Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-F)

Final Rule Summary

On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule to update regulations implementing section 1877 of the Social Security Act (the physician self-referral law). The final rule is scheduled to be published in the *Federal Register* on December 2, 2020. CMS finalizes exceptions for certain value-based compensation arrangements among physicians, providers of services and suppliers. The final rule also creates new exceptions for compensation arrangements for limited remuneration for physicians and for donations of cybersecurity technology and related services. CMS modifies the exception for electronic health record (EHR) items and services, and it makes a number of clarifications and modifications to existing exceptions and terminology. It also provides guidance to physicians, providers and suppliers.

The final rule is generally effective January 19, 2021. However, changes made to the regulations for group practice productivity bonuses and profit sharing are effective January 1, 2022.

Also on November 20, 2020, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) placed on public display at the *Federal Register* a final rule to revise safe harbors under the federal anti-kickback statute (AKS) and the civil monetary penalty (CMP) law that prohibits inducements offered to patients (beneficiary inducement CMP). Health Policy Alternatives is preparing a separate summary of that final rule.

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I. BACKGROUND

Section 1877 prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which the physician (or an immediate family member) has a financial relationship, unless an exception applies. It also prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for those referred services. The statute defines a financial relationship as an ownership or investment interest in the entity or a compensation arrangement with the entity, and it enumerates several exceptions and permits the Secretary of HHS to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral prohibitions to Medicaid. The preamble to the final rule includes a chronology of its rulemaking activities with respect to section 1877, including a description of modifications to its regulations to reflect later enactments of law.

CMS describes stakeholder concerns about the impact of the physician self-referral law, the AKS, and the beneficiary inducements CMP on beneficial arrangements among physicians, providers and suppliers to enter into innovative arrangements to improve quality outcomes, increase health system efficiencies, and lower costs. CMS published a Request for Information (CMS RFI) on June 25, 2018 on how to address undue impacts and burdens of the self-referral law and regulations, focusing on the structure of alternative payment arrangements, revisions to existing exceptions, and the need for new exceptions. Commenters requested new exceptions to protect compensation arrangements in alternative payment models and to protect the donation of cybersecurity technology and services to physicians. Some requested protection for care coordination arrangements. Others observed that new exceptions or easing current restrictions could exacerbate overutilization and produce other harms.

CMS notes that section 1877 was enacted to address concerns under Medicare's volume-based reimbursement system whereby a physician with an ownership or investment interest in an entity furnishing the DHS could increase both the entity's revenue through referrals as well as the physician's profit sharing. Subsequent legislation, such as the Affordable Care Act (ACA), laid the foundation for delivery system reform through, for example, the Medicare Shared Savings Program as well as the establishment of the Center for Medicare and Medicaid Innovation which tests different innovative payment and delivery models to reduce costs while enhancing quality

of care. Each program or model holds participants accountable for the care they furnish and provides incentives to improve care (and care coordination) or to lower costs, or both.

CMS examined value-based care delivery and payment models developed by commercial payors in order to develop policies that would permit financial relationships among providers who furnish services to non-Medicare patients. The agency's goals of the final rule are to remove regulatory barriers that impede care coordination, reduce regulatory burden, and to encourage new delivery system and payment models in Medicare and Medicaid.

II. PROVISIONS OF THE FINAL RULE

A. Facilitating the Transition to Value-Based Care & Fostering Care Coordination

1. Background

CMS notes consensus across the health care industry for moving from volume-based to value-based health care delivery and payment. To support that transition, CMS is finalizing a framework of interwoven definitions and exceptions designed to protect properly-structured value-based arrangements from the physician self-referral law's referral and billing prohibitions. During policy development, CMS purposefully made efforts to design policies that:

- Remove barriers to innovation and reduce provider burden while facilitating regulatory compliance;
- Align wherever feasible with policies of the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS);
- Ensure Medicare program integrity; and
- Contain sufficient flexibility to remain relevant over time as health care patterns evolve.

CMS emphasizes that the new exceptions would be applicable to arrangements involving Medicare beneficiaries, patients outside of Medicare, and mixed patient populations (i.e., not limited to CMS-sponsored models). The agency also states that these exceptions would not alter the potential for many existing value-based arrangements (e.g., pay-for-performance) to satisfy existing exceptions to the physician self-referral law and regulations.

2. Final Definitions (§411.351)

CMS proposed definitions for a set of six interconnected terms: value-based activity, value-based arrangement, value-based enterprise (VBE), value-based purpose, value-based enterprise participant, and target patient population. Modifications made, clarifications provided, and final actions taken by CMS are discussed below for each term.

a. Value-based activity

CMS had proposed to explicitly state that the making of a referral is not a value-based activity. Commenters disagreed, noting that *referral* as defined at §411.351 includes establishing a plan

of care, an activity integral to value-based care delivery. CMS agrees and does not finalize the proposed exclusion of making a referral (and any associated care planning) from the value-based activity definition.[1] CMS otherwise finalizes the definition of *value-based activity* as proposed.

b. Value-based arrangement

CMS revises the proposed language to emphasize that a *value-based arrangement* means a compensation arrangement between a physician and an entity that participate in the same value-based enterprise (e.g., physician and hospital of an accountable care organization). CMS clarifies that the definition does not cover compensation arrangements between a payor and a physician (e.g., physician participating in an Advanced Alternative Payment Model (APM) sponsored by CMS).

c. Value-based enterprise (VBE)

CMS clarifies that the definition of *value-based enterprise* does not preclude the addition of VBE participants after the start of a value-based arrangement. However, a separate and distinct compensation arrangement is created with each addition and must be analyzed separately for compliance under the physician self-referral law. CMS finalizes the definition of *value-based enterprise* as proposed.

d. Value-based purpose

CMS clarifies that maintaining care quality without concomitant cost control does not satisfy the definition of a value-based purpose. CMS also states that the list of activities previously found to qualify for the preparticipation waiver of the Medicare Shared Savings Program (e.g., care utilization management) may act as guidance for activities that would be considered to have value-based purposes.[2] CMS finalizes the definition of *value-based purpose* as proposed.

e. Value-based enterprise participant (VBE participant)

CMS clarifies that *entity* has a dual meaning in the physician self-referral regulations: 1) to indicate an entity (at §411.351) furnishing designated health services, and 2) a general meaning of an organization (e.g., a business) with an identity separate from those of its members. CMS states that *entity* will convey its general meaning when used in defining *VBE participant*. CMS modifies the proposed definition by replacing *individual or entity* with *person or entity*, noting that the latter term is widely used throughout the agency's regulations and refers to both natural and non-natural persons.[3]

[1] See also section II.D.2 of this rule for the agency's revision of the definition of referral.
[2] For the full list of waived activities, see **Medicare Program; Final Waivers in Connection With the Shared Savings Program; Final Rule** at 80 FR 66733, published October 29, 2015.
[3] CMS offers numerous examples of regulations that contain *person or entity* usage, such as for defining a referring physician as a physician making a referral or directing another *person or entity* to make a referral (§411.351).

In the proposed rule, CMS also considered but did not incorporate specific exclusions from the definition of *VBE participant* involving laboratories; suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); pharmaceutical manufacturers; DMEPOS manufacturers and distributors; pharmacy benefit managers; wholesalers; and distributors. After further consideration, CMS affirms its decision not to exclude any persons, entities, or organizations from the definition of *VBE participant*.

CMS finalizes the proposed definition of *VBE participant* with one modification, replacing *individual or entity* with *person or entity*.

f. Target patient population

In response to concerns voiced about use of the term *legitimate* in the context of target population selection criteria, CMS notes that *legitimate* has been used throughout the self-referral regulations for many years and does not need further definition. The agency adds that *legitimate* does not carry a new or different definition for purposes of interpreting the value-based definitions or the new exceptions at §411.357(aa). CMS states that the determination as to whether the selection criteria used to identify a target patient population are legitimate and verifiable is dependent on the facts and circumstances of the parties, and emphasizes that population selection may not be driven by profit motive or purely financial concerns. Finally, CMS notes having considered adding a requirement that all patients within a target patient population have at least one chronic condition in order to align with related OIG proposals, but chose not to do so. CMS finalizes the definition of *target patient population* as proposed without modification.

The proposed definitions applicable to the new exceptions from the physician self-referral law are finalized as indicated in the table below.

Term	**Final Definition**
Value-based activity	Any of the following that is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: provision of an item or service; taking of an action; or refraining from taking an action.
Value-based arrangement	A compensation 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 VBE.
Value-based enterprise (VBE)	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 VBE; (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 VBE and how the VBE participants intend to achieve its value-based purpose(s).
Value-based purpose	(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.

Term	Final Definition
VBE participant	A person or entity that engages in at least one value-based activity as part of a value-based enterprise.
Target patient population	An identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria.

4. Final Exceptions (§411.357(aa)).

Using the Secretary's authority under section 1877(b)(4) of the Act, CMS proposed three separate exceptions to the physician self-referral law for value-based arrangements:

- Applicable when a VBE has assumed full financial risk from a payor during the entire duration of the arrangement for patient care services furnished to a target patient population (§411.357(aa)(1);
- Applicable when a physician, as a value-based participant, has accepted meaningful downside financial risk for failure to achieve the value-based purposes of the VBE during the entire duration of the arrangement (§411.357(aa)(2)); or
- Applicable to any value-based arrangement that satisfies specified requirements (§411.357(aa)(3)), irrespective of the level of financial risk.

CMS finalizes all three exceptions with some modifications, discussed separately below with each type of exception. When considering the exceptions collectively, CMS notes that alignment with OIG regulations has been maximized, within the limitations imposed by the statutory and structural differences between self-referral exceptions and safe harbors. The agency affirms its decision not to add many "traditional" requirements for compensation arrangements (e.g., fair market value) under the new exceptions but does require the arrangements to be commercially reasonable. CMS clarifies that model-specific or program-specific waivers for existing CMS-sponsored models are not impacted by the new exceptions and will remain in place. CMS further clarifies that compensation arrangements covered under existing exceptions likewise are not impacted; either existing or new exceptions may be used for compensation arrangements whenever all of an exception's respective requirements are met. CMS similarly notes the availability to small and/or rural providers of all of the existing and new exceptions whenever all of an exception's specific requirements are met.

CMS states that the burden imposed by the writing, signature, and record retention requirements of the three finalized exceptions would be incurred by persons without federal regulation as part of normal business operations. CMS further states that the new exceptions to the self-referral law for value-based arrangements will reduce costs and improve quality not only for Medicare and its beneficiaries, but for patients and the health care system in general. CMS does, however, note that the agency is unable to quantify with certainty the overall net costs.

a. Full Financial Risk Exception (§411.357(aa)(1))

CMS proposed an exception to the physician self-referral law for remuneration paid under a value-based arrangement when the VBE is at full financial risk and the arrangement satisfies certain requirements. CMS finalizes the exception as proposed, with one modification. The

proposed exception allows the value-based arrangement to be protected from the self-referral law for a 6-month "pre-risk" period following the start date of the arrangement. During this time the VBE and its participants prepare to assume full risk at a future, specified, contractual start date while still providing care to the targeted patient population but without being at full risk. CMS finalizes extension of the pre-risk period from 6 months to 12 months, thereby emulating the timeframe of the Medicare Shared Savings Program's preparticipation waiver.

Additionally, for exceptions based on full financial risk bearing, CMS clarifies that:

- In-kind remuneration must not take the form of technology or infrastructure already possessed by the recipient.
- Prospectively-defined shared savings or other incentive payments conditioned on quality performance, and payments to offset shared losses above a prospectively-defined level, are not prohibited.
- Payments for referrals or business involving patients outside of the target population are not protected from the physician self-referral law.
- Remuneration related to covered patients could be used for the benefit of non-covered patients.
- The regulations in this rule do not preempt any applicable state law, for example when the latter requires obtaining a health plan license to take on full financial risk. Under such circumstances, VBEs may wish seek protection under other exceptions.

The finalized requirements of the full risk financial exception are excerpted below; to satisfy the exception, all of the requirements must be met by the arrangement.

- The VBE is at full financial risk (or is obligated contractually to be at full risk) for the entire duration of the value-based arrangement, starting within 12 months of the arrangement's commencement.
- Remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for members of the target patient population.
- Remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- 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.
- 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 the following conditions:
    - The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.
    - The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if: the patient expresses a different preference; the patient's insurer determines the provider, practitioner, or supplier; or the physician judges the referral not to be in the patient's best medical interests.

- Records of the methodology for determining the remuneration 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.
- "Full financial risk" means that the VBE 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 population for a specified period of time. "Prospective basis" means that the VBE has assumed financial responsibility for the cost of all items and services covered by the payor prior to providing care to members of the target population.

b. Meaningful Downside Financial Risk Exception (§411.357(aa)(2))

CMS proposed an exception to the physician self-referral law for remuneration paid under a value-based arrangement when the physician is at meaningful downside risk and the arrangement satisfies certain requirements. CMS states that this exception is designed to influence physician behavior during the transition to two-sided financial risk bearing prior to assuming full financial risk. CMS finalizes the exception as proposed, with several modifications to the definition of *meaningful downside risk*, described below.

CMS proposed to define *meaningful downside risk* as no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement. CMS linked this threshold percentage criterion to the 25 percent threshold for substantial financial risk used in the exception for physician incentive plans at §411.357(d)(2). CMS changes the percentage criterion to be no less than 10 percent, citing survey data from physicians concerning the proportion of their compensation that they are willing to have linked to quality and cost measures.[4]

CMS further proposed that the physician would be responsible *to pay* the entity the amount determined by the percentage criterion. CMS changes this language to read *to repay or forgo* to better describe the full range of permissible options for structuring the financial terms of a value-based arrangement between an entity and a physician (e.g., withholds, repayment requirements, or incentive pay tied to meeting goals or outcome measure). In a second language change, CMS specifies that the percentage to be repaid or foregone be applied to *the total value* received by the physician under the value-based arrangement, rather than to *the value* as proposed. The revised language more explicitly indicates that the threshold percentage includes in-kind remuneration (e.g., provision of infrastructure).

In addition to defining *meaningful downside risk* through a percentage criterion, CMS proposed an alternative, stating that meaningful downside risk was being assumed *when a physician was financially responsible 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 population for a specified period of time*. CMS agrees with commenters that the alternative definition is of low utility since a physician would be highly unlikely to assume full financial risk from a payor as described by the alternative. CMS does not finalize the alternative definition.

[4] https://www2.deloitte.com/us/en/insights/industry/health-care/volume-to-value-based-care.html

Reflecting all of the changes described above, CMS finalizes the following definition: *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.

CMS also states several clarifications regarding exceptions involving meaningful downside financial risk:

- The risk threshold percentage criterion relates to remuneration from an entity to a physician, not to payments from a payor for a physician's services.
- The exception for arrangements involving meaningful downside risk focuses on the value-based activities of an individual physician and as such is not designed to mirror the OIG's safe harbor for value-based arrangements with substantial financial risk.
- CMS replaces a cross-reference to §411.354(d)(4)(iv) with the referenced language itself.

The finalized requirements of the meaningful downside risk exception are excerpted below; to satisfy the exception, all of the requirements must be met by the arrangement.

- The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the VBE during the entire duration of the value-based arrangement.
- A description of the nature and extent of the physician's downside financial risk is set forth in writing.
- 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.
- Remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- Remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- 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.
- 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:
    - The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.
    - The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if: the patient expresses a different preference; the patient's insurer determines the provider, practitioner, or supplier; or the physician judges the referral not to be in the patient's best medical interests.
- Records of the methodology for determining the remuneration 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.
- "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.

c. Value-based Arrangement Exception (§411.357(aa)(3))

CMS proposed an exception to the physician self-referral law for compensation arrangements that qualify as value-based arrangements regardless of their risk parameters and that would cover both monetary and nonmonetary remuneration between the parties. Since no downside risk assumption is required, CMS structured the proposed exception with added safeguards, including regular mandatory monitoring of the arrangement and its participants for provision of value-based activities and progress towards attainment of any performance metrics specified under the arrangement. CMS finalizes the exception as proposed, with modifications to the requirements concerning performance metrics and their monitoring, as described below.

CMS proposed that the required description of the arrangement as set forth in writing would include *performance or quality standards*, if any, against which the recipient would be measured. CMS also proposed to require that the standards be objective and measurable, and that any changes to the standards be made prospectively and set forth in writing. To align with the corresponding OIG terminology, CMS replaces *performance or quality standards* with *outcome measure*, defining the latter as 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 maintaining or improving the quality of patient care. Further, CMS adds a requirement that outcome measures be selected based on clinical evidence or credible medical support, as well as being objective and measurable.

In the proposed rule, CMS discussed an implicit ongoing compliance monitoring obligation for arrangements qualifying for the value-based arrangements exception and invited input into the parameters of a monitoring process (e.g., monitoring frequency) but did not propose actual monitoring requirements. Given the potentially wide applicability of the value-based arrangements exception, CMS adds a set of mandatory monitoring requirements to serve as program safeguards when this exception is utilized. The added provisions specify the frequency of monitoring; outline what is to be monitored; and create a process for curing ineffective value-based activities and/or unattainable outcome measures that are identified through monitoring.

CMS also states several clarifications regarding the value-based arrangements exception:

- CMS considered as an alternative to limit the scope of this exception to nonmonetary remuneration only but rejected the alternative; the exception continues to include monetary and nonmonetary remuneration.
- CMS also considered an alternative to extend the conditioning of remuneration from patients outside of the target population to any patients, whether or not they are included in the target population. CMS does not adopt the alternative.
- CMS replaces a cross-reference to §411.354(d)(4)(iv) with the applicable language from that section.

The finalized requirements of the value-based arrangements exception are excerpted below; to satisfy the exception, all of the requirements must be met by the arrangement.

- The arrangement is set forth in writing and signed by the parties, including a description of: the value-based activities to be undertaken; how the value-based activities are expected to further the value-based purpose(s) of the VBE; the target patient population; the type or nature of the remuneration; the methodology used to determine the remuneration; and the outcome measures against which the recipient of the remuneration is assessed, if any.
- The outcome measures are objective, measurable, and selected based on clinical evidence or credible medical support. Any changes to the outcome measures must be made prospectively and set forth in writing.
- 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.
- Remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.
- No less frequently than annually, or at least once during the term of the arrangement if less than 1 year, the VBE or one or more of the parties monitor: whether the parties have furnished the required value-based activities; whether and how continuation of the value-based activities is expected to further the purpose(s) of the VBE; and progress made toward attainment of the outcome measure(s).
- If monitoring identifies a value-based activity to be ineffective, the parties must terminate the activity by terminating the arrangement within 30 days or modifying the arrangement to terminate the ineffective activity within 90 days.
- If monitoring identifies an unattainable outcome measure, the parties must terminate or replace the measure within 90 days.
- 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.
- Remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.
- Remuneration is not conditioned on referrals of patients who are not part of the target population or business not covered under the value-based arrangement.
- 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 complies with both of the following conditions:
    - The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.
    - The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if: the patient expresses a different preference; the patient's insurer determines the provider, practitioner, or supplier; or the physician judges the referral not to be in the patient's best medical interests.
- Records of the methodology for determining the remuneration and the actual amount of remuneration paid under the arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.
- "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 maintaining or improving the quality of patient care.

d. Indirect Compensation Arrangements to which the Exceptions at §411.357(aa) are Applicable (§411.354(c)(4))

Some features that are commonly part of value-based arrangements (e.g., services furnished for less than fair market value) are not permissible under the existing exception from the physician self-referral law for indirect compensation arrangements at §411.357(p). To avoid prohibiting the inclusion of value-based components within indirect compensation arrangements, CMS proposed that when a value-based arrangement is the link closest to the physician in an unbroken chain of financial relationships of an indirect compensation arrangement (i.e., the physician is a direct party to the value-based arrangement),[5] the indirect compensation arrangement would be considered an *indirect value-based arrangement*. Indirect value-based arrangements would then become eligible for self-referral protection through the application of one or more of the new self-referral exceptions described at §411.357(aa).

In this final rule, CMS clarifies the exception as follows:

- CMS affirms its decision not to exclude any of the following from the unbroken chain of relationships under the exception for an indirect value-based arrangement: pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; laboratory; pharmacy benefit manager; wholesaler; distributor; or health technology company.
- CMS notes that the existing exception for risk-sharing arrangements at §411.357(n) does not apply to either a direct or an indirect compensation arrangement between a physician and an entity that is anything other than a managed care organization (MCO) or independent practice association (IPA).
- CMS emphasizes that the new exceptions at §411.357(aa) are available to protect the physician's referrals to an entity furnishing designated health services when the unbroken chain of relationships (of an indirect compensation arrangement) includes that entity and a value-based arrangement to which the physician is a direct party. CMS offers as an example the chain of hospital – *parent organization – physician practice – physician* in which the physician practice employs the physician under a value-based compensation arrangement that is conditioned on specified hospital referral protocols. If the compensation arrangement meets the definition of a value-based arrangement at §411.351 and satisfies the requirements of one of the new exceptions, the physician's referrals to the hospital would be protected.

CMS finalizes at §411.354(c)(4)(iii) its proposal describing indirect compensation arrangements to which the new value-based arrangements exceptions at §411.357(aa) are applicable. The finalized regulation contains technical revisions to the proposed regulation to more explicitly specify which exceptions are available when the involved entity is or is not a MCO or IPA.

Relatedly, CMS takes the following actions involving the existing exception for risk-sharing arrangements at §411.357(n):

[5] "Physician" as used in this context also includes the physician organization in whose shoes the physician stands, when applicable. The link closest to the physician must be a compensation arrangement, not an ownership interest.

- Revises language at §411.357(n) to specify that the existing exception for risk-sharing arrangements is applicable to compensation paid directly or indirectly by a MCO or an IPA to a physician for services provided to enrollees of a health plan pursuant to a risk-sharing arrangement; and
- Adds regulations at §411.354(c)(4)(ii) and (iii)(B) to state that the existing exception at §411.357(n) for risk-sharing arrangements is applicable in the case of an indirect compensation arrangement in which the entity furnishing designated health services described in §411.354(c)(2)(i) is a MCO or IPA. The exception at §411.357(n) is not applicable when the entity with which the physician has an indirect compensation arrangement is not a MCO or IPA.

e. Price Transparency

CMS extensively discusses price transparency in the context of the physician self-referral law and as potentially applicable to the definitions and exceptions contained in this final rule. The discussion is largely informed by responses to questions about price transparency that were included in the June, 2018 CMS RFI about the physician self-referral law[6] and by comments received about price transparency issues that were raised by CMS in the proposed rule.[7] In this final rule, the agency addresses comments received about the merits of including a price transparency requirement in every self-referral exception created for value-based arrangements. The requirement would take the form of a public notice provided to patients that their out-of-pocket costs may vary based on site of service and insurance plan type when they are referred by a physician for items and services.

CMS reports receiving comments from representatives of health care consumers and health care service providers. CMS notes overwhelming commenter consensus in support of providing timely access for patients to clear, accurate, and actionable cost-sharing information. However, a requirement for price transparency embedded into all exceptions for value-based arrangements under the physician self-referral laws was viewed negatively by many of the same commenters. They characterized the requirement as an inappropriate mechanism for advancing price transparency given the strict liability nature of the self-referral law.

CMS ends the discussion of including price transparency requirements as part of the new exceptions for value-based arrangements under self-referral law without finalizing any price transparency provisions. Specifically, CMS does not add a requirement for providing public notice to patients about variable out-of-pocket costs as described above.

[6] Medicare Program; Request for Information Regarding the Physician Self-Referral Law. CMS-1720-NC. 83 FR 29526, published June 25, 2018.
[7] Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations. CMS-1720-P. 84 FR 55788-55789, published October 17, 2019.

B. Fundamental Terminology and Requirements

1. Background

CMS notes that stakeholders have regularly approached the agency seeking clarification on when an arrangement is commercially reasonable, under what circumstances compensation is considered to take into account the volume or value of referrals or other business generated between the parties, and how to determine the fair market value of compensation. In responding to the CMS RFI, stakeholders sought a bright-line, objective regulation for each of these fundamental requirements.

CMS finalizes a new definition of commercial reasonableness, revised definitions of fair market value and general market value, and special rules to clarify the volume or value and other business generated standards. The agency reiterates that the definitions and clarifications of these terms and requirements relate only to section 1877; where another statute uses the same terminology (such as the AKS and beneficiary inducement CMP law, the Internal Revenue Code, state laws and regulations, or even the Quality Payment Program under the Medicare physician fee schedule), the clarifications to the self-referral law in the final rule do not impact those other statutes and the agencies that implement them. CMS states that commenters agree with its position that each of the requirements for commercial reasonableness, fair market value, and volume or value of referrals or other business generated are separate and distinct requirements, each of which must be satisfied when included in an exception.

2. Commercially Reasonable (§411.351)

CMS proposed to add a definition of commercially reasonable to its regulations. CMS believes that the key question in determining whether an arrangement is commercially reasonable is whether the arrangement, from the perspective of the parties involved, makes sense as a means to accomplish the parties' goal. The issue is neither one of valuation nor whether the arrangement is profitable. Commenters noted many circumstances under which parties know in advance that an arrangement may result in losses to one or more parties, due to factors such as community need, ensuring timely access to health services, requirements under EMTALA, provision of charity care, or improvement of quality and health outcomes. CMS clarifies in its regulation text that compensation arrangements that do not result in profit for one or more parties may nonetheless be commercially reasonable.

CMS offered two alternative definitions of commercially reasonable for stakeholder comment:

- The particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements.
- The arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty.

CMS finalizes a definition that incorporates elements of both definitions. The term 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 drops the proposed requirement that the arrangement make commercial sense because some arrangements could be for noncommercial purposes. Under the finalized definition, the arrangement must be sensible considering the characteristics of the parties, including their size, type, scope, and specialty.

CMS notes that many examples offered by commenters to the CMS RFI could be commercially reasonable (i.e., may further a legitimate business purpose or make commercial sense), including under IRS Revenue Ruling 97-21. However, it cautions that arrangements that merely duplicate other arrangements that on their face are reasonable may not be commercially reasonable. CMS believes that the commercial reasonableness of multiple arrangements for the same services is questionable.
The agency also reiterates than an activity that violates criminal law would neither be a legitimate business purpose nor commercially reasonable. Further, mere absence of a criminal violation does not, alone, establish the commercial reasonableness of an arrangement.

CMS states that the general definition of commercially reasonable does not supersede any additional requirement under individual statutory or regulatory exceptions for an arrangement to be commercially reasonable "even if no referrals were made." Thus, where an exception also adds the "even if no referral were made" condition, that condition must still be met as part of the analysis to determine whether the arrangement complies with the exception.

CMS rejects suggestions from commenters to presume arrangements to be commercially reasonable if there is contemporaneous written documentation that the arrangement furthers a legitimate business purpose. CMS also declines to provide non-exhaustive examples of commercially reasonable arrangements in the regulation text.

Some commenters said that use of the term "legitimate business purpose" in the definition did not provide sufficient certainty. CMS responds that the term has the same meaning in the definition of commercially reasonable as it has under numerous exceptions (e.g., rental of office space at §411.357(a)(3), rental of equipment at §411.357(b)(2), and personal service arrangements §411.357(d)(1)(iii)). CMS notes that the condition for a legitimate business purpose is an objective standard and that identification of a legitimate business purpose is part of the initial analysis; the issue of whether the arrangement furthers a legitimate business purpose may require inquiry into the intent of the parties.

In the proposed rule, in describing the elements of the exception for personal service arrangements, CMS equated the statutory requirement that the arrangement may "not exceed what is reasonable and necessary" to a requirement that the arrangement be commercially reasonable. In response to comment, CMS retracts that statement. CMS clarifies that the requirement that a personal services arrangement may not exceed what is reasonable and necessary is to protect against sham arrangements for the services of a physician for which the entity has no genuine or reasonable use. Thus, while clarifying that the exception for personal

services arrangements does not include a requirement that the arrangement be commercially reasonable, CMS notes that the other requirements of the exception guard against program or patient abuse in what is essentially an equivalent manner.

3. Volume or Value Standard and Other Business Generated Standard (§411.354(d)(5) and (6))

Commenters have complained that guidance from the agency over the years on the volume or value standard and the other business generated standard does not provide an objective standard against which to judge whether a proposed compensation arrangement takes into account the volume or value of referrals or the volume or value of other business generated by a physician.

CMS finalizes its proposal to codify the volume or value standard and the other business generated standard in its physician self-referral regulations with some modifications. CMS adds special rules at §411.354(d)(5) and (6) that will supersede previous guidance. This codification does not apply to value-based arrangements (described above) since the exceptions for value-based arrangements do not include volume or value standards as requirements for remuneration between parties. The standards are prospective and represent the agency's policy on the volume or value standard and the other business generated standard going forward from the effective date of the final rule.

§411.354(d)(5) and (6) specify when compensation will be considered to take into account the volume or value of referrals or take into account other business generated between the parties. This applies only when the mathematical formula used to calculate that compensation includes referrals or other business generated as a variable and the amount of compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity. Generally, any compensation methodology outside the circumstances at §411.354(d)(5) and (6) is not considered to take into account volume or value or other business generated between the parties.

These standards are not defined; rather, they are special rules that apply for each standard and for payments from an entity to a physician (or immediate family member) as well as from a physician (or immediate family member) to an entity. However, the agency interprets these special rules as definitions which define the universe of circumstances under which compensation is considered to take into account the volume or value of referrals or other business generated by the physician.

The standards apply to the definition of remuneration under section 1877(h)(1)(C) of the Act and §411.351 of the regulations, the exception for academic medical centers (§411.355(e)(1)(ii)), and various exceptions for compensation arrangements in section 1877(e) of the Act and §411.357 of the regulations, including the new exception for limited remuneration to a physician (§411.357(z)). The standard for compensation from an entity to a physician at §411.354(d)(5)(i) applies to the group practice regulations at §411.352(g) and (i).

The final regulation text includes a reference to specific provisions of the regulations to which the standards do not apply; these are exceptions for medical staff incidental benefits

(§411.357(m)), professional courtesy (§411.357(s)), community-wide health information systems (§411.357(u)), electronic prescribing items and services (§411.357(v)), electronic health records items and services (§411.357(w)), and cybersecurity technology and related services (§411.357(bb)).

The standards also do not apply for purposes of determining the existence of an indirect compensation arrangement under §411.354(c)(2), applying the special rule on compensation deemed to be set in advance under §411.354(d)(1), or applying the special rules for unit-based compensation under §411.354(d)(2) and (d)(3).

a. Compensation from an Entity to a Physician

As finalized, compensation from an entity furnishing designated health services to a physician takes into account the volume or value of referrals only if 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.

The final regulations clarify that 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.

The same policies apply for determining when compensation from an entity to a physician (or immediate family member) takes into account other business generated.

b. Compensation from a Physician to an Entity

Compensation from a physician (or immediate family member) to an entity 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

The regulation clarifies that a negative correlation between two variables exists when one variable increases as the other variable decreases, or one variable decreases as the other variable increases.

The same policies apply for determining when compensation from a physician (or immediate family member) to an entity takes into account other business generated.

c. Major Modifications from the Proposed Rule

In the proposed rule, CMS stated that the special rule for unit-based compensation at §411.354(d)(2) still applies, and if the compensation arrangement met the conditions for that

special rule, the compensation would not take into account the volume or value of referrals or other business generated. In the final rule, CMS retracts this statement and states that the policies under §411.354(d)(2) and (d)(3) for unit-based compensation do not apply to compensation that takes into account the volume or value of referrals or other business generated under the finalized standards of §411.354(d)(5) and (6). A determination under §411.354(d)(5) and (6) that compensation does take into account the volume or value of referrals or other business generated is final; parties may not use the special rules for unit-based compensation to deem the compensation not to take into account the volume or value of referrals or other business generated. Notwithstanding the fact that on and after the effective date of the final rule the policies under §411.354(d)(2) and (d)(3) for unit-based compensation are either unnecessary or inapplicable to deem unit-based compensation not to take into the volume or value of referrals or other business generated, CMS retains the provisions in the regulations to assist parties in applying the historical policies in effect at the time of the compensation arrangement being analyzed.

CMS had also proposed under §411.354(d)(5) and (6) to include narrowly defined circumstances under which fixed-rate compensation would be considered to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation. CMS does not finalize this proposal. Instead, it revises §411.354(d)(4) (directed referral requirements under *bona fide* employment relationships, personal service arrangements, or managed care contracts) by adding a new clause (vi) to state that regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician, neither the existence of the compensation arrangement nor the amount of the compensation may be contingent on the volume or value of the physician's referrals to the particular provider, practitioner, or supplier.

d. Clarification of Previous Guidance

In response to commenters, CMS reaffirms the clarification in the proposed rule that its previous policy position expressed in the Phase II regulation with respect to employed physicians and productivity bonuses still applies. CMS states that productivity compensation based solely on a physician's personally performed services does not take into account the volume or value of the physician's referrals or other business generated by a physician under the policies adopted in this final rule. It notes that this type of compensation would satisfy the volume or value standard and the other business generated standard, where it appears, in the exceptions for bona fide employment relationships, personal service arrangements, and fair market value compensation, all of which apply to direct compensation arrangements between entities and physicians.

The agency also reaffirms this guidance extends to compensation arrangements that do not rely on the exception for bona fide employment relationships at §411.357(c), and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions at §411.354(d)(2). Thus, under a personal services arrangement, an entity may compensate a physician for personally performed services using a unit-based compensation formula even when the entity bills for DHS that

correspond to those services personally performed by the physician. CMS declines to codify this guidance in its regulations.

e. Revision to Indirect Compensation Arrangements

In response to comment, CMS no longer believes it must treat indirect compensation arrangements in the exact same manner it treats direct compensation arrangements. It revises the method it uses to analyze whether an unbroken chain of financial relationships between an entity and a physician (or immediate family member) poses a risk of program or patient abuse. CMS revises §411.354(c)(2)(ii) to effectively incorporate and apply the conditions of the special rules on unit-based compensation at the definitional level when determining if an indirect compensation arrangement satisfies an applicable exception.

As finalized, an unbroken chain of financial relationships between an entity and a physician will be considered an indirect compensation arrangement if it meets the following conditions:

- the 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 physician for the entity furnishing the designated health services; and
- any of the following are true:
    1. the individual unit of compensation received by the physician (or immediate family member) is not fair market value for items or services actually provided;
    2. the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes the physician's referrals to the entity furnishing designated health services 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. the individual unit of compensation received by the physician (or immediate family member) is calculated using a formula that includes other business generated by the physician for the entity furnishing designated health services 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.

Additionally, the entity must have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with the volume or value of referrals or other business generated by the referring physician for the entity.

CMS understands that its revised policy will reduce the number of unbroken chains of financial relationships that are subject to the physician self-referral law; it also understands that analyzing the unit-based compensation at the definitional stage will eliminate the writing requirement for many unbroken chains of financial relationships making law enforcement scrutiny more difficult.

However, the agency believes that other federal and state statutory and regulatory requirements may fill the void its revised policy creates.

4. Patient Choice and Directed Referrals (§411.354(d)(4))

CMS finalizes several revisions to the regulation text which it believes clarify the conditions for the patient choice and directed referrals exception. CMS clarifies that the compensation or the formula used to set the compensation (as opposed to the compensation arrangement) must be set in advance. Further the compensation (as opposed to the compensation arrangement) must be consistent with the fair market value of the physician's services. It eliminates language related to the volume or value standard previously included in §411.354(d)(4)(ii)) because it conflated the fair market value standard and the volume or value standard.

Because the changes to the volume or value standard described above reduce or eliminate the instances in which the special rule for patient choice and directed referral applies, CMS ensures these conditions continue to apply to the types of contracts or arrangements to which they applied historically. CMS adds to the requirements of several exceptions the additional condition that each exception must meet the requirements of the revised patient choice and directed referral special rule. This applies to the following exceptions:

- §411.355(e) (academic medical centers)
- §411.357(c) (*bona fide* employment relationships)
- §411.357(d)(1) (personal service arrangements)
- §411.357(d)(2) (physician incentive plans)
- §411.357(h) (group practice arrangements with a hospital)
- §411.357(l) (fair market value compensation)
- §411.357(p) (indirect compensation arrangements)
- §411.357(z) (limited remuneration to a physician)

CMS notes that compliance with §411.354(d)(4) is not extended to the exception for value-based arrangements finalized at §411.357(aa); however, specific requirements for remuneration paid to a physician conditioned on referrals to a specific provider, practitioner or supplier are included in that exception.

CMS adds a new clause (vi) to §411.354(d)(4) to specify that neither the existence of the compensation arrangement nor the amount of compensation may be contingent on the number or value of referrals to a particular provider, practitioner or supplier. This condition must be met without regard to whether the physician's compensation takes into account the volume or value of referrals to the entity with which the physician has the compensation arrangement. In other words, compensation conditioned (expressly or otherwise) on directed referrals of DHS should not be evaluated for compliance with the volume or value standard.

CMS notes that while a requirement under a compensation arrangement for a physician to make a certain number or value of referrals is prohibited, a requirement for an established percentage or ratio of referrals (e.g., 90 percent) to a particular provider, practitioner or supplier is permissible. In response to comments, CMS also states that the affirmative condition to comply

with §411.354(d)(4) under the exceptions listed above is not limited to express or written requirements to refer patients to particular providers, practitioners, or suppliers selected by the entity; the condition prohibits making the existence of the compensation arrangement (or any compensation paid) contingent on those referrals if it fails to meet the requirements of §411.354(d)(4). Commenters sought clarification on employee workplace requirements that require employed physicians to treat the employer's patients in a specified workplace; CMS responds that §411.354(d)(4) would not require the employer to permit the employed physician to personally treat the patient in a location other than that specified in the employment contract unless the general exclusions under §411.354(d)(4) apply, namely where a patient expresses a preference for a different provider, the patient's insurer determines the provider, or the referral is not in the best interests of the patient.

5. Fair Market Value (§411.351)

Fair market value is defined in section 1877(h)(3) of the Act and generally means the value in an arm's length transaction that is consistent with general market value. The statute also provides additional conditions for leases generally (e.g., the value of the rental property for general commercial purposes—not taking into account its intended use) and for office space leases (e.g., the value of the rental property is not adjusted to reflect additional value a lessee or lessor would attribute to proximity or convenience to the lessor who is a potential source of patient referrals). CMS initially codified the statutory definitions and later added a definition of general market value. In its rulemaking, CMS initially suggested a connection between the fair market value requirement and requirements relating to volume or value of physician referrals and other business generated. In the Phase II rulemaking, it incorporated a reference to the volume or value standard in many exceptions to the self-referral law.

CMS changes its position on this issue. The final rule eliminates the connection to the volume or value standard in the definitions of fair market value and general market value. CMS believes that the volume or value standard should not be incorporated in those definitions, observing that the requirements are separate and distinct from each other in the statute.

CMS also finalizes its proposed restructuring of the definition of fair market value; the final definition is as follows:

> *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.

The final definition does not include references to "like parties under like circumstances."

CMS also revises its definition of general market value (which was based in prior rulemaking on principles of reasonable cost reimbursement for end stage renal disease) to be consistent with the recognized valuation principle of market value. The final definition is as follows:

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.

In the preamble to the proposed rule, CMS had made statements equating general market value (as the term appears in the statute and regulations) to market value which CMS identified as uniformly used in the valuation industry. CMS retracts those statements because it fears they could have an unintended limiting effect on the regulated community and the valuation community. CMS believes that the general market value of a transaction is based solely on the consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another.

CMS notes that extenuating circumstances may dictate that parties to an arm's length transaction veer from general market values (such as those identified in salary surveys) and other valuation data that is not specific to the actual parties to the subject the transaction. For example, an average amount from a salary survey may not be appropriate for a particular practitioner who is highly sought after because he or she is one of the top practitioners in the nation. In the proposed rule, CMS had analyzed fair market value as a hypothetical transaction and general market value as an actual transaction; it abandons that analytical framework in the final rule. However, the many examples in the proposed rule supporting the fair market value of a transaction that veers from general market value are affirmed in the final rule.

Additionally, the agency strikes the statement "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" from the regulatory definition of fair market value because it is unnecessary for that definition, and it has caused confusion for stakeholders. Nonetheless, CMS notes that policy still applies notwithstanding its absence from the definition.

C. Group Practices (§411.352)

CMS addresses revisions to the group practice rules for distribution of profit shares and productivity bonuses. The agency reminds readers that it interprets the requirements of §411.352(g) and (i) to incorporate the volume or value standard. Thus, compensation to a physician who is a member of a group practice may not take into account the volume or value of the physician's referrals (except as permitted for distribution of profits shares and productivity bonuses under §411.352(i)), and profit shares and productivity bonuses paid to a physician in the group may not be determined in any manner that takes into account the volume or value of the physician's referrals (except that a productivity bonus may directly take into account the volume or value of the physician's referrals if the referrals are for services "incident to" the physician's personally performed services). CMS notes that new section §411.354(d)(5) (described above) establishes the universe of compensation considered to be determined in a manner that takes into account the volume or value of the physician's referrals to the entity paying the compensation.

CMS notes that nothing in the final rule prohibits a group practice (or any physician within a group practice) that furnishes DHS, and the physicians who are owners, employees or independent contractors of the group practice, from qualifying as a value-based enterprise assuming the requirements of the new exception for value-based arrangements at §411.357(aa)(3); CMS notes that those exceptions do not include volume or value or fair market value requirements.

CMS clarifies that the phrase "takes into account" as used in these regulations with respect to the volume or value standard is interchangeable with the phrases "based on," "related to," or "directly related to."

Because the policies finalized for group practices may require changes to the internal compensation practices in many medical groups, CMS delays the effective date of this portion of the final rule until January 1, 2022 to permit parties additional time to revise compensation methodologies and arrangements for group practice physicians.

a. Special Rules for Profit Shares and Productivity Bonuses §411.352(i)

CMS proposed to add a new special rule at §411.352(i)(3) to address downstream compensation deriving from payments made to a group practice (rather than directly to a physician in the group) that relate to the physician's participation in a value-based arrangement. Effective January 1, 2022, distribution of profits from DHS that are directly attributable to a physician's participation in a value-based enterprise are deemed to not directly take into account the volume or value of the physician's referrals. Thus, a group practice may distribute directly to the physician who participated in the value-based enterprise the profits from DHS furnished by the

group that derive from the physician's participation; this includes profits from DHS referred by the physician.

CMS had asked for comment on whether it should permit the distribution of "revenue" from DHS instead of its proposal to permit distribution of "profits" from DHS. Because it believes that the distribution of revenues instead of profits to a referring physician could induce additional and potentially inappropriate referrals to the group practice, it finalizes use of the term profits.

b. Clarifying Revisions

Because stakeholders expressed confusion over the definition of "overall profits" and its applicability under different circumstances, CMS finalizes its proposal to revise the definition with modifications as follows:

> (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.[8]

The revisions are intended to clarify the application of the term to group practices with fewer than five physicians. Additionally, CMS adds the modifier "all the" before DHS in the text to clarify that profits from all DHS services of the practice (or a component with at least 5 physicians) must be aggregated and distributed; the group practice may not distribute DHS profits on a service-by-service basis. CMS explains that insofar as a group practice wishes to pay shares of overall profits to any of its physicians, it must first aggregate the *entire* profits from the *entire* group or the *entire* profits from any component of the group that consists of at least 5 physicians.

More significantly, CMS clarifies that the group practice may use different distribution methodologies for each component of the group that consists of at least five physicians (referred to as the component of five rule). Thus, a group practice may use the component of five rule to aggregate and distribute profit shares and may use different distribution methodologies for each component of five. For each component of five, the group practice must aggregate the profits from all the DHS furnished by the group and referred by any of the physicians in the component.

With respect to the requirements for the calculation of productivity bonuses, the deeming provision related to total physician encounters or relative value units (RVUs) is revised to say a productivity bonus will be deemed not to take into account the volume or value of a physician's referrals if it is based on the physician's total patient encounters or the RVUs personally performed by the physician. CMS says this clarification is intended only to link the general requirement for productivity bonuses based on services personally performed by a physician with

[8] The section references in the preamble to §411.352(i)(1)(ii) are likely intended to refer to §411.352(i)(2) in the final regulation text; other changes described in the preamble do not necessarily appear in the final regulation text. For example, the second deeming provision in the regulation text at §411.352(i)(2)(ii) uses the term revenues whereas the preamble states that the first and second deeming provisions relate to overall profits.

the deeming provision that allows productivity bonuses based on total patient encounters or RVUs. CMS states that it is not intended to limit productivity bonus payments current allowed under regulations, and the agency does not believe the change will do so.

CMS reorganizes the structure of §411.352(i) in the regulation text and modifies the language to either mirror the statute more closely or clarify areas of confusion. This includes removing references to Medicaid as well as substituting references to DHS "payable by Medicare" for the current language that references DHS "payable by any federal health care program or private payor." The latter change is because DHS refers to certain services payable under the Medicare program.

D. Recalibrating Scope and Application of Regulations

1. Decoupling the Physician Self-Referral Law from the Federal Anti-Kickback Statute and Federal and State Laws or Regulations Governing Billing or Claims Submission

While section 1877 does not specifically require its exceptions for arrangements to not violate the anti-kickback statute (AKS) or any federal or state law or regulation governing billing and claims submissions, many of the exceptions CMS has established through rulemaking do. Responding to stakeholder opposition to this requirement, CMS proposed to remove requirements that an arrangement not violate the AKS or any federal or state law or regulation governing billing and claims submissions from exceptions in contained in the physician self-referral regulations (i.e., those under 42 CFR Part 411, subpart J). CMS noted that the proposal did not affect the exceptions for referral services (§411.357(q)) and obstetrical malpractice subsidies (§411.357(r)1)) which state that arrangements that comply with requirements of certain AKS safe harbors satisfy the requirements for the exceptions.

CMS finalizes its proposal with one modification. With respect only to the exception for fair market value compensation at §411.357(l), CMS does not think it is appropriate to remove the requirement to not violate the AKS because it serves as a substitute safeguard for the statutory exclusive use requirement for the rental of office space or equipment. For example, CMS is concerned about the potential for sham or "paper" leases where the lessor receives payment from a lessee for space that the lessor continues to use; thus, including a requirement that the arrangement not violate the AKS will prevent program or patient abuse. CMS notes that because it is retaining the requirement to not violate the AKS in the fair market value compensation exception, it is also retaining the definition of "does not violate the anti-kickback statute" in §411.351.

CMS finalizes its proposal to eliminate from all the exceptions, including the exception for fair market value compensation at §411.357, requirements that an arrangement not violate any federal or state law or regulation governing billing and claims submissions.

CMS explains that its final policies do not affect a party's liability under the AKS. The agency will monitor the changes and may propose to reinstate the requirements for some or all its exceptions if the agency determines it necessary to protect against program or patient abuse.

2. Definitions (§411.351)

a. Designated Health Services

The current definition of DHS is limited to DHS that is payable, in whole or in part, by Medicare. It does not include services reimbursed by Medicare as part of a composite rate (e.g., SNF Part A payments), except to the extent that DHS services listed in this definition are themselves payable through a composite rate (e.g., all services provided as home health services or inpatient and outpatient hospital services).

CMS finalizes its proposal to clarify the definition with respect to inpatient hospital services with some modifications. Specifically, a service furnished by a hospital to an inpatient does not constitute DHS 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 hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS), the Inpatient Rehabilitation Facility PPS (IRF PPS), the Inpatient Psychiatric Facility PPS (IPF PPS), or the Long-Term Care Hospital PPS (LTCH PPS). CMS reasons that because the amount of the payment under the DRG for the admission has already been determined, additional tests ordered by a specialist will not likely impact the amount of payment (unless an outlier payment is made); the agency emphasizes that this clarification applies only to inpatient services that do not affect the relevant inpatient hospital PPS reimbursement rates. In the final rule, CMS extends the policy to include the IRF PPS, IPF PPS and LTCH PPS. Because commenters were unclear what CMS intended by the phrase "would not impact the amount of payment," CMS changes the term "impact" to "increase" for clarity. CMS does not believe the modification should apply to hospital outpatient services, and notwithstanding suggestions to the contrary, it does not extend the policy to the OPPS.

b. Physician

CMS finalizes its proposed technical change to the definition of physician in §411.351 to cross-reference the definition of physician at section 1861(r) of the Act. This change is intended to ensure there are no inconsistencies between the statute and regulations, and any limitations imposed on physicians by reason of the statute extend to the term when used in the self-referral regulations. CMS believes this is necessary to clarify that when a physician is not considered a physician for purposes of Medicare reimbursement (e.g., chiropractors are considered physicians under Medicare for very limited circumstances), the self-referral rules do not apply.

The existing provision in the regulatory definition that treats a physician and the professional corporation of which he or she is a sole owner as the same continues to apply.

c. Referral

CMS finalizes its proposal to revise the definition of referral to codify its longstanding policy that a referral is not an item or service for purposes of the self-referral law and regulations. Thus,

payments to a physician for the benefit of receiving the physician's referrals contravene the law and regulations; no exception applies to such a payment.

d. Remuneration

CMS proposed to revise and clarify its policy for certain remuneration that does not constitute a compensation arrangement. Section 1877(h)(1)(C)(ii) of the Act provides an exception for items, devices, or supplies furnished at no cost and used solely to collect, transport, process or store specimens for the entity providing the items, devices, or supplies or to order or communicate the results of tests or procedures for the entity. The agency had previously explained that the "used solely" condition means that items or devices may only be used to collect, transport, process or store specimens for the entity that provided the item or device or to order or communicate the results of tests or procedures for the entity. Thus, items such as surgical tools would not meet this test because they are routinely used as part of a medical or surgical procedure. CMS believed that the statute envisioned single-use items, devices and supplies, and it is concerned that reusable items may have value to physicians outside the collection of specimens.

CMS finalizes revisions to the definition of remuneration in the context of the "used solely" standard. CMS states that the mere fact that an item, supply, or device is classified as a surgical device does not mean it could not qualify for the exception. Rather, the test for purposes of the availability of the exception is whether the item, device, or supply is used solely for one or more of the statutory purposes (i.e., to collect, transport, process or store specimens for the entity that provided the item, supply or device or to order or communicate the results of tests or procedures for the entity). CMS further clarifies that the primary purpose of the item, device or supply must be one or more of the uses allowed under the statute; an item, device or supply whose primary purpose is not one specified in the statute is not excluded from the definition of remuneration even if a physician uses it for one of the permitted purposes.

CMS is aware that an item could theoretically be used for another purpose (e.g., a specimen lockbox could be used as a doorstop); it clarifies that the mere fact that an item, supply, or device could be used for a purpose other than the ones listed in the statute does not necessarily mean that furnishing that item, supply, or device at no cost constitutes remuneration. CMS adds the words "in fact" to the "used solely" requirement to address this concern.

The agency's expectation is that these items, supplies or devices are of low value and that they have little or no independent value to the physician. CMS emphasizes that they must serve a purpose for the entity providing the items, supplies or devices (e.g., collecting specimens for the entity).

However, these revisions do not change the agency's position that the provision of items, devices, or supplies whose main function is to prevent contamination or infection (e.g., sterile gloves) constitutes remuneration. An item, device, or supply must not have a primary function of preventing infection or contamination, or some other purpose other than those listed in the statute, to avoid being considered remuneration. CMS also notes that even if this type of remuneration is protected under the self-referral law, it could implicate the anti-kickback statute.

e. Transaction

Section 1877(e)(6) of the Act provides an exception to the definition of compensation arrangement for isolated financial transactions. CMS added definitions of the terms "transaction" and "isolated transaction" to §411.351. It was intended to address one-time sales of property or a practice. The agency has found that certain parties are using this isolated transaction exception to protect service arrangements where a party makes a single payment for multiple services provided over an extended period of time, seeking to treat a single payment for those multiple services as an isolated financial transaction. CMS believes this is because the parties entered into services arrangements without setting the arrangement in writing before furnishing the services, effectively using the isolated transaction exception to cure noncompliance with the physician self-referral law.

CMS clarifies that the isolated transaction exception is not available to protect service arrangements when multiple services are provided over an extended period of time, even where there is a single payment. The final rule adds a definition of "isolated financial transaction" separate from the definition of transaction.

This separate definition clarifies what is included in the definition (i.e., a one-time sale of property or practice, or a similar one-time transaction) and what is excluded (i.e., a single payment for multiple or repeated services). In response to stakeholder concerns, the definition in the final rule adds another example of an isolated financial transaction: a single instance of forgiveness of an amount owed in settlement of a *bona fide* dispute. CMS cautions that the exception is not applicable to the compensation arrangement that is the subject of the dispute; in other words, a settlement of a *bona fide* legal dispute under §411.357(f) is a separate compensation arrangement from the compensation arrangement that gave rise to the *bona fide* dispute. Additionally, settlement of a *bona fide* legal dispute under §411.357(f) does not retroactively bring the compensation arrangement that gave rise to the *bona fide* dispute into compliance with the physician self-referral law. This additional example is still subject to existing conditions applicable to isolated financial transactions, including meeting fair market value and the volume or value of referrals or other business generated standards.

CMS also revises the isolated transactions exception at §411.357(f)(4) to clarify that an isolated financial transaction that is an instance of forgiveness of an amount owed in settlement of a bona fide dispute is not part of the compensation arrangement giving rise to the bona fide dispute. CMS also makes what it describes as conforming changes to the definition of transaction by eliminating the phrase "or process" because the agency acknowledges this phrase may have encouraged parties to apply the exception to payments for multiple services furnished over time.

CMS emphasizes that these changes in the final rule are prospective only. CMS notes parties may avail themselves of other exceptions, such as the personal service arrangements exception or the fair market value compensation exception for this type of arrangement. CMS also believes that its final rules for the writing and signature requirements at §411.354(e)(4) and the exception for limited remuneration at §411.357(z) provide additional flexibility for stakeholders for whom the personal service arrangement exception may not be available.

3. Denial of Payment for Services Furnished under a Prohibited Referral—Period of Disallowance (§411.353(c)(1))

The period of disallowance refers to the period of time during which a physician may not refer for DHS to an entity and the entity may not bill the program for the referred DHS when the financial relationship failed to satisfy conditions for an exception. Determining when the period begins (i.e., when the financial relationship failed to satisfy all the requirements of the applicable exception) is not as challenging as when the period ends.

Under regulations in effect before the effective date of this final rule, where the noncompliance is unrelated to the payment of compensation, the period of disallowance is deemed to end no later than the date that the financial relationship satisfies all those requirements. However, where the noncompliance relates to the payment of excessive or insufficient compensation, the period of disallowance is deemed to end no later than the date on which the excess compensation was repaid (or the additional compensation was paid) and the financial relationship satisfies the requirements of the exception.

CMS finalizes its proposal to delete its rules on the period of disallowance entirely; it now believes they are overly prescriptive and impractical. However, this change does not impact parties who have relied on those regulations. CMS emphasizes that this final action does not permit parties to a financial relationship to refer for DHS or to bill Medicare for services when the financial relationship does not meet all the requirements of an applicable exception.

CMS acknowledges that there are no definite rules for establishing in every case when a financial relationship has ended, and it believes the regulations fail to provide a clear, bright-line way to establish the end of the disallowance period. The agency notes that the steps described in paragraphs (ii) or (iii) of §411.353(c)(1) as in effect before the final rule are one way to establish the end of the period. It also clarifies that deleting those provisions from the regulations is not intended to preclude the use of those steps. Rather, the agency's intent is to no longer prescribe in rulemaking how the end of the period should be established by the parties.

In broad terms, if there is an unintended discrepancy (e.g., an administrative or operational error) during the course of the arrangement, the parties should remedy it. CMS expects entities to have effective compliance programs to identify and remedy discrepancies. Failure to correct the discrepancy during the term of the arrangement exposes the parties to referral and billing prohibitions during the entirety of the arrangement. In analyzing the compensation arrangement, CMS considers the actual arrangement between the parties on a case-by-case basis and determines whether the *actual* amount of the compensation paid exceeded the fair market value for the services furnished. Assuming the actual amount paid does not exceed the fair market value, CMS observes that a number of provisions in the regulations and the final rule may be available to limit the scope of noncompliance.

CMS clarifies its position on "turning back the clock" or retroactively curing a noncompliance. It states that correcting administrative or operational errors or discrepancies *during* an arrangement is not necessarily turning back the clock to address a noncompliance; the agency characterizes

this behavior as a normal business practice. However, after the financial arrangement has ended, the parties may not retroactively cure a previous noncompliance by recovering or repaying a problematic compensation. CMS believes this policy will encourage ongoing compliance reviews of arrangements.

In response to comments, CMS finalizes a policy at §411.353(h) establishing a 90-day grace period after the termination of a financial relationship for parties to reconcile discrepancies. To be protected under this new authority, parties must reconcile all payment discrepancies under their arrangement within 90 consecutive calendar days of the expiration or termination of the compensation arrangement, and following the reconciliation, the entire amount of remuneration for items or services must be paid as required under the terms and conditions of the arrangement. Additionally, the compensation arrangement itself (other than the payment discrepancies themselves) must meet all conditions of an applicable exception. If the payment discrepancies are not resolved during the 90-day period, parties may not cure any noncompliance resulting from the payment discrepancies.

CMS reiterates several points. Referrals are prohibited and claims may not be submitted during the period a financial relationship does not satisfy the conditions of an exception; thus if payment discrepancies are not reconciled during the course of the arrangement, or during the 90-day grace period after the termination of the arrangement, from the point of the payment discrepancy on, the arrangement does not meet the requirements for an exception. CMS also clarifies that reasonable efforts to reconcile payment discrepancies are not sufficient; the agency requires actual reconciliation of the payment discrepancies. Finally, CMS notes that parties to a legitimate dispute regarding a compensation arrangement may use the exception for isolated transactions (§411.357(f)) to protect the compensation arrangement that arises from the forgiveness of an obligation related to the settlement; however, that settlement does not retroactively return the original arrangement to compliance with the requirements of an exception.

4. Ownership or Investment Interests (§411.354(b)(3))

a. Titular Ownership or Investment Interest (§411.354(b)(3)(vi))

An ownership or investment interest is considered to be titular if a physician who is part of a physician organization may not receive any of the financial benefits of ownership or investment in that organization, including profit sharing, dividends, proceeds of a sale, etc. In 2009, CMS established the policy of titular ownership for the "stand in the shoes" provisions for compensation arrangements under §411.354(c).

CMS extends the concept of titular ownership or investment to its rules governing ownership or investment interest generally. The final rule adds to the regulatory list of interests excluded from ownership or investment interests at §411.354(b)(3) titular ownership or investment interests that exclude the ability or right to receive the financial benefits of ownership or investment. CMS believes this will provide greater certainty and flexibility, especially in states where the corporate practice of medicine is prohibited.

b. Employee Stock Ownership Program

§411.354(b)(3)(i) excludes from the definition of ownership or investment interest an interest in a retirement plan; CMS considers retirement contributions part of an employee's overall compensation. This exception is limited to retirement interests in the entity which employs the physician (or immediate family member). CMS believes that extending the exclusion to interests in other entities would run a risk of program or patient abuse.

In response to concerns raised by commenters, CMS adds another exclusion from the definition of ownership or investment interest for employee stock ownership plans (ESOPs) qualified under section 401(a) of the Internal Revenue Code (IRC). This exclusion is not restricted to an interest in an entity that both employs the physician and sponsors the retirement plan. CMS is satisfied that there are sufficient safeguards that apply to the operation of ESOPs under the Internal Revenue Code and the Employee Retirement Income Security Act of 1974 to protect against program and patient abuse. CMS notes that when determining whether a compensation arrangement satisfies all the requirements of an applicable exception, including fair market value and the volume or value of the physician's referrals, employer contributions to the ESOP are considered part of the employee's compensation under the arrangement.

5. Special Rules on Compensation Arrangements (§411.354(e))

a. Special Rule on Writing and Signature Requirements (§411.354(e)(4))

Section 50404 of the Bipartisan Budget Act of 2018 (P.L. 115-123) amended the physician self-referral statute regarding writing and signature requirements in certain compensation arrangement exceptions. The law permits the Secretary to determine how those requirements may be satisfied, such as through a collection of documents including contemporaneous documents evidencing the course of conduct between the parties. It also created a special rule for temporary noncompliance with signature requirements of an otherwise compliant compensation arrangement, permitting the signatures to be provided 90 days after the date of the noncompliance. CMS previously codified these policies and struck its own rule that limited use of the temporary noncompliance for signatures to once every three years.

CMS finalizes its proposal to strike regulations at §411.353(g) in effect before the final rule on this issue and to create a special rule for noncompliance with the signature or writing requirements of an applicable compensation arrangement. New section §411.354(e)(4) provides as follows:

> (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).

The reference to subpart in the regulation text above is to subpart J—the physician self-referral regulations. This authority could be used for a compensation arrangement that was noncompliant with both the signature and writing requirements. CMS notes that for short term compensation arrangements of less than 90 days, if the parties never obtained the required writing or signatures, the special rule would not be available to protect that arrangement.

CMS reiterates that a single formal written contract is not necessary to satisfy the writing requirement, and notes that parties may rely on this proposed special rule "like a safe harbor to be sure they have met the writing or signature requirements of an applicable exception." Further, the special rule would not be the only way to demonstrate compliance with these requirements.

CMS stresses that this additional flexibility does not amend or otherwise effect requirements under various exceptions that compensation must be set in advance.

b. Electronic Signatures (§411.354(e)(3))

In response to requests from commenters, CMS codifies its policy that a valid electronic signature under federal or state law satisfies the signature requirement. It also clarifies but declines to codify, that documents and records used to satisfy the writing requirement may include those that are stored electronically.

c. Set in Advance (§411.354(d)(1))

CMS did not propose changes to the special rule on compensation that is deemed to be set in advance (§411.354(d)(1)). Nonetheless, the final rule modifies the language of the deeming provision and codifies its policy for modifying compensation (or the formula used to determine compensation) during the course of an arrangement.

1. Deeming Rule. CMS emphasizes that the deeming rule (redesignated as §411.354(d)(1)(i)) is not a requirement; it is a manner by which parties can demonstrate that compensation under an arrangement is set in advance. Before the final rule, this deeming provision including a prohibition on changing or modifying the compensation in a manner that takes into account the volume or value of referrals or other business generated. Because CMS codifies its policy on modifications to compensation arrangements in the context of the set in advance requirement (described below), this language is removed from the deeming provision. In the proposed rule, CMS stated that it is not necessary for the parties to put the compensation rate in writing before furnishing services; CMS qualifies this statement. Under the final rule, compensation may be set in advance even if it is not set out in writing before the furnishing of items or services as long as

the compensation is not modified at any time during the period the parties seek to show the compensation was set in advance.

If the parties have documentation of a consistent rate of payment over the course of the arrangement, from the first payment to the last, CMS believes that will typically support an inference that the rate was set in advance. CMS believes there are numerous ways to document the amount or formula for compensation before furnishing services and includes the following examples: (i) informal communications via email or text, (ii) internal notes to file, (iii) similar payments between the same parties for similar items or services under prior arrangements, (iv) generally applicable fee schedules, or (v) where no formal generally applicable fee schedule exists, other documents showing a pattern of payments to or from other similarly situated physicians for the same or similar items or services.

CMS notes that parties that do not have the opportunity to set compensation in advance may, depending on the facts and circumstances, be able to use the new exception for limited remuneration to a physician at §411.357(z) to protect an arrangement at its outset.

2. Modifying Compensation During Arrangement. CMS finalizes conditions for modifying compensation (or the compensation formula) during the course of an arrangement at §411.354(d)(1)(ii). To satisfy the set in advance requirement, compensation (or a compensation formula) that is modified at any time during the course of a compensation arrangement, including the first 90 days of the arrangement, must meet all of the following conditions:

> (A) All requirements of an applicable exception must be met on the effective date of the modified compensation (or compensation formula).
> (B) The modified compensation (or compensation formula) 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.

Parties will not have 90 days to reduce the modified compensation (or compensation formula) to writing. Rather, it must set forth in writing in sufficient detail so that it can be objectively verified before the furnishing of items, services, office space, or equipment for which the modified compensation is to be paid.

These rules apply and must be satisfied each time there is a modification to a compensation arrangement. For example, for each modification, the modified compensation or formula must meet requirements for fair market value or the volume or value or other business generated standards that apply under the exception. CMS clarifies that the modified compensation or formula may not be applied to payments for services furnished before the effective date of the modification. CMS notes that there is no requirement for the modified compensation (or formula) to remain in place for at least one year. While there is no limit on the number of times

parties may modify the compensation or formula under a compensation arrangement, the agency cautions against frequent or repeated modifications of the course of the arrangement.

6. Exceptions for Rental of Office Space and Rental of Equipment (§411.357(a) and (b))

Certain arrangements for rental of office space or equipment are afforded an exception to the physician self-referral prohibition if, among other things, the office space or equipment is used exclusively by the lessee. The purpose of the exclusive use requirement was to prevent sham leases and to ensure that rental space or equipment could not be shared with the lessor (or any party related to the lessor).

In response to a stakeholder concern, CMS clarifies that its policy is not intended to prevent multiple lessees from using the space or equipment at the same time or to prevent a lessee from inviting a party (other than the lessor or a person or entity related to the lessor) to use the space or equipment.

CMS clarifies that the lessor (or a person or entity related to the lessor) is the only party that must be excluded from using the space or equipment. The following new language is added to §411.357(a)(3) and (b)(2): "…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 cautions that this clarification does not later requirements to comply with other conditions of each exception.

Under changes made by the final rule, the exception for fair market value compensation at §411.357(l), which does not include an exclusive use requirement, may be used for office space and equipment lease arrangements; however, other conditions of that exception (e.g., that the arrangement not violate the anti-kickback statute, commercial reasonableness etc.) would apply.

7. Exception for Physician Recruitment (§411.357(e))

This exception permits payments by a hospital to induce a physician to relocate to join the hospital's medical staff; it also permits payments by a hospital (or a FQHC) to a physician to join a physician practice. In the first case, the hospital and the physician sign the recruitment arrangement, and in the latter case the hospital and the physician practice (being the entity to which the hospital makes the recruitment payment) must sign the agreement.

To accommodate recruitment arrangements to physician practices under which payment is made directly to the recruited physician (or passed on by the practice to that physician), CMS finalizes its proposal to eliminate the signature requirement for a physician practice that receives no financial benefit under the recruitment arrangement. Thus, the physician practice is only required to sign a recruitment arrangement if the remuneration is provided indirectly to the recruited physician through payments made to the physician practice and the practice does not pass all of

the remuneration directly to the physician. CMS notes that a physician practice includes a sole practice consisting of one physician.

8. Exception for Remuneration Unrelated to the Provision of DHS (§411.357(g))

Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician does not create a compensation arrangement for purposes of the physician self-referral law if the remuneration does not relate to the provision of DHS. CMS provides extensive background on the exception for remuneration unrelated to the provision of DHS, including the legislative and rulemaking history underlying it. Commenters to the CMS RFI argued the exception did not apply to any remuneration since it was unclear what item, cost, or service could not be allocated to Medicare or Medicaid under cost reporting principles.

CMS agreed with commenters that the current exception is too restrictive, and it proposed to rewrite the requirements for the exception which deleted much of the existing language. While commenters agreed with the proposed policy, they nonetheless were concerned that expanding the exception without guidance and examples would risk program or patient abuse. CMS agrees and does not finalize any of the proposals at this time though it may undertake rulemaking in the future. The proposals are included below for reference.

- CMS proposed to substitute a more general concept "not related to patient care services" to determine when an item or service is unrelated to the furnishing of DHS for the current conditions relating to "an item, cost, or service that (i) can be allocated (in whole or in part) to Medicare or Medicaid under cost reporting principles, and (ii) 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." Thus, remuneration from a hospital to a physician for the provision of DHS would be eligible for the exception if the item or service is not related to patient care services.

- CMS proposed to remove the earlier standard which was limited to remuneration that is unrelated in any manner whatsoever; under its revised interpretation of the section 1877(e)(4) of the Act it proposed a standard to except remuneration that is unrelated to the act or process of furnishing DHS. CMS noted that a direct one-to-one correlation between a physician's services and the provision of DHS is not a condition for payments to be related to DHS.

9. Exception for Payments by a Physician (§411.357(i))

Section 1877(e)(8) of the Act excepts payments made by a physician to a laboratory in exchange for clinical laboratory services, or to an entity as compensation for other items and services if the items and services are furnished at fair market value. In codifying the exception at §411.357(i), CMS established a policy that precluded use of this exception for arrangements involving any items and services specifically excepted by another exception in §§411.355 through 411.357,

which includes the exception for fair market value compensation at §411.357(l). CMS also stated that the exception was not available to protect lease of office space.

Commenters to the CMS RFI complained that this limitation on the use of §411.357(i) unreasonably narrowed the scope of the statutory exception. The exception for payments by a physician is generally less burdensome to satisfy than the conditions for other available exceptions. In the final rule, CMS modifies this exception.

CMS makes a distinction between exceptions created in the statute (i.e., section 1877(e) of the Act) and those established by regulation. CMS believes that in the case of statutory exceptions, it must maintain the policy that the exception for payments by a physician is not available if a compensation arrangement is specifically permitted by another exception established in section 1877(e) of the Act. However, CMS believes it has the latitude to change that position for the exceptions that the agency creates through rulemaking (at §411.357(j) et seq.). It also now believes that the use of the exception for payments by a physician is not limited by exceptions created in other provisions of the statute, namely sections 1877(b) and (c) of the Act (codified at §§411.355 and 411.356) which relate to general exceptions to the referral prohibition related to both ownership/investment and compensation, and exceptions to the referral prohibition related to ownership or investment interests, respectively.

CMS finalizes its proposal to permit the use of the exception for payments by a physician unless a compensation arrangement is specifically addressed in exceptions created in paragraphs (1) through (7) of section 1877(e) of the Act (codified at §§411.357(a) through (h)). Thus, parties may rely on the exception for payments by a physician to protect fair market value payments by a physician to an entity for items and services furnished by the entity. However, this exception is not available for arrangements for rental of office space or equipment; those seeking to protect such a rental must satisfy requirements at paragraphs (a), (b), (l), or (p) of §411.357. CMS observes that the exception for payments by a physician could be used for lease or use of space that is not office space.

CMS emphasizes that items and services furnished by the entity under this exception may not include cash or cash equivalents (i.e., “in kind” payments to the entity for cash from the entity). This does not apply where the exact same amount of money was exchanged between the parties, such as paying $10 for a gift card worth $10.

Finally, CMS retracts its previous policy statement that office space is neither an item or a service; it further clarifies that office space is not a service (and thus could not qualify for protection under the personal service arrangements exception). CMS explains that this statement is no longer necessary under its interpretation of the statute explained in the final rule and was set forth because it did not believe that the exception for payments by a physician should be available to protect the type of arrangement for which the Congress established a specific exception in statute (e.g., the rental of office space or equipment). Therefore, an arrangement for the rental of office space or equipment must satisfy the requirements of §411.357(a), §411.357(b), §411.357(l) (for direct compensation arrangements), or §411.357(p) (for indirect compensation arrangements).

10. Exception for Fair Market Value Compensation (§411.357(l))

Though CMS believed the exception for fair market value compensation is an open-ended exception to protect compensation arrangements that may not be specifically addressed by other statutory exceptions, the agency previously declined to permit the exception to be used for rental of office space. It reasoned that because rental of office space was not a payment for an item or service and because office space rental had been subject to abuse, the fair market value compensation exception could not be used.

CMS finalizes its proposal to change its policy to permit the use of this exception to apply for rental or lease of office space. CMS is aware of "legitimate, nonabusive" arrangements for office space rental that cannot meet other exceptions because, for example, the lease term was less than one year. However, because CMS remains concerned with percentage-based compensation arrangements and per-click formulas to determine rental charges, it prohibits them under the final revisions to the fair market value exception in the same manner as they are restricted in the exceptions for rental of office space or equipment and other exceptions (e.g., indirect compensation arrangements).

Under this exception, parties may only enter into an arrangement once per year. However, parties may renew the arrangements on the same terms and conditions any number of times as long as the terms of the arrangement and the compensation for the same office space do not change. In the preamble to final rule, CMS states that parties are not required to renew the arrangement in writing.

In the final rule, CMS retains the condition at §411.357(l)(6) that services performed under the arrangement do not violate the anti-kickback statute. The agency believes this serves as an important substitute safeguard for requirements included in certain statutory exceptions for the rental of office space or equipment, such as the exclusive use requirement in those exceptions. However, the agency does remove the requirement that the arrangement not violate any federal or state law or regulation governing billing and claims submission.

CMS adds the modifying phrase "even if no referrals were made between the parties" to the commercially reasonable requirement at §411.357(l)(4). CMS allows parties to rely on this exception and the exception for limited remuneration to a physician at §411.357(z) to protect an arrangement for the same items, services, office space, or equipment during the course of a year.

11. Electronic Health Records (EHR) Items and Services

Changes are made to the conditions that must be met under the "EHR exception" to the referral prohibition related to compensation arrangements. The exception (at §411.357(w)) addresses certain arrangements involving the donation of interoperable EHR software or information technology and training services.

Specifically, CMS updates provisions of the exception pertaining to interoperability, removes provisions of the exception addressing information blocking, clarifies that donations of certain

cybersecurity software and services are permitted under the EHR exception, removes the December 31, 2021 expiration date, and modifies the definition of interoperability to conform to the Cures Act. In addition, the 15 percent physician contribution requirement is retained with a change in the timing of payment for updates, and certain donations of replacement technology are permitted. In finalizing these provisions CMS has aimed to be as consistent as possible with the OIG AKS final rule.

In this section, CMS refers to the final rule issued by the Office of the National Coordinator (ONC) to implement provisions of Title IV of the Cures Act (85 FR 25642). That rule adopted changes to the ONC Health Information Technology (HIT) Certification Program and provisions regarding information blocking. For purposes of this summary, the rule is referred to as the "ONC Cures Act final rule."

a. Interoperability

(1) Interoperability "Deeming Provision"

Under section §411.357(w)(2), software donated under the EHR exception must be interoperable, and software certified under the ONC certification program is deemed to be interoperable. CMS finalizes what it refers to as clarifying changes to the regulatory text.

First, the final regulations require that at the time the software is provided to the physician, it *is certified* to the certification criteria identified in the then-applicable 45 CFR part 170, meaning that the certification must be current. Software that has been certified in the past but on the date of donation is no longer maintaining certification does not meet this condition. (The previous language referred to software that *has been certified.*)

CMS emphasizes that the regulations require that the electronic health record software be interoperable, not that it meet the deeming provision. The deeming provision is optional and allows the parties to demonstrate interoperability through certification by a certifying body authorized by the ONC. CMS notes that if the software loses its ONC certification, then new donations of that software, including updates and patches of that software, will not be *deemed* to be interoperable under §411.357(w)(2). However, if the software still meets the definition of interoperable, then the EHR exception remains available to protect ongoing donations of the software, including updates and patches, provided that all other requirements of the exception are satisfied. If, on the other hand, the software that loses its certification is no longer interoperable, then new donations of the software, including updates and patches, are not protected under the EHR exception.

Second, to be consistent with changes adopted in the ONC Cures Act final rule, the regulatory text is modified to remove the reference to "an edition" of the certification criteria. CMS believes that the regulatory language referencing "then-applicable" criteria is sufficient to require that the certification be current as of the date of the donation. Finally, in a change from the proposed rule, the final regulations also eliminate the phrase "electronic health record certification criteria" in favor of "certification criteria" to reflect changes in the ONC Cures Act final rule.

CMS notes that this rule also finalizes an update to the definition of "interoperable," as discussed further in section II.D.11.d below. It emphasizes that these changes to the definition are prospective only; donated software that met the definition of interoperable or met the deeming requirements at the time of the donation continues to be protected by the EHR exception.

(2) Information Blocking and Data Lock-in

In a change from the proposed rule, CMS eliminates the condition of the EHR exception at §411.357(w)(3) that prohibits the donor from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems (including, but not limited to, health IT applications, products, or services).

CMS agrees with commenters that this provision, which was adopted in the 2006 EHR final rule (71 FR 45140), has been superseded by new enforcement authorities regarding information blocking. For example, CMS notes that the Cures Act provides ONC and the HHS OIG with direct authority to address information blocking, and that CMS itself has separate authority to address providers that engage in information blocking.

Therefore, instead of finalizing its proposal to modify the regulatory text to require that the donor does not engage in a practice that constitutes information blocking in connection with the donated items or services, CMS strikes the provision altogether. It believes that maintaining the interoperability requirement at §411.357(w)(2) will ensure that donations of items and services that satisfy all the requirements of the EHR exception will further the HHS policy goal of an interoperable health system and prevent donations of items and services intended to lock in referrals by limiting the flow of electronic health information. Parties are encouraged to report concerns about potential information blocking to https://inquiry.healthit.gov/support/plugins/servlet/desk/portal/6/create/67.

b. Cybersecurity

CMS finalizes its proposal to add a specific reference to cybersecurity in the introductory text to §411.357(w) to clarify that the EHR exception is available to protect the donation of cybersecurity software and services and software that "protects" EHRs. Specifically, the final language states that the EHR exception applies to software or IT and training services, *including cybersecurity software and services*, necessary and used predominantly to create, maintain, transmit, receive *or protect* electronic health records if the identified conditions are met. (The proposed rule would have referred to "certain cybersecurity software and services," but CMS does not finalize use of the word "certain" to avoid ambiguity about the scope of the EHR exception.)

Elsewhere in this final rule (see section II.E.2 below), CMS finalizes a new exception to protect arrangements involving the donation of cybersecurity technology and related services. This separate "cybersecurity exception" is broader and includes fewer requirements than the EHR exception. For example, there is no cost contribution requirement under the cybersecurity

exception. In addition, that exception covers donations of cybersecurity hardware and standalone cybersecurity software that is used predominantly to implement, maintain, or re-establish cybersecurity, whereas the EHR exception is focused on software or information technology and training services used predominantly to create, maintain, transmit, receive, or protect electronic health records.

The modification to the EHR exception is intended to make clear that an entity donating EHR software and providing training and other related services may also donate cybersecurity software to protect the EHR. The definition of cybersecurity discussed in II.E.2 also applies to the EHR exception. The donation of cybersecurity software and services must comply with only one of the two exceptions.

c. Sunset Provision

The EHR exception was originally adopted in the 2006 EHR final rule (71 FR 45140) and was scheduled to expire on December 31, 2013. The sunset was included because CMS believed that the need for the exception would diminish over time as the use of EHR technology became a standard and expected part of medical practice. In subsequent rulemaking the sunset date was extended to December 31, 2021, as CMS continued to believe that the need for the exception would diminish over time.

CMS finalizes its proposal to make the EHR exception permanent. It now believes that continued availability of the EHR exception promotes EHR technology adoption by providing certainty with respect to the cost of EHR items and services for recipients and in other ways.

d. Definitions

With changes from what it proposed, CMS updates the definition of "interoperable" in §411.351 to reflect terms and provisions of the Cures Act. Under the final rule, *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 authorized use under applicable State or Federal law.

The new definition of interoperability is intended to reflect updated terminology. CMS does not include its proposed reference to the prohibition of information blocking in the definition of interoperable out of concern that it could prohibit parties from engaging in practices that might not be prohibited under ONC rules. In addition, the proposed inclusion of a reference to exchange of data without special effort is not finalized to avoid the implication that CMS is incorporating a certification requirement into the definition of interoperable.

CMS does not finalize any proposed changes to the definition of "electronic health record" because it agrees with commenters that the proposed definition could inadvertently have made a substantive change in the scope of the EHR exception. In addition, CMS notes that the definition

of electronic health information in the ONC Cures Act final rule differs from the definition it had referenced in the proposed definition of electronic health record.

In the unchanged definition, *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.

e. Additional Proposals and Considerations

(1) 15 Percent Recipient Contribution

The final rule retains the requirement at §411.357(w)(4) that, as a condition to the EHR exception, before receiving donated items and services the physician must pay 15 percent of the donor's cost of the item or service; changes are made to the timing of the payments, however. Specifically, the final language provides that with respect to items and services received from the donor *after* the initial donation, the physician pays 15 percent of the donor's cost for the items and services *at reasonable intervals*. That is, the payment need not be made prior to receipt of the donated items and services made after the initial donation.

CMS recognizes that updates may need to take place quickly to remedy security problems or other issues with EHR software. It does not believe there is a risk of program or patient abuse to allow payment to be made after receipt of the updates if payments are made at reasonable intervals. By contrast, CMS notes that the initial donation can be planned by the parties with all expenses known in advance. It further notes that the EHR exception does not require a specific billing method, but payments must be made by the physician at regular intervals.

In the proposed rule, CMS sought comments on alternatives that would eliminate or reduce the 15 percent contribution requirement for all physician recipients, for small or rural physician organizations, or for updates to previously donated EHR software or technology. After considering comments, CMS concludes that retaining the contribution requirement is an important safeguard to protect against program or patient abuse. It believes that when physicians are expected to contribute to the cost, they are more likely to only accept donations of items and services they need. It believes the program integrity risks of donation of EHR items and services are present regardless of the geography or size of the recipient. Further, CMS believes that applying the cost contribution requirement only to the initial donation and not to updates, as supported by some commenters, could result in gaming of how the donations are structured.

CMS reminds readers that depending on the facts and circumstances, donations of EHR items and services may qualify under the new exceptions for value-based arrangements (discussed in section II.A above) which do not require a cost contribution. In addition, as noted above the new cybersecurity exception does not require a cost contribution for donated items and services. In the final rule, CMS also responds in detail to a question about how the cost contribution requirement is operationalized when the donation is made to a physician organization rather than an individual physician.

(2) Equivalent Items and Services (Replacement Technology)

The final rule allows donations of replacement EHR technology under the EHR exception by striking §411.357(w)(8), which prohibits the donation of equivalent technology or services. Replacement items and services will be treated the same as a new donation, and arrangements for donation of replacement EHR items and services will need to meet all the requirements of the exception to avoid the self-referral prohibitions. CMS believes that this policy will make necessary replacements financially feasible for recipients while maintaining safeguards to protect against program or patient abuse.

12. Exception for Assistance to Compensate a Nonphysician Practitioner (NPP) (§411.357(x))

Under this exception a hospital, a FQHC, and a rural health clinic may provide remuneration to a physician to assist with the employment of an NPP to provide patient care services (e.g., recruitment costs), subject to several conditions. One of those conditions was that the NPP may not have, within one year of the commencement of the compensation arrangement with the physician, (i) practiced in the geographic area served by the hospital or (ii) been employed or otherwise engaged to provide patient care services by a physician or physician organization with a medical practice site in the geographic area served by the hospital. Commenters expressed concerns or confusion with this and other provisions of the exception; CMS finalizes its proposals to address stakeholder confusion and concern.

CMS creates a new term "NPP patient care services" that means direct patient care services furnished by an NPP that address medical needs of specific patients or any task performed by an NPP that promotes care of patients of the physician or physician organization with which the NPP has a compensation arrangement. That term is substituted for the term "patient care services" throughout the exception. Similarly, CMS substitutes the term "furnished NPP services" for the more general term "practiced." This is intended to address the situation where before becoming an NPP, an individual may have been a registered nurse and provided patient care services; those services would not count as NPP patient care services for purposes of the one-year requirement.

CMS makes a similar clarifying revision to the term "referral" as defined in §411.357(x)(4), using instead the term "NPP referral" in this exception.

The final rule adds a requirement that the compensation arrangement between the hospital (or FQHC or rural clinic) and the physician must begin before the physician enters into the compensation arrangement with the NPP. This is intended to clarify that the exception is not available for a hospital to simply reimburse a physician for overhead costs of current employees.

13. Updating and Eliminating Out-of-Date References (§411.355(c)(5))

§411.355(c) exempts services furnished by an organization (or its contractors or subcontractors) to enrollees of prepaid health plans listed in the regulation from the ownership or investment and

compensation prohibitions, including coordinated care plans offered by Medicare Advantage organizations. It excludes medical savings account plans and private fee-for-service plans.

CMS makes technical changes to the language of §411.355(c)(5). The modifier "Medicare Advantage" is inserted before "organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter" to update the language of the regulation. Additionally, "Web site" is changed to "website."

E. Providing Flexibility for Nonabusive Business Practices

1. Limited Remuneration to a Physician (§411.357(z))

CMS says it is aware of several nonabusive arrangements under which limited amounts of remuneration were paid to a physician for the provision of items or services to the entity but that were not covered by any existing exception. These include ongoing service arrangements for sporadically furnished services or for a low compensation rate, or services furnished for short periods of time. CMS cites the example of the appointment of a temporary medical director while the hospital was finalizing its engagement of a new medical director. The arrangements failed to satisfy existing exceptions because the compensation was not set in advance, was not in writing and signed by the parties, or exceeded limits for de minimis compensation or nonmonetary compensation.

a. Finalized Exception

CMS proposed a new exception at §411.357(z) for limited remuneration to a physician. The agency finalizes its proposal with several modifications. The exception protects remuneration that does not exceed an aggregate of $5,000 per year (adjusted annually for inflation by CPI-U) from an entity to a physician for the physician to provide items or services 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 are made between the parties.
iv. Compensation for the lease of office space or equipment is not determined using a formula based on—
    - 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
    - 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 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
- 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) (relating to requirements for directed referrals under the rules on special compensation).

b. Modifications from the Proposed Rule

The final rule increases the annual aggregate limit for the first year from $3,500 to $5,000; CMS reminds readers that the limit resets each year. For arrangements that straddle calendar years, remuneration should be allocated based on the date the items or services are provided. CMS notes that the exception may be applied to different types of services provided by the physician, and the limit is determined by adding compensation for all the various items and services.

Another modification from the proposed rule is that the exception will permit the physician to provide items or services through employees whom the physician has hired to perform the services, through wholly-owned entities, or through *locum tenens* physicians (as defined at §411.351, except that the regular physician does not have to be a member of a group practice). However, the exception will not allow a physician to provide items and services through an independent contractor. Additionally, CMS clarifies that any payments for items or services provided through the physician's employee, wholly owned entity, or *locum tenens* physician will be counted towards the annual aggregate limit on remuneration for the physician.

For arrangements seeking to use this exception that require physician referrals to a particular provider, practitioner, supplier, CMS adds a condition to require that those arrangements satisfy the requirements of 411.354(d)(4) (described above in section II.C.4.), including that the compensation be set out in advance for the duration of the arrangement, and the directed referral requirement is set out in writing and signed by the parties. These conditions do not otherwise apply under the limited remuneration to a physician exception; however, to protect patient choice, CMS includes these requirements only for directed referral arrangements that seek to use this exception.

CMS revises its proposal with respect to the per-click and percentage-based compensation provisions. CMS narrows the application of those conditions to apply only to timeshare arrangements. Responding to concerns that the proposed condition could have an impact on arrangements other than timeshare arrangements, which is what CMS intended to address with its proposed condition, the condition as finalized applies only to the use of premises (including office space) or equipment.

Noting that most exceptions that include a commercial reasonableness requirement stipulate that the arrangement must be commercially reasonable "even if no referrals are made" between the parties (including the exceptions that could apply to the new limited remuneration to a physician exception), CMS conforms the commercial reasonableness in this new exception to meet the same standard.

In the proposed rule, CMS noted that it would not require an arrangement for limited remuneration to a physician to be covered by a personal service arrangement protected under §411.357(d) or listed in a master list of contracts. Similarly, the agency would not consider an arrangement for limited remuneration to a physician to violate prohibition on entering into an arrangement for the same items and services during a calendar year under the fair market value exception. In the final rule, CMS adds regulation text at §411.357(d)(1)(ii) (for the personal service exception) and at §411.357(l)(2) (for the exception for fair market value compensation) to codify those policies.

c. Other Clarifications

With the exception of the requirement for arrangements with directed referrals, the exception for limited remuneration to a physician applies even in the absence of documentation for the arrangement and even when the amount or formula for calculating the remuneration is not set out in advance.

CMS does not count toward the $5,000 limit compensation to a physician for items and services provided outside the arrangement if those items and services are protected under (i) the general exceptions to the referral prohibition related to both ownership/investment and compensation under §411.355 or (ii) an exception for compensation arrangements under §411.357. CMS cautions that if an entity has multiple undocumented, unsigned arrangements under which it compensates physicians for items and services, CMS considers the parties to have a single compensation arrangement for those items and services. In this case, the aggregate compensation under the arrangements could not exceed $5,000 during the year to qualify for protection under this exception. On the other hand, CMS notes that this exception could be used in conjunction with other exceptions, including as a temporary measure before the parties satisfy the requirements for another exception.

In response to comment, CMS notes that the exception was structured to apply to remuneration form an entity to a physician. It did not propose (or finalize) an exception that permits a specific amount of remuneration from an entity to a physician organization. CMS notes that compensation arrangement requirements at §411.354(c) treat remuneration from an entity to a physician organization as a direct compensation arrangement between the entity and each physician who stands in the shoes of the physician organization. The agency states that the exception for limited remuneration to a physician is available to protect direct compensation arrangements to an individual physician as well as a deemed direct compensation arrangement with each physician who stands in the shoes of the physician organization. Compensation received under the latter circumstance is counted towards the annual aggregate limit of *each* physician who stands in the shoes of the physician organization.

This exception does not apply to payments from an entity to a physician's immediate family member or to payments for items and services furnished by the physician's immediate family member. However, CMS notes that the exception will permit compensation to a physician for services furnished through an immediate family member if that family member is an employee of the physicians and is acting at the direction of the physician (assuming all other conditions of the exception are met).

Because CMS has throughout the proposed rule stated that it is retracting earlier statements that office space is not an item or a service, leasing of office space or equipment is included in this exception as are limits on percentage-based compensation and per-unit of service compensation.

CMS does not include a requirement that the arrangement must not violate the anti-kickback statute or other federal or state law or regulation on billing and claim submission. CMS notes that if remuneration implicates the anti-kickback statute, the exception neither affects a party's obligation to comply with that statute nor ensures compliance with that statute.

2. Cybersecurity Technology and Related Services (§411.357(bb))

A new exception to the referral prohibition related to compensation arrangements is adopted for certain arrangements involving donation of cybersecurity technology and related services ("the cybersecurity exception"). It appears as a new §411.357(bb). A related provision is included in the OIG AKS final rule.

The addition of this exception is made to support improvements in the cybersecurity status of the health care industry. CMS cites recent cyberattacks on health care systems, and notes that the entire interconnected health information system bears the risks associated with a cyberattack originating with weak links. The Health Care Industry Cybersecurity Task Force report issued in June 2017[9] recommended that Congress consider a cybersecurity exception to the physician-self referral law and anti-kickback statute similar to the EHR exception. CMS believes that an entity wishing to protect itself from cyberattacks has an interest in assuring that physicians with whom it shares data are also protected, especially when the connections are bi-directional. It believes the cybersecurity exception promotes increased security without protecting potentially abusive arrangements.

Under the final rule, nonmonetary remuneration (consisting of technology and services) necessary and used predominantly to implement, maintain, or reestablish cybersecurity is excepted from the referral prohibition related to compensation arrangements if all the following conditions are met. For purposes of this exception, technology means any software or other types of information technology.

[9] The report is available at https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf

- Neither the eligibility of a physician for the technology or services, nor the amount and 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.
- Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of, or the amount or nature of, the technology or services a condition of doing business with the donor.
- The arrangement is documented in writing.

a. Covered Technology and Services

The cybersecurity exception applies broadly to technology or services that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. CMS says that it takes a neutral position on the types software that can receive protection. It does not distinguish between cloud-based software and software installed locally.

CMS provides illustrative and non-exhaustive examples of the types of technology and services to which the cybersecurity exception applies. The types of technology include software that provides malware prevention, software security measures to protect endpoints that allow for network access control, business continuity software, data protection and encryption, and email traffic filtering. CMS notes that software patches and updates are not excluded if all the requirements of the exception are met. The types of services include those associated with developing, installing, and updating cybersecurity software; cybersecurity training services; cybersecurity services for business continuity and data recovery services; models that rely on a third-party service provider to manage, monitor, or operate cybersecurity of a recipient; services associated with performing a cybersecurity risk assessment or analysis, vulnerability analysis, or penetration test; and services associated with sharing information about known cyber threats, and assisting recipients responding to threats or attacks on their systems.

In addition, in a change from the proposed rule, the finalized the exception also applies to hardware that is necessary and used predominantly to implement, maintain, or reestablish cybersecurity. The discussion in section II.E.2.b below regarding the definition of "technology" elaborates on this change.

CMS emphasizes that to meet the conditions of the exception the technology or service must predominantly be used for cybersecurity. For example, the exception would not apply to general IT help desk services used predominantly in the normal course of the recipient's business but would apply to help desk services specific to cybersecurity. Parties must show on a case-by-case basis that the "used predominantly" requirement is met. As it does for the EHR exception, CMS will apply a "core functionality" principle. That is, while donated technology and services may include functions other than cybersecurity, the core functionality must be implementing, maintaining, or reestablishing cybersecurity, and the cybersecurity use must predominate. To meet the exception, the technology and services must also be necessary for implementing, maintaining, or reestablishing cybersecurity. CMS emphasizes that in all cases, the donation of services must be nonmonetary.

CMS had sought comments on whether to deem that donors and recipients satisfy the "necessary to" requirement if they demonstrate that the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework or set of standards. No deeming policy is adopted in the final rule, however, after CMS concludes that any deeming provision that is specific enough to address program integrity concerns would be of limited or no use to stakeholders.

The final regulatory text is restructured from the proposed rule to be parallel to the EHR exception, with the general requirement for necessity and predominant use for cybersecurity in the introductory matter before the specific conditions that must be met.

b. Definitions

CMS defines "cybersecurity" as the process of protecting information by preventing, detecting, and responding to cyberattacks. The definition (at §411.351) applies to this cybersecurity exception and also to the modified EHR exception at §411.357(w) discussed in II.D.11 above. This broad definition is derived from the National Institute for Standards and Technology Cybersecurity Framework (NIST CSF), which is not specific to the health care industry. CMS aimed to avoid a narrow definition that might become obsolete over time. Although the cybersecurity exception does not require compliance with the NIST CSF, potential donors and recipients are encouraged to ensure a comprehensive, systematic approach to identifying and managing cybersecurity risks.

"Technology" is defined in §411.357(bb) as any software or other types of information technology. CMS notes that the definition captures Application Programming Interface technology, which is neither software nor a service.

In a change from the proposed rule, the final definition of technology does not exclude hardware. Many commenters had suggested that the exception apply to certain types of hardware, and CMS concludes that its program integrity concerns are adequately addressed by limiting the exception to donated services and technology that are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

Examples of hardware that could be permitted under the exception (if all requirements are met) include encrypted servers, encrypted drives, and network appliances, computer privacy screens, two-factor authentication dongles and security tokens, facial recognition cameras for secure access, biometric authentication, secure identification card and device readers, intrusion detection systems, data backup systems, and data recovery systems.

CMS notes that if, for example, an encrypted server is used predominantly to host the computer infrastructure of a recipient, it would not satisfy the necessary and used predominantly requirement of the cybersecurity exception, even if the encrypted server has ancillary cybersecurity uses and functionality. Further, CMS offers that certain examples raised by commenters, including locks on doors, upgraded wiring, physical security systems, fire retardant or warning technology, and high security doors do not qualify as technology under the exception

because they are physical infrastructure improvements, not software or other information technology.

c. Requirements for Donors

The final cybersecurity exception requires that eligibility of a physician for the technology or services, and its amount and nature are not determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. CMS recognizes that donors provide cybersecurity technology and services only to physicians that connect to their systems, but the condition prohibits the donor from conditioning the donation on referrals or other business generated.

CMS states that nothing would require a donor to donate cybersecurity technology and services to every physician connected to its system. Recipients could be selected in a variety of ways as long as selection is not based on the volume or value of referrals or other business generated. A donor could, for example, choose to provide a higher level of cybersecurity technology to physicians with whom it has bi-directional connections than those with a read-only connection. Other examples are offered.

As was proposed, the cybersecurity exception does not include a list of selection criteria which would be deemed to meet this requirement, as is the case with the EHR exception (§411.357(w)(6)).[10] CMS considered the comments it sought and received on this issue but is concerned that such safe harbor provisions would be interpreted as prescriptive and act as limits on the type or range of items and services deemed acceptable and as a result, inhibit appropriate cybersecurity donations. Moreover, the final rule does not restrict the types of entities that may make donations under the cybersecurity exception. CMS believes that the program integrity risks associated with arrangements for the donation of cybersecurity technology and services differ from those associated with donations of other valuable technology, such as EHR items and services.

d. Requirements for Recipients

The cybersecurity exception prohibits a potential recipient or the potential recipient's practice (including employees or staff members) from making receipt of the technology or services or the amount and nature of the technology or services a condition of doing business with the donor. A parallel requirement is included in the EHR exception and the OIG AKS final rule.

[10] §411.357(w)(6) provides that for purposes of the EHR exception, the determination of a donation is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if it is based on any of the following: (I) the total number of prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program); (ii) the size of the physician's medical practice; (iii) the total number of hours that the physician practices medicine; (iv) the physician's overall use of automated technology in his or her medical practice; (v) whether the physician is a member of the donor's medical staff; (vi) the level of uncompensated care provided by the physician; or (vii) the determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

No requirement for a recipient contribution is included under the cybersecurity exception because CMS seeks to remove a barrier to donations that improve cybersecurity in the health care industry. It does not believe that a minimum contribution requirement is necessary or practical. Because the level of services might vary by recipient and over time, some physician practices, particularly solo practices or those in rural areas, might not be able to make the required contribution which would threaten cybersecurity of the systems in which they participate. Similarly, if donors were to aggregate costs of cybersecurity updates and allocate them across recipients, contribution requirements may become a barrier to adoption of improvements because of the costs allocated to each recipient. However, CMS notes that donors are free to require recipients to contribute to the cost and such contributions are permissible if all other conditions of the cybersecurity exception are met. CMS cautions that the amount of a required contribution may not take into account the volume or value of the physician recipient's referrals or other business between the parties.

e. Written Documentation

Under the final cybersecurity exception, the arrangement between a donor and recipient must be documented in writing. CMS expects that this documentation will identify the recipient, provide a general description of the cybersecurity technology and services donated, the timeframe for the arrangement, a reasonable estimate of the value of the donation, and any financial responsibility to be borne by the recipient. A signed contract is not required, as CMS believes this could result in inadvertent violations if a donor needs to act quickly to provide cybersecurity technology and this occurs before a contract is signed.

CMS notes that the regulatory text does not specify which terms of the arrangement must be in writing. Citing the 2016 Medicare physician fee schedule final rule (80 FR 71315), it believes that the appropriate standard is that the writing requirement is satisfied if contemporaneous documents permit a reasonable person to verify compliance with the exception at the time that a referral is made.

F. Nonsubstantive Changes and Out-of-Scope Comments

CMS provides the entire text of §§411.351 through 411.357 in the final rule for stakeholders. In doing so, it reports having made some updated or new citation references in these sections. Further, terminology is updated, such as changing "can" to "may" or other changes that reflect the agency's current lexicon.

Out-of-scope comments are not addressed in this final rule but may be addressed in other rulemaking. CMS cautions that silence with respect to these out-of-scope comments should not be interpreted as an affirmation of any views of the commenters.

III. Collection of Information Requirements (ICR)

Under the Paperwork Reduction Act of 1995, CMS is required to provide notice and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. CMS, however, believes that the information required for the exception for value-based arrangements and other exceptions added or modified by the final rule do not increase burden and so are exempt from ICR requirements. CMS states that the documentation that would be necessary to support these exceptions are necessary for normal business operations to enforce the legal obligations of the parties, so there is no increase in burden.

IV. Regulatory Impact Statement

CMS examined the impact of the final rule as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, the Regulatory Flexibility Act (RFA), section 202 of the Unfunded Mandates Reform Act of 1995, Executive Order 13132 on Federalism, the Congressional Review Act, and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs.

In response to those requirements:

- CMS does not provide an analysis for the RFA because it determines that the rule would not have a significant economic impact on a substantial number of small entities. Instead, CMS asserts that it will likely to reduce, not increase, regulatory burden. CMS estimates that entities will incur costs of less than $1,000 per entity.
- CMS does not provide an analysis of the rule's potential impact on the operations of a substantial number of small rural hospitals because it is expected to have a minimal impact on such facilities.
- CMS states that the final rule changes do not impose any costs on state, local or tribal governments, or the private sector.
- Because the rule is a deregulatory action, CMS does not provide an estimate of the costs associated with significant new regulations nor offset those costs by eliminating prior regulations.

CMS estimates the total costs of review of the final rule by all directly affected entities during the first year after it is published to be $64 million. Other budgetary effects are not estimated although CMS expects many of the changes will reduce compliance burden for impacted providers.

Alternatives considered. CMS considered maintaining the status quo but believes that a transition to a value-based system and improvements to care coordination are urgently needed; it sees these additional flexibilities as critical to that transition and those improvements.

CMS also considered limiting exceptions to CMS-sponsored models or establishing separate exceptions for models not sponsored by CMS but determined that broader scale changes were necessary. CMS also considered establishing an exception to protect care coordination activities

performed outside of a value-based enterprise but rejected doing so because of program integrity concerns. It also rejected including exceptions for value-based arrangements that would require compensation to be set in advance, be fair market value, or not be determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated between the parties; however, it concluded that those changes would conflict with the goal of addressing barriers to value-based transformation. CMS also considered excluding laboratories and DMEPOS suppliers from the definition of the term VBE participant; however, it does not exclude any entity from the final definition of that term. CMS states that it took great care to provide additional guidance in the clearest manner possible. For example, it considered whether to provide guidance on the applicability of the physician self-referral law to referrals for inpatient hospital services after admission by modifying the definition of the term referral; however, due to concerns that modifying the definition of referral to address the issue would have broader applicability and would not be as clear, it abandoned that approach. CMS notes that it did not receive any comments to the section of the proposed rule describing alternative considered.