and reserve this section. |

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| **Following Cataract Surgery** | | | |
| **§ 411.355(i)(3) – Eyeglasses and Contact Lenses Following Cataract Surgery** | (3) All billing and claims submission for the eyeglasses or contact lenses does not violate any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.355(j)(1)(iv) – Intra-Family Rural Referrals** | (iv) The financial relationship does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **Exceptions to the referral prohibition related to compensation arrangements.** | | | |
| **§ 411.357(a)(3) – Rental of Office Space** | (3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. | (3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. For purposes of this paragraph (a), exclusive use means that the lessee (and any other lessees of the same office space) uses the office space to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space. | CMS is proposing to clarify that the exclusive use requirement does not prohibit multiple lessees from using rented office space and that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the office space. |
| **§ 411.357(a)(5)(i) – Rental of Office Space** | (i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or | (i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or | CMS proposes to specify that the arrangement is not determined in <u>any</u> manner that |

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| | | | takes into account the volume or value of referrals or other business generated between the parties. |
| **§ 411.357(b)(2) – Rental of Equipment** | (2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). | (2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). For purposes of this paragraph (b), exclusive use means that the lessee (and any other lessees of the same equipment) uses the equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the equipment. | CMS proposing to clarify that the exclusive use requirement does not prohibit multiple lessees from using rented equipment and that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the equipment. |
| **§ 411.357(b)(4)(i) – Rental of Equipment** | (i) In a manner that takes into account the volume or value of any referrals or other business generated between the parties; or | (i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or | CMS proposes to specify the arrangement is not determined in <u>any</u> manner that takes into account the volume or value of referrals or other business generated between the parties. |
| **§ 411.357(c)(2)(ii) – Bona Fide Employment Relationships – Remuneration** | (ii) Except as provided in paragraph (c)(4) of this section, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician. | (ii) Except as provided in paragraph (c)(4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician. | CMS proposes to specify that the arrangement is not determined in <u>any</u> manner that takes into account the volume or value of referrals. |
| **§ 411.357(c)(5)(ii) – Bona Fide Employment Relationships** | *N/A* | (5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4). | CMS is proposing to require §411.354(d)(4) compliance in connection with this exception. |
| **§ 411.357(d)(1)(v) – Personal Service** | (v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § | (v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined in | CMS proposes to specify that payment is not determined in <u>any</u> manner that takes into account the volume or value of |

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| **Arrangements - General** | 411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. | §411.351), is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties. | referrals or other business generated between the parties. |
| **§ 411.357(d)(1)(viii) – Personal Service Arrangements - General** | *N/A* | (viii) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4). | CMS is proposing to require §411.354(d)(4) compliance in connection with this exception. |
| **§ 411.357(d)(2) – Personal Service Arrangements – Physician Incentive Plan Exception** | (2) *Physician incentive plan exception*. In the case of a physician incentive plan (as defined at § 411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements: | (2) *Physician incentive plan exception*. In the case of a physician incentive plan (as defined at §411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in any manner (through a withhold, capitation, bonus, or otherwise) that takes into account the volume or value of referrals or other business generated between the parties, if the plan meets the following requirements: | CMS proposes to move the reference to "any." |
| **§ 411.357(d)(2)(iv) – Personal Service Arrangements – Physician Incentive Plan Exception** | *N/A* | (iv) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4). | CMS is proposing to require §411.354(d)(4) compliance in connection with this exception. |
| **§ 411.357(e)(1)(iii) – Physician Recruitment** | (iii) The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and | (iii) The amount of remuneration under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the physician or other business generated between the parties; and | CMS proposes to specify that payment is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties. |
| **§ 411.357(e)(4)(i) – Physician Recruitment** | (i) The writing in paragraph (e)(1) of this section is also signed by the physician practice. | (i) The writing in paragraph (e)(1) of this section is also signed by the physician practice if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital. | CMS is proposing to modify the signature requirement at §411.357(e)(4)(i). CMS proposes to (i) eliminate the signature requirement for a physician practice that receives no financial benefit under the recruitment arrangement, and |

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| | | | (ii) require the physician practice to sign the writing documenting the recruitment arrangement, if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital. |
| **§ 411.357(e)(4)(v) – Physician Recruitment** | (v) The remuneration from the hospital under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital. | (v) The remuneration from the hospital under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital. | CMS proposes to specify that payment is not determined in any manner that takes into account the volume or value of referrals. |
| **§ 411.357(e)(4)(vii) – Physician Recruitment** | (vii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | *N/A* | CMS proposes to remove this section. |
| **§ 411.357(e)(6)(i) – Physician Recruitment** | (i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | (i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital. | CMS proposes to decouple AKS from the Stark Law by deleting: ", provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission." |
| **§ 411.357(f)(1) – Isolated Transactions** | (1) The amount of remuneration under the isolated transaction is -<br>(i) Consistent with the fair market value of the transaction; and | (1) The amount of remuneration under the isolated financial transaction is—<br><br>(i) Consistent with the fair market value of the isolated financial transaction; and | CMS proposes to specify that payment is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties. |

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| | (ii) Not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties. | (ii) Not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties. | |
| **§ 411.357(f)(3) – Isolated Transactions** | (3) There are no additional transactions between the parties for 6 months after the isolated transaction, except for transactions that are specifically excepted under the other provisions in § 411.355 through § 411.357 and except for commercially reasonable post-closing adjustments that do not take into account (directly or indirectly) the volume or value of referrals or other business generated by the referring physician. | (3) There are no additional transactions between the parties for 6 months after the isolated financial transaction, except for transactions that are specifically excepted under the other provisions in §§411.355 through 411.357 and except for commercially reasonable post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the referring physician. | CMS proposes to remove the reference to "isolated transaction" and replace with "isolated financial transaction" and to remove the reference to "(directly or indirectly)." |
| **§ 411.357(g) – Certain Arrangements With Hospitals** | (g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to a physician if the remuneration does not relate, directly or indirectly, to the furnishing of DHS. To qualify as "unrelated," remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals. Remuneration relates to the furnishing of DHS if it –<br><br>(1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles;<br><br>(2) Is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or<br><br>(3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician. | (g) *Remuneration unrelated to the provision of designated health services*. Remuneration provided by a hospital to a physician if the remuneration does not relate to the provision of designated health services. Remuneration does not relate to the provision of designated health services if—<br><br>(1) The remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals; and<br><br>(2) The remuneration is for an item or service that is not related to the provision of patient care services.<br>(3) For purposes of this this paragraph (g):<br><br>(i) Items that are related to the provision of patient care services include, but are not limited to, any item, supply, device, equipment, or space that is used in the diagnosis or treatment of patients and any technology that is used to communicate with patients regarding patient care services. | CMS is proposing certain modifications to the exception at §411.357(g) to broaden the application of the exception. |

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| | | (ii) A service is deemed to be not related to the provision of patient care services if the service could be provided by a person who is not a licensed medical professional. | |
| **§ 411.357(h)(5) – Group Practice Arrangements With a Hospital** | (5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. | (5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties. | CMS proposes to specify that payment is not determined in <u>any</u> manner that takes into account the volume or value of referrals or other business generated between the parties. |
| **§ 411.357(h)(7) – Group Practice Arrangements With a Hospital** | *N/A* | (7) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4). | CMS is proposing to require §411.354(d)(4) compliance in connection with this exception. |
| **§ 411.357(i)(2) – Payments by a Physician** | (2) To an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value, and that are not specifically excepted by another provision in §§ 411.355 through 411.357 (including, but not limited to, § 411.357(l)). "Services" in this context means services of any kind (not merely those defined as "services" for purposes of the Medicare program in § 400.202 of this chapter). | (2) To an entity as compensation for any other items or services—<br><br>(i) That are furnished at a price that is consistent with fair market value; and<br><br>(ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable. | CMS is proposing to remove from §411.357(i)(2) the reference to the regulatory exceptions, including the parenthetical referencing the exception for fair market value compensation. CMS is also proposing that the exception at §411.357(i) would not be available to protect compensation arrangements specifically addressed by one of the statutory exceptions, codified at §411.357(a) through (h). |
| **§ 411.357(i)(3) – Payments by a Physician** | *N/A* | (3) For purposes of this paragraph (i), "services" means services of any kind (not merely those defined as "services" for purposes of the Medicare program in §400.202 of this chapter). | CMS proposes to define "services" as used in the payments by a physician exception. |
| **§ 411.357(j)(3) – Charitable Donations by a Physician** | (3) The donation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |

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| **§ 411.357(k)(1)(iii) – Nonmonetary Compensation** | (iii) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission. | *N/A* | CMS proposes to remove this section. |
| **§ 411.357(k)(2) – Nonmonetary Compensation** | (2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index - Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp. | (2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index - Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp. | CMS proposes to remove the term "Web site" and added in its place the term "website." |
| **§ 411.357(l) – Fair Market Value Compensation** | (l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:<br><br>(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing.<br><br>(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement may be renewed any number | (l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or services or for the use of office space or equipment, if the arrangement meets the following conditions:<br><br>(1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment, all of which are specified in writing.<br><br>(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items, services, office space, or equipment during the course of a year. An arrangement may be renewed any number of | CMS proposes to make the fair market value compensation exception available to protect arrangements for the rental or lease of office space. CMS is proposing to require §411.354(d)(4) compliance as part of the exception. Further, CMS is proposing to remove the requirement that the arrangement does not violate the AKS or any Federal or State law or regulation governing billing or claims submission. |

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| | of times if the terms of the arrangement and the compensation for the same items or services do not change.<br><br>(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of equipment may not be determined using a formula based on –<br><br>(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated through the use of the equipment; or<br><br>(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.<br><br>(4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.<br><br>(5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.<br><br>(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. | times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change.<br><br>(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—<br><br>(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or<br><br>(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.<br><br>(4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction).<br><br>(5) [Reserved]<br><br>(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.<br><br>(7) The arrangement satisfies the requirements of §411.354(d)(4) in the case of— | |

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| | | (i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or<br><br>(ii) Remuneration paid to the group of physicians that is conditioned on one of the group's physician's referrals to a particular provider, practitioner, or supplier. | |
| **§ 411.357(m)(1) – Medical Staff Incidental Benefits** | (1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in a manner that takes into account the volume or value of referrals or other business generated between the parties. | (1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in any manner that takes into account the volume or value of referrals or other business generated between the parties. | CMS proposes to specify that payment is not determined in <u>any</u> manner that takes into account the volume or value of referrals or other business generated between the parties. |
| **§ 411.357(m)(2) – Medical Staff Incidental Benefits** | (2) Except with respect to identification of medical staff on a hospital Web site or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients. | (2) Except with respect to identification of medical staff on a hospital website or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients. | CMS proposes to remove the term "Web site" and add in its place the term "website." |
| **§ 411.357(m)(3) – Medical Staff Incidental Benefits** | (3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web site or in hospital advertising, meets the "on campus" requirement of this paragraph (m). | (3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital website or in hospital advertising, meets the "on campus" requirement of this paragraph (m). | CMS proposes to remove the term "Web site" and add in its place the term "website." |
| **§ 411.357(m)(5) – Medical Staff Incidental Benefits** | (5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who | (5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is | CMS proposes to remove the term "Web site" and add in its place the term "website." |

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| | are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index - Urban All Items (CPI-I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-I for the 12 month period and the new limits on the physician self-referral Web site at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp. | serving patients who are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index - Urban All Items (CPI-I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-I for the 12 month period and the new limits on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp. | |
| **§ 411.357(m)(7) – Medical Staff Incidental Benefits** | (7) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.357(n) – Risk-Sharing Arrangements** | (n) *Risk-sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. For purposes of this paragraph (n), “health plan” and “enrollees” have the meanings set forth in § 1001.952(l) of this title. | (n) *Risk-sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan. For purposes of this paragraph (n), “health plan” and “enrollees” have the meanings set forth in §1001.952(l) of this title. | In an effort to decouple the Stark Law from the AKS, CMS is proposing to remove the requirement that the arrangement does not violate the AKS or any Federal or State law or regulation governing billing or claims submission. |
| **§ 411.357(p)(3) – Indirect Compensation Arrangements** | (3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | *N/A* | CMS proposes to remove this section. |
| **§ 411.357(r)(2)(iv) – Obstetrical Malpractice Insurance Subsidies** | (iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by | (iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in any manner that takes into account the volume or value of | CMS proposes to specify that payment is not determined in <u>any</u> manner that takes into account the volume or value of referrals by the physician or |

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| | the physician or any other business generated between the parties. | referrals by the physician or other business generated between the parties. | other business generated between the parties. |
| **§ 411.357(r)(2)(x) – Obstetrical Malpractice Insurance Subsidies** | (x) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | *N/A* | CMS proposes to remove this section. |
| **§ 411.357(s)(5) – Professional Courtesy** | (5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.357(t)(3)(iv) – Retention Payments in Underserved Areas - Remuneration** | (iv) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | *N/A* | CMS proposes to remove this section. |
| **§ 411.357(u)(3) – Community-Wide Health Information Systems** | (3) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.357(w) – Electronic Health Records Items and Services** | (w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met: | (w) *Electronic health records items and services*. Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including certain cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met: | CMS proposes to clarify that donations of certain cybersecurity software and services are permitted under the EHR exception. |
| **§ 411.357(w)(2) – Electronic Health Records Items and Services** | (2) The software is interoperable (as defined in § 411.351) at the time it is provided to the physician. For purposes of this paragraph, software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria | (2) The software is interoperable (as defined in §411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to electronic health record certification criteria | CMS proposes to update provisions in the EHR exception pertaining to interoperability. |

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| | identified in the then-applicable version of 45 CFR part 170. | identified in the then-applicable version of 45 CFR part 170. | |
| **§ 411.357(w)(3) – Electronic Health Records Items and Services** | (3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services). | (3) The donor (or any person on the donor's behalf) does not engage in a practice constituting information blocking, as defined in section 3022 of the Public Health Service Act, in connection with the donated items or services. | CMS proposed to prohibit the donor (or any person on the donor's behalf) from engaging in a practice constituting information blocking, as defined in section 3022 of the PHSA, in connection with the donated items or services. |
| **§ 411.357(w)(6) – Electronic Health Records Items and Services** | (6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met: | (6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met: | CMS proposes to specify that the eligibility of a physician for the items or services, nor the amount or nature of the items or services is not determined in <u>any</u> manner that takes into account the volume or value of referrals or other business generated between the parties. |
| **§ 411.357(w)(11) – Electronic Health Records Items and Services** | (11) [Reserved] | *N/A* | CMS proposes to remove this section. |
| **§ 411.357(w)(12) – Electronic Health Records Items and Services** | (12) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | *N/A* | CMS proposes to remove this section. |
| **§ 411.357(w)(13) – Electronic Health Records Items and Services** | (13) The transfer of the items or services occurs and all conditions in this paragraph (w) are satisfied on or before December 31, 2021. | *N/A* | CMS proposes to remove this section. |
| **§ 411.357(x)(1) – Assistance to Compensate a** | (1) Remuneration provided by a hospital to a physician to compensate a nonphysician | (1) Remuneration provided by a hospital to a physician to compensate a nonphysician | CMS is proposing to replace the term "practiced" with "furnished NPP patient care |

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| **Nonphysician Practitioner** | practitioner to provide patient care services, if all of the following conditions are met:<br><br>(i) The arrangement is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner.<br><br>(ii) The arrangement is not conditioned on –<br><br>(A) The physician's referrals to the hospital; or<br><br>(B) The nonphysician practitioner's referrals to the hospital.<br><br>(iii) The remuneration from the hospital –<br><br>(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and<br><br>(B) Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by –<br><br>(1) The physician (or any physician in the physician's practice) or other business generated between the parties; or<br><br>(2) The nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties. | practitioner to provide NPP patient care services, if all of the following conditions are met:<br><br>(i) The arrangement—<br><br>(A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; and<br><br>(B) Commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation arrangement described in paragraph (x)(1)(vi)(A) of this section.<br><br>(ii) The arrangement is not conditioned on—<br><br>(A) The physician's referrals to the hospital; or<br><br>(B) The nonphysician practitioner's NPP referrals to the hospital.<br><br>(iii) The remuneration from the hospital—<br><br>A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and<br><br>(B) Is not determined in any manner that takes into account the volume or value of actual or anticipated— | services." Under the proposal, a hospital would not violate §411.357(x)(1)(v)(A) if the hospital provided remuneration to a physician to compensate an NPP, and the individual receiving compensation from the physician furnished services in the hospital's geographic service area within 1 year of the commencement of his or her compensation arrangement with the physician, provided that the services furnished by the individual during the 1-year period were not NPP patient care services, as CMS is proposing to define the term at §411.357(x)(4)(i). To ensure that compensation arrangements protected under the exception do not pose a risk of program or patient abuse, CMS is proposing to amend §411.357(x)(1)(i) to expressly require that the compensation arrangement between the hospital, FQHC, or RHC and the physician commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation with the NPP.<br><br>Further, in an effort to decouple the Stark Law from the AKS, CMS is proposing to remove |

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| | (iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the patient care services furnished by the nonphysician practitioner to patients of the physician's practice.<br><br>(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) –<br><br>(A) Practiced in the geographic area served by the hospital; or<br><br>(B) Been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished services at the medical practice site located in the geographic area served by the hospital.<br><br>(vi)<br><br>(A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization in whose shoes the physician stands under § 411.354(c); and<br><br>(B) Substantially all of the services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services. | (1) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or<br><br>(2) NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.<br><br>(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the NPP patient care services furnished by the nonphysician practitioner to patients of the physician's practice.<br><br>(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under §411.354(c))—<br><br>(A)Furnished NPP patient care services in the geographic area served by the hospital; or<br><br>(B) Been employed or otherwise engaged to provide NPP patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished NPP patient care services at the medical practice site located in the geographic area served by the hospital.<br><br>(vi)<br><br>(A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization in whose | the requirement that the arrangement does not violate the AKS or any Federal or State law or regulation governing billing or claims submission. |

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| | (vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide patient care services in the geographic area served by the hospital.<br><br>(viii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission. | shoes the physician stands under §411.354(c); and<br><br>(B) Substantially all of the NPP patient care services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.<br><br>(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide NPP patient care services in the geographic area served by the hospital.<br><br>( ) [Reserved] | |
| **§ 411.357(x)(4) – Assistance to Compensate a Nonphysician Practitioner** | (4) For purposes of paragraphs (x)(1)(ii)(B) and (x)(1)(iii)(B)(2) of this section, "referral" means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the nonphysician practitioner. | (4) For purposes of this paragraph (x), the following terms have the meanings indicated.<br><br>(i) "NPP patient care services" means direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement.<br><br>(ii) "NPP referral" means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include | To clarify the meaning of "patient care services" for purposes of the exception for assistance to compensate an NPP, CMS is proposing to revise §411.357(x) to change the references to "patient care services" to "NPP patient care services" and include a definition of the term "NPP patient care services" in the exception at §411.357(x)(4)(i). In addition, CMS is proposing to revise §411.357(x) to change references to "referral" when describing the actions of an NPP to "NPP referral" and revise §411.357(x)(4) accordingly. As a result, CMS is proposing to move the definition of "NPP referral" to §411.357(x)(4)(ii) in order to |

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| | | any designated health service personally performed or provided by the nonphysician practitioner. | accommodate the inclusion of the related definition of "NPP patient care services" within section §411.357(x)(4). |
| **§ 411.357(x)(7)(ii) – Assistance to Compensate a Nonphysician Practitioner** | (ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide patient care services if - | (ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide NPP patient care services if - | CMS proposes to change "Patient care services" to "NPP patient care services." |
| **§ 411.357(x)(7)(ii)(A) – Assistance to Compensate a Nonphysician Practitioner** | (A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and | (A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide NPP patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and | CMS proposes to change "Patient care services" to "NPP patient care services." |
| **§ 411.357(y)(6)(i) – Timeshare Arrangements** | (i) In a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; or | (i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or | CMS proposes to specify that the arrangement is not determined in <u>any</u> manner that takes into account the volume or value of referrals or other business generated between the parties. |
| **§ 411.357(y)(8) – Timeshare Arrangements** | (8) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission. | [Reserved] | CMS proposes to remove and reserve this section. |
| **§ 411.357(z)** | *N/A* | (z) *Limited remuneration to a physician*—(1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of $3,500 per calendar year, as adjusted for inflation in accordance with paragraph (z)(2) of this section, if all of the following conditions are satisfied: | CMS proposes a new exception for limited remuneration to a physician. |

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| | | (i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.<br><br>(ii) The compensation does not exceed the fair market value of the items or services.<br><br>(iii) The arrangement is commercially reasonable.<br><br>(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—<br><br>(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or<br><br>(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.<br><br>(v) Compensation for the use of premises, equipment, personnel, items, supplies, or services is not determined using a formula based on—<br><br>(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or | |

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| | | (B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.<br><br>(2) The annual remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new remuneration limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp. | |
| **§ 411.357(aa)** | *N/A* | (aa) *Arrangements that facilitate value-based health care delivery and payment.*<br><br>(1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met:<br><br>(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 6 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.<br><br>(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. | CMS proposes to create three new exceptions that would protect arrangements that facilitate value-based health care delivery and payment: (i) the full financial risk exception, (ii) the meaningful downside financial risk exception, and (iii) the value-based arrangement exception. |

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| | | (iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.<br><br>(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.<br><br>(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).<br><br>(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.<br><br>(vii) For purposes of this paragraph (aa), "full financial risk" means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), "prospective basis" means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.<br><br>(2) *Value-based arrangements with meaningful downside financial risk to the physician*— Remuneration paid under a value-based | |

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| | | arrangement, as defined in §411.351, if the following conditions are met:<br><br>(i) The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.<br><br>(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing.<br><br>(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.<br><br>(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.<br><br>(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.<br><br>(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.<br><br>(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv). | |

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| | | (viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.<br><br>(ix) For purposes of this paragraph (aa), "meaningful downside financial risk" means that the physician—<br><br>(A) Is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or<br><br>(B) Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.<br><br>(3) *Value-based arrangements*—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met:<br><br>(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—<br><br>(A) The value-based activities to be undertaken under the arrangement;<br><br>(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; | |

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| | | (C) The target patient population for the arrangement;<br><br>(D) The type or nature of the remuneration;<br><br>(E) The methodology used to determine the remuneration; and<br><br>(F) The performance or quality standards against which the recipient will be measured, if any.<br><br>(ii) The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.<br><br>(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.<br><br>(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.<br><br>(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.<br><br>(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.<br><br>(vii) If the remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the | |

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| | | value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).<br><br>(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request. | |
| **§ 411.357(bb)** | *N/A* | (bb) *Cybersecurity technology and related services*—(1) Nonmonetary remuneration (consisting of certain types of technology and services), if all of the following conditions are met:<br><br>(i) The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.<br><br>(ii) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.<br><br>(iii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.<br><br>(iv) The arrangement is documented in writing.<br><br>(2) For purposes of this paragraph (bb), "technology" means any software or other types of information technology other than hardware. | CMS is proposing a new exception specifically to protect arrangements involving the donation of cybersecurity technology and related services. |

* Note that sections §411.362, §411.372, and §411.384 were each amended by removing each instance of the term "web site" and adding in its place each time the word "website."

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