Stark Law Regulations
Comparison Chart of the Current Regulations, Proposed Regulations, and Final Amended Regulations, effective January 19, 2021

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Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
		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.	*Commercially reasonable* means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.	CMS added a definition for "Commercially reasonable," with minimal changes from the Proposed Regulation.
§ 411.351 – Cybersecurity	*N/A*	*Cybersecurity* means the process of protecting information by preventing, detecting, and responding to cyberattacks.	*Cybersecurity* means the process of protecting information by preventing, detecting, and responding to cyberattacks.	CMS added 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	(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	(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 paid 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 under 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 increase the amount of Medicare's payment to the	CMS revised 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).

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	services or inpatient and outpa tient hospital services are DHS).	Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS).	hospital under any of the following prospective payment systems (PPS): (1) Acute Care Hospital Inpatient (IPPS); (2) Inpatient Rehabilitation Facility (IRF PPS); (3) Inpatient Psychiatric Facility (IPF PPS); (4) or (iv) Long-Term Care Hospital (LTCH PPS).	
§ 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— (1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at §1001.952 of this title, "Exceptions"; (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	Deleted	*Does not violate the anti-kickback statute*, as used in this subpart only, means that the particular arrangement— (1)(i) Meets a safe harbor under the anti-kickback statute, as set forth at §1001.952 of this title, "Exceptions"; (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 (iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act. (2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that—	CMS did not delete the definition of "Does not violate the anti-kickback statute" in the Final Regulations.

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	this title, "Advisory Opinions by the OIG"; or (iii) Does not violate the anti-kickback provisions in section 1128B(b) of the Act. (2) For purposes of this definition, a favorable advisory opinion means an opinion in which the OIG opines that— (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 (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.		(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 (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— (1) Is transmitted by or maintained in electronic media; and	*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.	CMS did not revise the definition of "electronic health record" in the Final Regulations.

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		(2) Relates to the past, present, or future health or condition of an individual or the provision of health care to an individual.		
§ 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	*Fair market value* means— (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. (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. (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.	*Fair market value* means— (1) *General*. The value in an arm's-length transaction, consistent with the general market value of the subject transaction. (2) *Rental of equipment*. With respect to the rental of equipment, the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction. (3) *Rental of office space*. With respect to the rental of office space, the value in an arm's-length transaction 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 modified 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. There were minimal changes from the language in the Proposed Regulations.

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	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.			

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§ 411.351 – General market value	Incorporated into definition of "fair market value."	*General market value* means— (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. (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.	*General market value* means— (1) Assets. With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other. (2) Compensation. With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other. (3) Rental of equipment or office space. With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.	CMS established a definition of "general market value" to better reflect the belief that general market value of a transaction is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another. In the Final Rule, CMS retracted its statements equating "general market value," as that term appears in the statute and regulations, with "market value," the term identified as uniformly used in the valuation industry. Also, CMS eliminated the volume or value standard from the definition as presented in the existing regulations.
§ 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	*Interoperable* means— (1) Able to securely exchange data with and use data from other health information technology without special effort on the part of the user;	*Interoperable* means— (1) Able to securely exchange data with and use data from other health information technology; and (2) Allows for complete access, exchange, and use of all electronically accessible health information for	CMS revised the definition of "interoperable" but omitted the reference to "information blocking" based on the belief that "newer and separate authorities are better suited than the EHR exception to deter information blocking

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	data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.	(2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (3) Does not constitute information blocking as defined in section 3022 of the Public Health Service Act.	authorized use under applicable State or Federal law.	and hold individuals and entities that engage in information blocking appropriately accountable."
§ 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— (i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and (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. (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).	*Isolated financial transaction*—(1) Isolated financial transaction means a one-time transaction involving a single payment between two or more persons or a one-time transaction that involves integrally related installment payments, provided that— (i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and (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. (2) An isolated financial transaction includes a one-time sale of property or a practice, single instance of forgiveness of an amount owed in settlement of a bona fide dispute, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as payment for services previously provided but not yet compensated).	CMS established a definition of "isolated financial transaction" that is independent of the definition of "transaction" and clarified that an "isolated financial transaction" does not include payment for multiple services provided over an extended period, even if there is only one payment for such services.

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§ 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.	*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 revised 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—* (1) Means either of the following: (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	The following paragraph is added: (4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.	The following paragraph is added: (4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.	CMS added a new paragraph (4) to the definition of "Referral" to explicitly state 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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	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. (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,			

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	independent contractors, or group practice members. (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— (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 (ii) The tests or services are furnished by or under the supervision of the pathologist, radiologist, or 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.			

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	(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: (1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors. (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: (i) Collecting specimens for the entity furnishing the items, devices or supplies; (ii) Transporting specimens for the entity furnishing the items, devices or supplies; (iii) Processing specimens for the entity furnishing the items, devices or supplies;	(2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes: (3) (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.	*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: (1) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors. (2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes: (i)Collecting specimens for the entity furnishing the items, devices or supplies; (ii) Transporting specimens for the entity furnishing the items, devices or supplies; (iii) Processing specimens for the entity furnishing the items, devices or supplies; (iv) Storing specimens for the entity furnishing the items, devices or supplies; (v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or	CMS finalized their proposed changes to paragraph (2) 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 in paragraph (3) (iii) to remove the modifier "directly or indirectly" in connection with the volume or value standard.

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	(iv) Storing specimens for the entity furnishing the items, devices or supplies; (v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or (vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies. (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— (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;		(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies. (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— (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; (ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and (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 referrals.	

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	(ii) The payment is made to the physician on behalf of the covered individual and would otherwise be made directly to the individual; and (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— (1) Are set out in writing in advance of the commencement of the value-based arrangement; and (2) Further the value-based enterprise's value-based purpose(s).	*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— (1) Are set out in writing in advance of the commencement of the value-based arrangement; and (2) Further the value-based enterprise's value-based purpose(s).	CMS added the definition of "target patient population" that is used in connection with the value based arrangement exceptions to the Stark Law.
§ 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	*Transaction* means an instance or process of two or more persons or entities doing business.	*Transaction* means an instance of two or more persons or entities doing business.	CMS removed the reference to an "isolated financial transaction" from the definition of "transaction" in the Final Regulations.

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	a transaction that involves integrally related installment payments provided that – (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 (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.			
§ 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: (i) The provision of an item or service; (ii) The taking of an action; or (iii) The refraining from taking an action.	*Value-based activity* 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: (1) The provision of an item or service; (2) The taking of an action; or (3) The refraining from taking an action.	CMS added a definition of "value-based activity" that is used in connection with the value based arrangement exceptions to the Stark Law, with minimal changes from the Proposed Regulation.

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		(2) The making of a referral is not a value-based activity.		
§ 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— (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.	*Value-based arrangement* means an arrangement for the provision of at least one value-based activity for a target patient population to which the only parties are— (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.	CMS added a definition of "value-based arrangement" that is used in connection with the value based arrangement exceptions to the Stark Law.
§ 411.351 – Value-Based Enterprise	*N/A*	*Value-based enterprise* (VBE) means two or more VBE participants— (1) Collaborating to achieve at least one value-based purpose; (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; (3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (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).	*Value-based enterprise* (VBE) means two or more VBE participants— (1) Collaborating to achieve at least one value-based purpose; (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; (3) That have an accountable body or person responsible for the financial and operational oversight of the value-based enterprise; and (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 added a definition of "value-based enterprise" that is used in connection with the value based arrangement exceptions to the Stark Law.
§ 411.351 – Value-	*N/A*	*Value-based purpose* means— (1) Coordinating and managing the care of a target patient population;	*Value-based purpose* means any of the following:	CMS added a definition of "value-based purpose" that is used in connection with the

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Based Purpose		(2) Improving the quality of care for a target patient population; (3) Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or (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 control of costs of care for a target patient population.	(1) Coordinating and managing the care of a target patient population; (2) Improving the quality of care for a target patient population; (3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a target patient population; or (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 control of costs of care for a target patient population.	value based arrangement exceptions to the Stark Law.
§ 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.	*VBE participant* means a person or entity that engages in at least one value-based activity as part of a value-based enterprise.	CMS added a 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	(1) *Overall profits.* (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. (ii) Overall profits means the profits derived from all the designated health services of any component of the group	*(1) Overall profits.* (i)Notwithstanding paragraph (g) of this section, a physician in the group may be paid a share of overall profits that is not directly related to the volume or value of the physician's referrals. (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,	CMS made clarifying revisions regarding a physician group's distributions of overall profits to its group physicians. [These revisions are effective 1/1/2022]

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	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). (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:	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. (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: (A) Overall profits are divided *per capita* (for example, per member of the group or per physician in the group). (B) Overall profits derived from designated health services are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare. (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.	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. (iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to directly relate to the volume or value of referrals if one of the following conditions is met: (A) Overall profits are divided per capita (for example, per member of the group or per physician in the group). (B) Overall profits are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare. (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.	

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
	(i) The group's profits are divided per capita (for example, per member of the group or per physician in the group). (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. (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.			
§ 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:	(2) *Productivity bonuses.* (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	*(2) Productivity bonuses*. (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 not directly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or	CMS has renumbered the regulation that lists the provisions related to the payment of productivity bonuses from §411.352(i)(3) to §411.352(i)(2), and has made clarifying changes.. [These revisions are effective 1/1/2022]

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
	(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.) (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. (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 percent or less of his or her total compensation from the group practice.	volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services). (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: (A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician. (The methodology for establishing RVUs is set forth in §414.22 of this chapter.) (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. (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.	value of the physician's referrals if the referrals are for services "incident to" the physician's personally performed services). (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: (A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician. (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. (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)(3) – Special Rules for Profit Shares	*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	*(3) Value-based enterprise participation.* Notwithstanding paragraph (g) of this section, profits from designated health	CMS added a new §411.352(i)(3) to address downstream compensation that derives from payments

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
and Productivity Bonuses – Value-Based Enterprise Participation		enterprise, as defined in §411.351, are distributed to the participating physician.	services that are directly attributable to a physician's participation in a value-based enterprise, as defined at §411.351, may be distributed to the participating physician.	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. [These revisions are effective 1/1/2022]
§ 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.	*(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 made a clarifying edit to reference the new section. [These revisions are effective 1/1/2022]
	Prohibition on Certain Referrals by Physicians and Limitations on Billing			
§ 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	(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.	(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 deleted the provisions setting forth the "period of disallowance" (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

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	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 – (i) Where the noncompliance is unrelated to compensation, the date that the financial relationship satisfies all of the requirements of an applicable exception; (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 (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			between the parties failed to satisfy the requirements of any applicable exception), but stress in the final rule that it does not affect the billing and referral prohibitions at §411.353(a) and (b).

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	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.			
§ 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 relationship became noncompliant with the exception; and	(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; and	CMS proposes to remove ";" and add in its place "; and" (these changes are made because § 411.353(f)(1)(iii) was deleted).
§ 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.	(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. (2) Paragraph (f)(1) of this section applies only to DHS furnished during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days following the date on which the financial relationship became noncompliant with an exception. (3) Paragraph (f)(1) may be used by an entity only once every 3 years with respect to the same referring physician. (4) Paragraph (f)(1) does not apply if the exception with which the financial relationship	CMS proposes to remove "; and" and add in its place a period (these changes are made because § 411.353(f)(1)(iii) was deleted).

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			previously complied was §411.357(k) or (m).	
§ 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*	*N/A*	In an effort to decouple the Stark Law from the AKS, CMS removed 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.* (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 – (i) The compensation arrangement bet ween 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	*N/A*	[Reserved]	CMS removed and reserved this section.

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	(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement be came noncompliant and the compensation arrangement oth erwise complies with all criteria of the applicable exception. (2) [Reserved]			
§ 411.353(h) – Special Rule for Reconciling Compensation	*N/A*	*N/A*	(h) *Special rule for reconciling compensation.* 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— (1) No later than 90 consecutive calendar days following the expiration or termination of a compensation arrangement, the entity and the physician (or immediate family member of a physician) that are parties to the compensation arrangement reconcile all discrepancies in payments under the arrangement such that, following the reconciliation, the entire amount of remuneration for items or services has been paid as required under the terms and conditions of the arrangement; and (2) Except for the discrepancies in payments described in paragraph (h)(1) of this section, the compensation arrangement	CMS added a special rule for reconciling compensation relating to payment discrepancies, to confirm CMS's policy view.

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			fully complies with an applicable exception in this subpart.	
	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);	(iii) 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 ";" (these changes are made because §411.353(f)(1)(iii) was deleted)
§ 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);	(iv) 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	(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	CMS added §411.354(b)(3)(vi), to exclude titular ownership or investment interests from "ownership and investment interests" that create a financial relationship with an entity that furnishes DHS.

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
§ 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).	(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).	CMS added §411.354(b)(3)(vii), to exclude ESOP ownership from "ownership and investment interests" that create a financial relationship with an entity that furnishes DHS.
§ 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 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	(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 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	(ii)(A) 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 the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS and the individual unit of compensation received by the physician (or immediate family member)— (1) Is not fair market value for items or services actually provided; (2) Includes the physician's referrals to the entity furnishing DHS 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 (3) Includes other business generated by the physician for the entity furnishing DHS as a variable, resulting in an increase or decrease in the physician's (or	CMS revised this section relating to whether an "indirect compensation arrangement" exists.

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
	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 wit h company C, which has a compensation arrangement wit h 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 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));	immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity. (B) For purposes of applying paragraph (c)(2)(ii)(A) of this section, 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. (C) 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 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 non-ownership 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)).	

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
§ 411.354(c)(4) – Compensation Arrangement – Exceptions Applicable to Indirect Compensation Arrangements	*N/A*	(4) *Exceptions applicable to indirect compensation arrangements.* (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. (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 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.	(4)(i) *Exceptions applicable to indirect compensation arrangements–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. *(D) Special rule for indirect compensation arrangements involving a MCO or IPA and a referring physician*. Only the exceptions at §§411.355, 411.357(n), and 411.357(p) are applicable in the case of an indirect compensation arrangement in which the entity furnishing DHS described in paragraph (c)(2)(i) of this section is a MCO or IPA. *(iii) 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 at §411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party— 1) Only the exceptions at §§411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the	CMS added language clarifying which exceptions are applicable to indirect compensation arrangements.

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
			entity furnishing DHS is not a MCO or IPA; and 2) Only the exceptions at §§411.355, 411.357(n), 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement if the entity furnishing DHS is a MCO or IPA.	
§ 411.354(d)(1) – Special Rules on Compensation	(1) Compensation is considered "set in advance" if the aggregate compensation, a time based or per unit of service based (whether per use or per service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the arrangement in any many that takes into account the volume or value of referrals or other business generated by the referring physicians.	*N/A*	(1) Set in advance. (i) Compensation is deemed to be "set in advance" if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified. (ii) Notwithstanding paragraph (d)(1)(i) of this section, compensation (or a formula for determining the compensation) may be modified at any time during the course of a compensation arrangement and satisfy the requirement that it is "set in advance" if all of the following conditions are met: (A) All requirements of an applicable exception in §§411.355 through 411.357 are met on the effective date of the	CMS clarified what it means for compensation to be "set in advance" and sets forth additional details regarding changes to compensation during the course of a compensation arrangement continue to satisfy the "set in advance" requirement.

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
			modified compensation (or the formula for determining the modified compensation). (B) The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid. (C) Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified. Paragraph (e)(4) of this section does not apply for purposes of this paragraph (d)(1)(ii)(C).	
§ 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.	(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 of designated health services. This paragraph (d)(2) does not apply for purposes of paragraphs (d)(5)(i) and (6)(i) of this section.	CMS declined to remove the reference to designated health services, but carves out specific circumstances in which this paragraph does not apply.

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
§ 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).	(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 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). This paragraph (d)(3) does not apply for purposes of paragraphs (d)(5)(ii) and (d)(6)(ii) of this section.	CMS clarified 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 other business generated by the referring physician 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 me ets all of the following	(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. (i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for	(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. (i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for	CMS revised §411.354(d)(4) to eliminate certain language regarding: (1) whether the "set in advance" and "fair market value" conditions of the special rule apply to the compensation arrangement (as stated in the regulation) or to the compensation itself; and (2) when compensation is considered fair market value. CMS clarified that the physician's compensation

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	conditions. The compensation arrangement: (i) Is set in advance for the term of the arrangement. (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). (iii) Otherwise complies with an applicable exception under § 411.355 or § 411.357. (iv) Complies with both of the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties. (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,	determining the compensation) must be made prospectively. (ii) The compensation is consistent with the fair market value of the physician's services. (iii) The compensation arrangement otherwise complies with an applicable exception at §§411.355 or 411.357. (iv) The compensation arrangement complies with both of the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties. (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. (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	determining the compensation) must be made prospectively. (ii) The compensation is consistent with the fair market value of the physician's services. (iii) The compensation arrangement otherwise satisfies the requirements of an applicable exception at § 411.355 or § 411.357. (iv) The compensation arrangement complies with both of the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties. (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. (v) The required referrals relate solely to the physician's services covered by the scope of the employment personal	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 clarified that the physician's compensation must be consistent with the fair market value of the services performed. In addition, CMS eliminated certain parenthetical language as it conflates the concept of fair market value and the volume or value standard. CMS also clarified that the requirement to make referrals may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.

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	practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. (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.	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, personal service arrangement, or managed care contract.	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 employment, personal service arrangement, or managed care contract. (vi) Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician as set forth at paragraph (d)(5)(i) of this section, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier. The requirement to make referrals to a particular provider, practitioner, or supplier may require that the physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner, or supplier.	
§ 411.354(d)(5) – Special Rules on Compensation	*N/A*	(5) (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—	(5) (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 the formula used to calculate the	CMS created a bright-line rule for determining whether compensation takes into account the volume or value of referrals or take into account other business

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		(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 (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. (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— (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 physician's generation of other business for the entity; or	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. (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 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 physician's generation of other business for the entity. (E) 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. (iv) This paragraph (d)(5) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this	generated between the parties. 411.354(d)(5) addresses situations involving compensation from an entity furnishing DHS to a physician. The final rule did not include references to a "predetermined, direct correlation" between physician referrals and prospective rate of compensation to be paid over the course of the arrangement.

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		(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. (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. (iv) This paragraph (d)(5) applies only to section 1877 of the Act.	section or the exceptions at §411.357(m), (s), (u), (v), (w), and (bb).	
§ 411.354(d)(6) – Special Rules on Compensation	*N/A*	(6) (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— (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 (B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective	(6) (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 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. (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	CMS created 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. The final rule did not include references to a "predetermined, direct correlation" between physician referrals and prospective rate of compensation to be paid over

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
		rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined. (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— (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 (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. (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.	business generated only if 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. (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. (iv) This paragraph (d)(6) does not apply for purposes of applying the special rules in paragraphs (d)(2) and (3) of this section or the exceptions at §411.357(m), (s), (u), (v), (w), and (bb).	the course of the arrangement.

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		(iv) This paragraph (d)(6) applies only to section 1877 of the Act.		
§ 411.354(e) – Special Rule on Compensation Arrangements – Special Rule on Writing and Signature Requirements	*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— (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 (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.	(3) *Signature Requirement.* In the case of any signature requirement in this subpart, such requirement may be satisfied by an electronic or other signature that is valid under applicable Federal or State law. *(4) 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— (i) The compensation arrangement between the entity and the physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and (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 (that is, the date on which the writing(s) or signature(s) were required under the applicable exception but the parties had not yet obtained them).	CMS added a special rule outlining circumstances in which compliance with the writing and signature requirements may be achieved.

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	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]	[Reserved]	CMS removed and reserved 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.	(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 referenced designated health services furnished 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)(iii)(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.	(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 specified 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)(iii)(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).	(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 conditions of §411.354(d)(4).	CMS added compliance with the directed referral requirements at §411.354(d)(4) compliance in connection with this exception.

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
§ 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]	Removed from text altogether	CMS removed and reserved 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]	[Reserved]	CMS removed and reserved 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]	[Reserved]	CMS removed and reserved 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]	[Reserved]	CMS removed and reserved 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]	[Reserved]	CMS removed and reserved this section.
§ 411.355(h)(2)	(2) The arrangement for the provision of the preventive screening tests,	[Reserved]	[Reserved]	CMS removed and reserved this section.

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– Preventative Screening Tests, Immunizations, and Vaccines	immunizations, and vaccines does not violate the anti-kickback statute (section 1128B(b) of the Act).			
§ 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]	[Reserved]	CMS removed and reserved this section.
§ 411.355(i)(2) – Eyeglasses and Contact Lenses Following Cataract Surgery	(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]	[Reserved]	CMS removed and reserved this section.
§ 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]	Removed from text altogether	CMS removed this section.
§ 411.355(j)(1)(i	(iv) The financial relationship does not violate the anti-kickback	[Reserved]	Removed from text altogether	CMS removed this section.

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v) – Intra-Family Rural Referrals	statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.			
	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.	CMS proposed to add at the end of paragraph (3): 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 added to the end of paragraph (3): 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 clarified 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	(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or	CMS specified that the arrangement is not determined in <u>any</u> manner that takes into account the volume or value of referrals

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				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).	CMS proposed to add at the end of paragraph (2): 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.	(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 clarified 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	(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.	(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 specified 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)–	*N/A*	(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or	(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or	CMS added compliance with the directed referral requirements at

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Bona Fide Employment Relationships		supplier, the arrangement satisfies the requirements of §411.354(d)(4).	supplier, the arrangement satisfies the conditions of §411.354(d)(4).	§411.354(d)(4) compliance in connection with this exception.
§ 411.357(d)(1)(v) – Personal Service Arrangements - General	(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 § 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.	(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 §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.	(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 §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.	CMS specified 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(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).	(viii) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).	CMS added compliance with the directed referral requirements at §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	(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:	(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 moved the reference to "any" and removed the reference to "directly or indirectly."

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	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:			
§ 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).	(iv) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).	CMS required §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	(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 <u>any</u> manner that takes into account the volume or value of referrals or other business generated between the parties. CMS removed the reference to "directly or indirectly."
§ 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.	(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 modified the signature requirement such that the writing only needs to be 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

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				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.	(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 specified that payment is not determined in <u>any</u> manner that takes into account the volume or value of referrals. CMS removed the reference to "directly or indirectly."
§ 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*	*N/A*	In an effort to decouple the Stark Law from the AKS, CMS removed 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	(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.	(6)(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 decoupled 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."

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	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 - (i) Consistent with the fair market value of the transaction; and (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.	(1) The amount of remuneration under the isolated financial transaction is— (i) Consistent with the fair market value of the isolated financial transaction; and (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.	(1) The amount of remuneration under the isolated financial transaction is— (i) Consistent with the fair market value of the isolated financial transaction; and (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.	CMS specifies that payment under an isolated financial transaction may not be 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(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.	(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 the volume or value of referrals or other business generated by the referring physician.	CMS removed the reference to "isolated transaction" and replace with "isolated financial transaction" and removed the reference to "(directly or indirectly)."

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§ 411.357(f)(4) – Isolated Transactions	N/A		(4) An isolated financial transaction that is an instance of forgiveness of an amount owed in settlements of a bona fide dispute is not part of the compensation arrangement giving rise to the bona fide dispute.	CMS clarified when an instance of forgiveness is an "isolated financial transaction" and not part of the compensation arrangement.
§ 411.357(g) – Certain Arrangements With Hospitals	(g) *Certain arrangements with hospitals.* Remuneration provi ded 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 mus t 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 – (1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid unde r cost reporting principles; (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	(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— (1) The remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals; and (2) The remuneration is for an item or service that is not related to the provision of patient care services. (3) For purposes of this this paragraph (g): (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.	(g) *Certain arrangements with hospitals.* Remuneration provided by a hospital to 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— (1) Is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles; (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 (3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.	CMS declined to make the proposed changes.

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	position to make or influence referrals; or (3) Otherwise takes into account the volume or value of referrals or other business generated by the referring physician.	(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.	(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 specified 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).	(7) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4).	CMS required §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	(2) To an entity as compensation for any other items or services— (i) That are furnished at a price that is consistent with fair market value; and (ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.	(2) To an entity as compensation for any other items or services— (i) That are furnished at a price that is consistent with fair market value; and (ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.	CMS removed 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 finalized language clarifying that the exception at §411.357(i) would not be

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	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).			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).	(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 defined "services" as it is 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]	Removed.	In an effort to decouple the Stark Law from the AKS, CMS removed this section.
§ 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*	Removed.	CMS removed 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	(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	(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	CMS updated the terminology to replace "Web site" with "website."

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	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.	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.	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.	
§ 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:	(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: (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. (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	(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 lease of office space or equipment 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: (1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment. The writing specifies— (i) The items, services, office space, or equipment covered under the arrangement;	CMS expanded the fair market value compensation exception to protect arrangements for the rental or lease of office space. CMS also requires complianc with §411.354(d)(4) as part of the exception. Further, CMS removed requirements that the arrangement not violate any Federal or State law or regulation governing billing or claims submission, but continues to require the arrangement not violate the AKS.

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	(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing. (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 of times if the terms of the arrangement and the compensation for the same items or services do not change. (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	during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change. (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— (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 (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. (4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction).	(ii) The compensation that will be provided under the arrangement; and (iii) The timeframe for the arrangement. (2) An arrangement may be for any period of time and contain a termination clause. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change. Other than an arrangement that satisfies all of the conditions of paragraph (z) of this section, the parties may not enter into more than one arrangement for the same items, services, office space, or equipment during the course of a year. (3) 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— (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 (ii) Per-unit of service rental charges, to the extent that such charges reflect services	

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	equipment may not be determined using a formula based on – (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 (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. (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. (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. (6) The services to be performed under	(5) [Reserved] (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. (7) The arrangement satisfies the requirements of §411.354(d)(4) in the case of— (i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or (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.	provided to patients referred by the lessor to the lessee. (4) The arrangement would be commercially reasonable even if no referrals were made between the parties. (5) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act). (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. (7) The arrangement satisfies the requirements of §411.354(d)(4) in the case of— (i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or (ii) Remuneration paid to the group of physicians that is conditioned on one or more of the group's physicians' referrals to a particular provider, practitioner, or supplier.	

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	the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.			
§ 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.	(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 specified 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.	(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 updated the terminology to replace "Web site" with "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	(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	(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	CMS updated the terminology to replace "Web site" with "website."

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	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).	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).	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).	
§ 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 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/Ph	(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 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.	(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 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.	CMS updated the terminology to replace "Web site" with "website."

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	ysicianSelfReferral/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]	[Reserved]	CMS removed the requirements that the compensation arrangement not violate the AKS or any Federal or State law or regulation governing billing or claims submission.
§ 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.	(n) Risk-sharing arrangements. Compensation paid directly or indirectly by a MCO or an IPA to a physician pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) for services provided by the physician 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 removed 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	(3) The compensation arrangement does not violate the anti-	*N/A*	[Reserved]	In an effort to decouple the Stark Law from the AKS,

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Compensation Arrangements	kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.			CMS removed this requirement.
§ 411.357(p)(4) – Indirect Compensation Arrangements	N/A		(4) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the compensation arrangement described in §411.354(c)(2)(ii) satisfies the conditions of §411.354(d)(4).	CMS clarified that indirect compensation arrangements must comply with §411.354(d)(4).
§ 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 the physician or any other business generated between the parties.	(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 referrals by the physician or other business generated between the parties.	(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 referrals by the physician or any other business generated between the parties.	CMS proposes to specified that payment is not determined in <u>any</u> manner that takes into account the volume or value of referrals by the physician or 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*	Removed.	In an effort to decouple the Stark Law from the AKS, CMS removed 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	[Reserved]	Removed.	In an effort to decouple the Stark Law from the AKS, CMS removed this section.

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	governing billing or claims submission.			
§ 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*	Removed.	In an effort to decouple the Stark Law from the AKS. CMS removed 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]	Removed.	In an effort to decouple the Stark Law from the AKS. CMS removed 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:	(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 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 clarified that donations of certain cybersecurity software and services are permitted under the EHR exception.
§ 411.357(w)(2) – Electronic Health	(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	(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	(2) The software is interoperable (as defined at §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	CMS updated provisions in the EHR exception pertaining to interoperability.

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Records Items and Services	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 identified in the then-applicable version of 45 CFR part 170.	by a certifying body authorized by the National Coordinator for Health Information Technology to electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.	a certifying body authorized by the National Coordinator for Health Information Technology to certification criteria 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.	[Reserved]	CMS removed and reserved the provision limiting the donor from restricting interoperability.
§ 411.357(w)(4) – Electronic Health Records Items and Services	(4) Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.	(4) Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.	4)(i) Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor's cost for the items and services. (ii) Except as provided in paragraph (w)(4)(i) of this section, with respect to items and services received from the donor after the initial donation of items and services or the donation of replacement	CMS added requirements related to the contribution requirement of the exception.

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			items and services, the physician pays 15 percent of the donor's cost for the items and services at reasonable intervals. (iii) The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and 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:	(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 specified 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)(8)	The donor does not have actual knowledge of and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses of has obtained items or services equivalent to those provided by the donor.	Reserved	Reserved	CMS removed and reserved this section.
§ 411.357(w)(11) – Electronic	(11) [Reserved]	Deleted	Deleted	CMS removed this section.

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Health Records Items and Services				
§ 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.	Deleted	Deleted	In an effort to decouple the Stark Law from the AKS. CMS removed 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.	Deleted	Deleted	CMS removed this section.
§ 411.357(x)(1) – Assistance to Compensate a Nonphysician Practitioner	(1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide patient care services, if all of the following conditions are met: (i) The arrangement is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner. (ii) The arrangement is not conditioned on – (A) The physician's referrals t o the hospital; or	(1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services, if all of the following conditions are met: (i) The arrangement— (A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; and (B) Commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation arrangement	(1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services, if all of the following conditions are met: (i) The arrangement— (A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practioner; and (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.	CMS replaced the term "practiced" with "furnished NPP patient care 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

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	(B) The nonphysician practitioner's referrals to the hospital. (iii) The remuneration from the hospital – (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 bet ween the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and (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 – (1) The physician (or any physician in the physician's practice) or other business generated between the parties; or	described in paragraph (x)(1)(vi)(A) of this section. (ii) The arrangement is not conditioned on— (A) The physician's referrals to the hospital; or (B) The nonphysician practitioner's NPP referrals to the hospital. (iii) The remuneration from the hospital— 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 (B) Is not determined in any manner that takes into account the volume or value of actual or anticipated— (1) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or (2) NPP referrals by the nonphysician practitioner (or any nonphysician	(ii) The arrangement is not conditioned on— (A) The physician's referrals to the hospital; or (B) The nonphysician practitioner's NPP referrals to the hospital. (iii) The remuneration from the hospital— (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 (B) Is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by— (1) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or (2) NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.	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. Further, in an effort to decouple the Stark Law from the AKS, CMS removed 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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	(2) The nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties. (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. (v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement wit h the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) – (A) Practiced in the geographic area served by the hospital; or (B) Been employed or otherwise engaged to	practitioner in the physician's practice) or other business generated between the parties. (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. (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))— (A)Furnished NPP patient care services in the geographic area served by the hospital; or (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. (vi)	(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. (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))— (A) Furnished NPP patient care services in the geographic area served by the hospital; or (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. (vi) (A) The nonphysician practitioner has a compensation arrangement directly with the physician or the physician organization	

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	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. (vi) (A) The nonphysician practitioner has a compensation arrangement dir ectly with the physician or the physician organization in whose shoes the physician stands under § 411.354(c); and (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. (vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the	(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 (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. (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. ( ) [Reserved]	in whose shoes the physician stands under §411.354(c); and (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. (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.	

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	nonphysician practitioner's ability to provide patient care services in the geographic area served by the hospital. (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.			
§ 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. (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. (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	(4) For purposes of this paragraph (x), the following terms have the meanings indicated. (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. (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	To clarify the meaning of "patient care services" for purposes of the exception for assistance to compensate an NPP, CMS revised §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 revised §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 moved the definition of "NPP referral" to §411.357(x)(4)(ii) in order to

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		certifying or recertifying of the need for such a designated health service, but does not include any designated health service personally performed or provided by the nonphysician practitioner.	health service, or the certifying or recertifying of the need for such a designated health service, but does not include 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 -	(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 changed "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	(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 changed "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	(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or	CMS specified 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.

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§ 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]	[Reserved]	CMS removed and reserved this section.
§ 411.357(z) – Limited Remuneration to a Physician	*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: (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. (ii) The compensation does not exceed the fair market value of the items or services. (iii) The arrangement is commercially reasonable. (iv) Compensation for the lease of office space or equipment is not determined using a formula based on— (A) A percentage of the revenue raised, earned, billed, collected, or otherwise	(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 $5,000 per calendar year, as adjusted for inflation in accordance with paragraph (z)(3) of this section, if all of the following conditions are satisfied: (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. (ii) The compensation does not exceed the fair market value of the items or services. (iii) The arrangement would be commercially reasonable even if no referrals were made between the parties. (iv) Compensation for the lease of office space or equipment is not determined using a formula based on— (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	CMS added a new exception for limited remuneration to a physician.

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		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 (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. (v) Compensation for the use of premises, equipment, personnel, items, supplies, or services is not determined using a formula based on— (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 (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. (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—	the services performed on or business generated through the use of the equipment; or (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. (v) Compensation for the use of premises or equipment is not determined using a formula based on— (A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises or equipment covered by the arrangement; or (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 or equipment covered by the arrangement to the party to which the permission is granted. (vi) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the conditions of §411.354(d)(4). (2) A physician may provide items or services through employees whom the physician has hired for the purpose of	

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		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.	performing the services; through a wholly-owned entity; or through locum tenens physicians (as defined at §411.351, except that the regular physician need not be a member of a group practice). (3) The annual aggregate 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)(1) – Full Financial Risk	*N/A*	(aa) *Arrangements that facilitate value-based health care delivery and payment.* (1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met: (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.	(aa) *Arrangements that facilitate value-based health care delivery and payment—* (1) Full financial risk—Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met: (i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 12 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.	CMS created a new exception to protect arrangements that facilitate value-based health care delivery and payment when a value-based enterprise is at full financial risk.

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		(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. (iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. (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. (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). (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. (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	(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. (iii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. (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. (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 complies with both of the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties. (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.	

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		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.	(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. (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.	
§ 411.357(aa)(2) - Value-based arrangements with meaningful downside financial risk to the physician	*N/A*	(2) *Value-based arrangements with meaningful downside financial risk to the physician*—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met: (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.	(2) *Value-based arrangements with meaningful downside financial risk to the physician*—Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met: (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.	CMS created a new exception to protect arrangements that facilitate value-based health care delivery and payment when a value-based enterprise is at full financial risk when the physician is at meaningful downside financial risk exception.

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
		(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing. (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. (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. (v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. (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. (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). (viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a	(ii) A description of the nature and extent of the physician's downside financial risk is set forth in writing. (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. (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. (v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. (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. (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 complies with both of the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.	

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
		period of at least 6 years and made available to the Secretary upon request. (ix) For purposes of this paragraph (aa), "meaningful downside financial risk" means that the physician— (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 (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.	(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. (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. (ix) For purposes of this paragraph (aa), "meaningful downside financial risk" means that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement.	
§ 411.357(aa)(3) - Value-based arrangements	*N/A*	(3) *Value-based arrangements*—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met: (i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—	(3) *Value-based arrangements.* Remuneration paid under a value-based arrangement, as defined at §411.351, if the following conditions are met: (i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—	CMS created a new exception to protect arrangements that facilitate value-based health care delivery and payment regardless of the amount of financial risk assumed.

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
		(A) The value-based activities to be undertaken under the arrangement; (B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; (C) The target patient population for the arrangement; (D) The type or nature of the remuneration; (E) The methodology used to determine the remuneration; and (F) The performance or quality standards against which the recipient will be measured, if any. (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. (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. (iv) The remuneration is for or results from value-based activities undertaken by	(A) The value-based activities to be undertaken under the arrangement; (B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; (C) The target patient population for the arrangement; (D) The type or nature of the remuneration; (E) The methodology used to determine the remuneration; and (F) The outcome measures against which the recipient of the remuneration is assessed, if any. (ii) The outcome measures against which the recipient of the remuneration is assessed, if any, are objective, measurable, and selected based on clinical evidence or credible medical support. (iii) Any changes to the outcome measures against which the recipient of the remuneration will be assessed are made prospectively and set forth in writing. (iv) 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.	

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
		the recipient of the remuneration for patients in the target patient population. (v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. (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. (vii) If the 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). (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.	(v) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. (vi) The arrangement is commercially reasonable. (vii)(A) No less frequently than annually, or at least once during the term of the arrangement if the arrangement has a duration of less than 1 year, the value-based enterprise or one or more of the parties monitor: (1) Whether the parties have furnished the value-based activities required under the arrangement; (2) Whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise; and (3) Progress toward attainment of the outcome measure(s), if any, against which the recipient of the remuneration is assessed. (B) If the monitoring indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity. Following completion of	

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
			monitoring that identifies an ineffective value-based activity, the value-based activity is deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise— (1) For 30 consecutive calendar days after completion of the monitoring, if the parties terminate the arrangement; or (2) For 90 consecutive calendar days after completion of the monitoring, if the parties modify the arrangement to terminate the ineffective value-based activity. (C) If the monitoring indicates that an outcome measure is unattainable during the remaining term of the arrangement, the parties must terminate or replace the unattainable outcome measure within 90 consecutive calendar days after completion of the monitoring. (viii) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient. (ix) 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. (x) If the remuneration paid to the physician is conditioned on the physician's	

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
			referrals to a particular provider, practitioner, or supplier, the value-based arrangement complies with both of the following conditions: (A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties. (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. (xi) 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. (xii) For purposes of this paragraph (aa)(3), "outcome measure" means a benchmark that quantifies: (A) Improvements in or maintenance of the quality of patient care; or (B) Reductions in the costs to or reductions in growth in expenditures of payors while	

Reference	Current Regulations prior to January 19, 2021	Proposed Regulations	Final Amended Regulations, effective January 19, 2021	Change / Comments
			maintaining or improving the quality of patient care	
§ 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: (i) The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. (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. (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. (iv) The arrangement is documented in writing. (2) For purposes of this paragraph (bb), "technology" means any software or other types of information technology other than hardware.	(bb) *Cybersecurity technology and related services.* (1) Nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity, if all of the following conditions are met: (i) 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. (ii) 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. (iii) The arrangement is documented in writing. (2) For purposes of this paragraph (bb), "technology" means any software or other types of information technology.	CMS added 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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