

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

Proposed Rule Summary

On October 17, 2019, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* (84 FR 55766-55847) a proposed rule to update regulations implementing section 1877 of the Social Security Act (the physician self-referral law). CMS proposes exceptions for certain value-based compensation arrangements among physicians, providers of services and suppliers. It would also create new exceptions for compensation arrangements for limited remuneration for physicians, and for donations of cybersecurity technology and related services. CMS also proposes to modify the exception for electronic health record (EHR) items and services, and makes a number of clarifications and modifications to existing exceptions and terminology. It also provides guidance to physicians, providers and suppliers.

Also on October 17, 2019, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published in the *Federal Register* (84 FR 55694-55765) a proposed 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 proposed rule.

Comments on both proposed rules must be submitted by close of business on December 31, 2019.

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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 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 proposed 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 (CMS-1720-NC; 83 FR 29524) 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.

Noting that section 1877 was enacted to address concerns under Medicare’s volume-based reimbursement system (which rewarded quantity of services ordered as opposed to quality of services furnished to beneficiaries) 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 proposed 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.

CMS states that it now has vast knowledge of aspects of financial relationships that result in program or patient abuse, including through submissions to its Voluntary Self-Referral Disclosure Protocol. The agency believes that while many financial arrangements ran afoul of the physician self-referral law, they did not pose any real risk of Medicare program or patient abuse.

CMS notes that it coordinated with the Office of Inspector General in developing its proposals because many compensation arrangements implicate the AKS and the beneficiary inducement CMP law. Where possible, the agencies seek to promote alignment to ease compliance burden on industry stakeholders; however, CMS notes that the underlying statutes differ in a number of respects which complicates efforts to align the policies. CMS says that it reassessed the appropriate scope of the physician self-referral law in balancing what it refers to as genuine program integrity concerns against the burden of compliance with the law.

II. PROVISIONS OF THE PROPOSED REGULATIONS

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

1. Context

CMS begins by highlighting concepts that were widely-supported by respondents to the CMS RFI: the urgency of moving from the Medicare program's legacy, volume-based structure to a value-based care delivery system; the critical importance of identifying and dismantling regulatory barriers to value-based care transformation; and the intrinsic potential of integrated care models to minimize overutilization by aligning clinical and economic performance benchmarks. CMS indicates support for these concepts but also for making changes cautiously while the healthcare landscape is actively evolving and fee-for-service (FFS) Medicare continues to be predominant. CMS notes that most commenters requested several new and revised exceptions to the physician self-referral law, although a few argued for a single exception applicable to any value-based compensation arrangement in order to reduce legal complexity and to minimize providers' regulatory burden. CMS expresses skepticism that the latter "one size fits all" approach would succeed given the wide variability currently found among value-based arrangements. CMS closes by stating a belief that the exceptions proposed in this rule would appropriately balance ensuring program integrity with making compliance with the physician self-referral law readily achievable, while providing the flexibility required for success by participants in value-based health care delivery and payment systems.

2. Proposed Exceptions and Definitions: General Considerations

a. Goals

CMS discusses at length the challenges of protecting against patient and program abuses while removing regulatory barriers to innovation during a period of transformation from volume-based to value-based care, when many new payment models include elements of FFS and value-based payment mechanisms. Reflecting responses received to the CMS RFI and experience gained in administering accountable care models, CMS articulates overarching goals for self-referral exceptions: 1) creating space and flexibility for industry-led innovations that deliver more efficient and better-coordinated care; 2) permitting self-referral law exceptions that incent increased assumption of downside risk by providers; and 3) facilitating rather than inhibiting healthcare marketplace experimentation by maintaining neutrality regarding allowable types of value-based arrangements and enterprises.

b. Fair Market Value, Referral Volume and Value, and Commercial Reasonableness

CMS also identifies requirements of current self-referral exceptions that it believes may actually inhibit value-based payment such as setting compensation in advance, providing fair market value, and prohibiting consideration of the volume or value of referrals. CMS indicates a belief that carefully-crafted definitions built into value-based self-referral exceptions will suffice to protect against program or patient abuse, particularly when meaningful or full downside risk is assumed by providers. CMS proposes to require that the methodology used to set compensation under an excepted value-based arrangement, but not the actual amount, be set before care is furnished. However, CMS does not propose requirements for compensation to be at fair market value or to ignore the volume or value of referrals. **CMS seeks comment on this approach to proposing self-referral exceptions, particularly whether the concepts of fair market value, volume or value of referrals, or commercial reasonableness should be incorporated into the requirements for the excepted arrangements.**

c. Special Rule §411.354(d)(4) and Protecting Patient Choice

Relatedly, CMS notes that the current special rule at §411.354(d)(4) generally would not be applicable to arrangements protected under the proposed value-based self-referral exceptions, as these arrangements would not prohibit compensation based upon volume or value of referrals. (The special rule permits the entity to which a physician belongs to direct the physician's referrals so long as physician medical judgment and patient choice are preserved.) However, to emphasize the critical importance of patient choice in the context of physician self-referrals, CMS proposes to incorporate compliance specifically with §411.354(d)(4)(iv) by reference into the proposed self-referral exceptions for value-based arrangements. (Under §411.354(d)(4), physician compensation arrangements must both describe in a signed writing the requirement to make directed referrals and allow that the directed referral requirement would not be applicable when the patient expresses a preference for a different provider, practitioner, or supplier or when the physician judges the referral not to be in the patient's best medical interests.) Alternatively, the self-referral exception for value-based arrangements proposed at §411.357(aa) could include a separate requirement to ensure that, regardless of the nature of the value-based arrangement

and its value-based purpose(s), the regulation adequately protects a patient’s choice of provider and the physician’s medical judgment. **CMS seeks comment about the two approaches to protecting patient choice in excepted value-based arrangements.**

d. Model Applicability

As previously noted, CMS has adopted the goal of maintaining neutrality regarding allowable types of excepted value-based arrangements and enterprises. By so doing, CMS seeks to avoid making self-referral law compliance either a driver or a barrier to healthcare system innovation. To support innovation on a broad scale and across all payer types, CMS is not proposing to limit exceptions for value-based arrangements to CMS-sponsored models or to establish separate exceptions and different criteria for arrangements other than CMS-sponsored models.

e. Implementation

CMS is proposing three new exceptions to the physician self-referral law for value-based compensation arrangements at §411.357(aa): the full financial risk exception, the meaningful downside risk exception, and the value-based arrangements exception. The exceptions are differentiated by their arrangement characteristics and the risk levels assumed by participants. All three exceptions would be applicable to arrangements involving Medicare beneficiaries, patients outside of Medicare, or mixed patient populations. CMS emphasizes that the new exceptions would not alter the potential for many existing value-based arrangements (e.g., pay-for-performance) to satisfy currently-available self-referral law exceptions.

Concomitantly, CMS proposes definitions for six new terms at §411.351 that would enable the exceptions to be applied, as the exceptions are open only to value-based arrangements and participants that meet the relevant definitions. CMS intends that the definitions and exceptions when combined would create a single set of requirements whose satisfaction would provide protection from the law’s referral and claims submission prohibitions. Finally, CMS describes coordinating closely with OIG during the development of the proposed exceptions, definitions, and related policies, thereby seeking alignment with OIG’s proposals wherever feasible to limit providers’ compliance burden.

3. Specific Proposed Definitions (§411.351)

To implement the proposed value-based arrangements exceptions to the physician self-referral law, CMS proposes six interrelated definitions, excerpted in the table below and expanded upon in the subsequent narrative.

Term	Proposed 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 between or among — (1) The value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same VBE.

Term	Proposed Definition
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.
VBE participant	An individual 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.

a. Value-Based Activity

The activity or activities serve as the basis for the compensation arrangement although may not involve one-to-one payment for a specific item or service (e.g., shared savings distribution). CMS emphasizes that merely making a referral is not a value-based activity.

b. Value-Based Arrangement

Effectively, parties to the arrangement would be an entity (as defined at §411.351) furnishing designated health services and a physician, otherwise the self-referral law would not apply. CMS expects that patient care coordination and management would be part of most arrangements but is not proposing to limit the universe of qualifying compensation arrangements only to those for care coordination and management. **CMS seeks comment whether this flexible approach poses a risk of program or patient abuse that should be addressed through a revised definition of “value-based arrangement” that would require care coordination and management in order to qualify as a value-based arrangement.**

c. Value-Based Enterprise (VBE)

CMS states an intent for VBEs to include only organized groups of healthcare providers, suppliers, and other entities who collaborate to achieve value-based healthcare goals (e.g., improved patient outcomes). A VBE would not be required to be a distinct legal entity and would have no upper size limit.

d. Value-Based Purpose

A value-based purpose would be required to serve one more of the four core goals enumerated in the definition. Achieving the goal(s) must be furthered by one or more value-based activities. **CMS seeks comment as to whether the core goals are well-understood concepts or need additional interpretation. Specifically, CMS seeks comment whether the meaning of “coordinating and managing care” should be included in regulation text and, if so, proposes a definition similar to one being considered by OIG (i.e., the deliberate organization of patient care activities and sharing of information between two or more VBE participants, tailored to improving the health outcomes of the target patient population, in order to achieve safer and more effective care for the target patient population). Further, CMS seeks comment on permissible ways to determine whether quality of care has improved, a methodology for determining whether costs are reduced or expenditure growth has been stopped, or what parties must do to show they are 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.** CMS voices concern that the absence of defined boundaries for volume-to-value transitioning could complicate ascertaining whether an arrangement’s purpose is in fact value-based and merits a self-referral exception. **CMS also seeks comment on its decision not to propose that the reduction of costs to patients be considered a value-based purpose, a decision made to reduce incentives for gaming and inappropriate cost-shifting by participants.**

e. VBE Participant

CMS seeks comment about potential confusion generated by using the term “entity” in the definition of a VBE participant, because the current definition of entity at §411.354 (primarily focused on various physician practice and health plan configurations) does not mesh well with the participant types for many value-based arrangements. **CMS also seeks input about explicitly excluding laboratories and durable medical equipment, prosthetics, and orthotics supplies (DMEPOS) suppliers in the definition of VBE participants because of fraud and abuse concerns, or, alternatively, explicitly stating under each of the proposed new self-referral law exceptions that laboratories and DMEPOS suppliers would not be eligible to be VBE participants.**

f. Target Patient Population

Criteria for patient population selection must be appropriate to the value-based purpose(s) of the arrangement and set out in writing before the arrangement starts. “Legitimate and verifiable” criteria may include medical or health characteristics (e.g., patients with a specified disease), geography (e.g., patients within a county), or payor status (e.g., patients within a health plan), but would not include purely financial characteristics that could lead to selecting only adherent patients (“cherry-picking”) or avoiding noncompliant patients (“lemon dropping”). **CMS seeks comment on the proposed requirement for legitimate and verifiable population selection criteria as well as on additional or substitute criteria appropriate for target population selection.**

4. Specific Proposed Exceptions (§411.357(aa))

CMS invokes the Secretary's authority under section 1877(b)(4) of the Act to propose three separate exceptions to the physician self-referral law applicable, respectively, to value-based arrangements in which the value-based enterprise assumes full financial risk, meaningful downside financial risk, or meets specified requirements regardless of financial risk level. CMS anticipates that, taken collectively, these exceptions, if finalized, would eliminate the need for future new waivers of section 1877 of the Act for CMS-sponsored value-based arrangements.

However, CMS seeks comment about CMS-sponsored arrangements that might not qualify for any of the three proposed exceptions and how such arrangements could be excepted.

CMS states that existing exceptions applicable to certain value-based arrangements (e.g., §411.355(c) and §411.357(n)) would not be impacted by the proposed new exceptions.

CMS also states a belief that the proposed three exceptions would not pose a risk of program or patient abuse because program integrity safeguards are embedded in the proposed definitions that must be satisfied by value-based arrangements that would qualify for exceptions. CMS further states that the risk of program or patient abuse would be further reduced by the assumption of financial risk by value-based participants, since risk assumption provides inherent disincentives for overutilization and stinting. CMS notes that it focused the exceptions on considerations of financial risk, rather than operational or other types of risk that may be assumed under value-based arrangements. CMS chose to focus on financial risk for its ability to influence physician choices when ordering items or services for patients, an ability that CMS does not attribute to other types of risk. **However, CMS seeks comment about the protection against program or patient abuse provided by assumption of financial risk.**

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

CMS proposes an exception to the physician self-referral law for remuneration paid under value-based arrangements that meet all of the conditions described below. CMS notes that the proposed exception includes elements similar to those of the exception for risk sharing arrangements at §411.357(n).

- The value-based enterprise is at full financial risk (or is obligated contractually to be a full risk within 6 months of the start of the arrangement) over the entire duration of the arrangement.
 - Full financial risk mechanisms could include but would not be limited to capitation or global budget payments.
- The value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.
 - Prospective financial responsibility must begin prior to furnishing items or services to members of the target patient population.
 - The value-based arrangement may not permit additional payments to be made from the payor to the enterprise for costs incurred to provide the contracted items and services nor may VBE participants claim payment from the payor for furnishing the contracted items and services. Prospectively-defined shared savings or other incentive payments conditioned on quality performance, and

payments to offset shared losses above a prospectively-defined level, would not be prohibited.

- For Medicare beneficiaries, the value-based enterprise at a minimum must be responsible for all items and services covered under Parts A and B.
- Remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for members of the target patient population. A direct, one-to-one relationship between payment and an item, service, or value-based activity would not be required (e.g., gainsharing would be permissible). In-kind remuneration must not take the form of technology or infrastructure already possessed by the recipient.
- 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.
 - Payments for referrals or business involving patients outside of the target population would not be protected from the physician self-referral law.
 - Remuneration related to covered patients could be used for the benefit of non-covered patients
- Remuneration is not an inducement to reduce or limit medically necessary items or services to any patient (unrelated to payor identity or target population membership).
- If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv). (See related discussion at section A.2(c) above.)
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

Related to the full financial risk exception, CMS seeks comment on the following:

- Whether 6 months suffices for parties to construct arrangements and begin preparations for implementing full risk assumption by the enterprise;
- Whether a minimum period of full financial risk should be necessary to qualify for the exception;
- Details of full financial risk mechanisms other than capitation or global budget payments that currently exist or are anticipated by commenters;
- Whether a value-based enterprise is at full financial risk if it is responsible only for the costs of a defined set of patient care services for a target population; and
- Whether to specify that the value-based activities provided to patients must include care coordination and management or that the value-based arrangement be reasonably designed (at a minimum) to coordinate and manage patient care for the target patient population.

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

CMS recognizes that most physicians and providers are not yet willing or prepared to assume full financial risk. However, CMS also states a belief that assumption of meaningful downside risk for failing to achieve performance benchmarks under value-based arrangements offers inherent protections against program or patient abuse. Therefore, CMS proposes an exception to

the physician self-referral law for remuneration occurring under the latter scenario when all of the conditions below are met.

- The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.
- 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. The special rule on compensation at §411.354(d)(1) would also apply.
- 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 satisfies the requirements of §411.354(d)(4)(iv).
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.
- Meaningful downside financial risk means that the physician is either A) responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement, or B) financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.
 - This risk threshold is consistent with that for "substantial financial risk" as prescribed for the physician incentive plan exception at §411.357(d)(2).

Related to the meaningful downside financial risk exception, CMS seeks comment on the following:

- Whether a physician would be incented sufficiently to modify his or her practice and referral patterns to achieve the goals of the exception if the party assuming the meaningful downside financial risk and who is paying remuneration to the physician under the value-based arrangement is the entity furnishing designated health services (entity as defined at §411.354);
- Whether the definition of meaningful downside financial risk is sufficient to curb the incentives associated with FFS payment;
- Whether the definition of meaningful downside financial risk should be limited solely to arrangements under which the physician is responsible for no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement, in order to prevent gaming via total cost of care arrangements under which contracted sets of patient care items and services are very narrowly defined; and

- Whether the value-based enterprise assuming meaningful downside financial risk should be protected for a 6-month period prior to the start of the risk arrangement to facilitate preparation for risk assumption.

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

CMS notes that respondents to the CMS RFI agreed on the critical importance to value-based healthcare systems of strong partnerships between physicians and entities furnishing designated health services, regardless of the risk parameters incorporated into their partnerships (even when risk is zero or upside only). CMS proposes an exception for compensation arrangements that qualify as value-based arrangements regardless of their risk parameters. Remuneration could be monetary and/or nonmonetary and would be protected from the self-referral law when all of the conditions below are met.

- The arrangement is set forth in writing and signed by the parties.
 - The writing includes a description of: (A) value-based activities to be undertaken under the arrangement; (B) how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; (C) target patient population for the arrangement; (D) type or nature of the remuneration; (E) methodology used to determine the remuneration; and (F) performance or quality standards against which the recipient will be measured, if any.
 - The exception would not protect a “side” arrangement between two VBE participants that is unrelated to the overall value-based purposes (e.g., goals and objectives) of the value-based enterprise of which they are participant.
- The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.
 - The exception would not apply when standards are set retrospectively or do not require measurable change.
- 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 the remuneration paid to the physician is conditioned on the physician’s referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).
- Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

Related to the value-based arrangement exception, CMS seeks comment on the following:

- Whether the exception should be limited to nonmonetary remuneration and the impact of such limitation on the transition to value-based care;
- Whether the policy concerning “side” arrangements should be addressed as a standalone requirement rather than linked to the writing requirement;
- Whether to require separately that performance or quality standards be designed to drive meaningful improvements and the burden and cost of such a requirement;
- What types of monitoring of compliance with the terms of the exception are being performed under existing value-based arrangements;
- Whether to require the recipient of any nonmonetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor’s cost of that nonmonetary remuneration (within 90 days for a one-time cost or at regular intervals for ongoing costs);
 - Setting an appropriate contribution level and the associated burden, especially for small or rural physicians, providers, or suppliers; and
- Whether there are any requirements being proposed by OIG for the safe harbor at §1001.952(ee) that should be adopted by CMS for the value-based arrangements exception.

Regarding monitoring by the parties of their compliance with the terms of the value-based arrangements exception, CMS solicits comment on whether to require that:

- The value-based enterprise or the VBE participant providing the remuneration must monitor to determine whether the arrangement’s value-based activities are furthering the value-based purpose(s) of the value-based enterprise;
- If the value-based activities will be unable to achieve the value-based purpose(s) of the arrangement, the physician must cease referring designated health services to the entity, either immediately upon determining that the purpose(s) will not be achieved through the value-based activities or within 60 days of such determination;
- Compliance monitoring should occur at specified intervals and, if so, what the intervals should be; and
- The value-based purpose of the arrangement must be achieved within a certain timeframe (e.g., 3 years) and, if it is not, the purpose would be deemed not achievable through the arrangement’s value-based activities.

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

Currently, the only exception under which remuneration from indirect compensation arrangements is protected from the physician self-referral law is found at §411.357(p). Indirect compensation arrangements may involve a chain of relationships between the physician being remunerated and the entity to which the physician refers designated health services. CMS anticipates that a value-based arrangement (using the proposed definition) could be part of an unbroken chain of relationships and thereby form an indirect compensation arrangement for self-referral law purposes. Value-based arrangements in a chained indirect compensation

arrangement may not qualify for protection under §411.357(p) because of value-based features such as services furnished below fair market value to a defined target population.

CMS proposes that when the value-based arrangement is the link in the unbroken chain closest to the physician—that is, the physician is a direct party to the value-based arrangement—the indirect compensation arrangement would be considered an “indirect value-based arrangement”. The latter arrangement then would become eligible for self-referral protection through the application of one or more of the newly proposed self-referral exceptions described at §411.357(aa)(1-3). The link closest to the physician must be a compensation arrangement, not an ownership interest.

Because of heightened fraud and abuse concerns, CMS discusses excluding from consideration as indirect value-based arrangements in which the link closest to the physician involves compensation from a pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; laboratory; pharmacy benefit manager; wholesaler; or distributor. CMS also discusses invoking a similar exclusion when any link in the unbroken chain is a pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; laboratory; pharmacy benefit manager; wholesaler; or distributor. Finally, CMS discusses extending the exclusion to health technology companies. **CMS seeks comment on the effectiveness of such exclusions as program integrity tools.**

CMS goes on to describe in detail an alternative under which the term “indirect value-based arrangement” would be defined in regulation. CMS proposes that an indirect value-based arrangement would exist if: (1) between the physician and the entity there exists if an unbroken chain of any number (but not fewer than one) of persons (including but not limited to natural persons, corporations, and municipal organizations) that have financial relationships (as defined at §411.354(a)) between them (that is, each person in the unbroken chain is linked to the preceding person by either an ownership or investment interest or a compensation arrangement); (2) the financial relationship between the physician and the person with which he or she is directly linked is a value-based arrangement; and (3) the entity has actual knowledge of the value-based arrangement in subparagraph (2). Qualifying arrangements would become eligible for the self-referral exceptions at §411.357(aa)(1-3), if those exceptions are finalized. **CMS seeks comment on the best approach to address value-based arrangements that are part of an unbroken chain of financial relationships between a physician and an entity to which he or she refers patients for designated health services, and whether new regulations in fact are needed.**

e. Price Transparency Comment Requests

CMS expresses a belief that healthcare price transparency can empower better-informed decision-making by patients and slow the growth of health care costs. CMS discusses responses to the CMS RFI dealing with price transparency. Many commenters supported that information about a physician’s financial relationships with other providers and health care prices would be valuable to patients. Other commenters voiced concern that financial relationship and pricing information about physicians would simply add to the confusion and burden already felt by patients who are already being inundated with HIPAA-mandated disclosures, informed consent

documents, insurance authorization forms, and other healthcare paperwork. CMS notes already having made price transparency proposals as part of CY 2020 rulemaking in response to the Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First issued on June 24, 2019.

CMS seeks comment on how to pursue price transparency in the context of the physician self-referral law. CMS indicates interest in comments that specifically address: the availability of pricing information and out-of-pocket costs to patients (including information specific to a particular patient's insurance, such as the satisfaction of the patient's applicable deductible, copayment, and coinsurance obligations); the appropriate timing for the dissemination of information (that is, whether the information should be provided at the time of the referral, the time the service is scheduled, or some other time); and the burden associated with compliance with a requirement in an exception to the physician self-referral law to provide information about the factors that may affect the cost of services for which a patient is referred. Comment is also sought on whether the inclusion of a price transparency requirement in a value-based exception would provide additional protections against program or patient abuse through the active participation of patients in selecting their health care providers and suppliers.

CMS also notes it is considering whether to include a requirement related to price transparency in every exception for value-based arrangements at proposed §411.357(aa). CMS provides the example of requiring that a physician provide a notice or have a policy regarding the provision of a public notice that alerts patients that their out of pocket costs for items and services for which they are referred by the physician may vary based on the site where the services are furnished and based on the type of insurance that they have. **CMS solicits comment that if such a requirement were finalized, whether it would be helpful for CMS to provide a sample notice and, if it provides a sample notice, whether it should deem such a notice to satisfy the requirement described. CMS concludes by inviting comment on other options for price transparency requirements in the value-based exceptions to the physician self-referral law of this proposed rule, as well as whether to consider in future rulemaking the inclusion of price transparency requirements in exceptions to the physician self-referral law included in its existing regulations.**

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 proposes to clarify the definitions of commercial reasonableness and fair market value as well as to clarify the volume or value and other business generated standards. The agency states that its 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 this proposed rule would not impact those other statutes and the agencies that implement them.

2. Commercially Reasonable (§411.351)

CMS proposes 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 proposes to clarify in its regulation text that compensation arrangements that do not result in profit for one or more parties may nonetheless be commercially reasonable.

CMS offers 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 invites comment on other possible definitions. It also seeks comment on how parties could determine whether an arrangement is on similar terms and conditions as like arrangements.

CMS notes that the 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.

The agency also believes that 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 clarifies that its proposed general definition of commercially reasonable would 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, it must still be met as part of the analysis to determine whether the arrangement complies with the exception.

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 proposes to codify the volume or value standard and the other business generated standard in its physician self-referral regulations. It proposes to add special rules at §411.354(d)(5) and (6) that, if finalized, will supersede previous guidance. This codification does not apply to value-based arrangements (described above) since the proposed exceptions for value-based arrangements do not include volume or value standards as requirements for remuneration between parties.

CMS proposes to 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. Under the proposal, this would apply 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. Any compensation outside the circumstances at §411.354(d)(5) and (6) would not be considered to take into account volume or value or other business generated between the parties.

CMS does not attempt to define these standards; instead it proposes special rules that would 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 would interpret the proposed 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.

a. Compensation from an Entity to a Physician

Compensation from an entity to a physician would take 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; or
- There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

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

CMS notes 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.

b. Compensation from a Physician to an Entity

Compensation from a physician (or immediate family member) to an entity would take 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; or
- There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

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

While CMS believes it would be unlikely, if a compensation arrangement met the conditions for unit-based compensation, the compensation would not into account the volume or value of referrals or other business generated.

c. Clarification of Previous Guidance

In response to commenters, CMS clarifies that its previous policy position expressed in the Phase II regulation with respect to employed physicians and productivity bonuses still applies. Thus, a productivity bonus does not take into account the volume or value of an employed physician's referrals solely because corresponding hospital services (i.e., DHS) are billed each time the employed physician personally performs a service.

CMS also clarifies that 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.

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

CMS proposes several revisions to the regulation text which it believes will clarify the conditions for the patient choice and directed referrals exception. Specifically, 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) would have to be consistent with the fair market value of the physician's services. It also proposes to strike language related to the volume or value standard included in §411.354(d)(4)(ii) because it conflates the fair market value standard and the volume or value standard.

CMS is concerned that its proposal for the volume or value standard may reduce or eliminate the instances in which the special rule for patient choice and directed referral applies. Thus, to ensure these conditions continue to apply to the types of contracts or arrangements to which they applied historically, CMS proposes to include in several exceptions the additional condition that each exception must meet the patient choice and directed referral special rule. This would apply 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)

CMS seeks comment on whether the requirement is necessary in the case of the exception for academic medical centers.

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. It proposes to eliminate the connection to the volume or value standard in the definition of fair market value. It now believes that the volume or value standard should not be incorporated in the definition of fair market value, observing that the requirements are separate and distinct from each other in the statute.

CMS would revise 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 proposed definition is as follows:

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

(2) *Rental of equipment or office space*. The price that rental property would bring as the result of *bona fide* bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement.

CMS believes that fair market value is the value of an asset or service to hypothetical parties in a hypothetical transaction (i.e., typical transactions for like assets or services, with like buyers and sellers, under like circumstances). On the other hand, general market value is the value of an asset or service to actual parties to a transaction that will occur within a specified timeframe. Thus, the hypothetical value of a transaction must be consistent with (though not necessarily equal to) the value of the actual transaction between the buyer and seller. 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 hypothetical 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.

CMS proposes to restructure its definitions for clarity. Further 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" would be struck from the regulation text because it is unnecessary for the definition of fair market value, and it has caused confusion for stakeholders.

C. Group Practices (§411.352)

CMS RFI commenters raised concerns with a number of aspects of the group practice rules, including the definition of single legal entity, the full range of care test, the substantially all test, and special rules for profit shares and productivity bonuses. CMS only addresses revisions to the rules for distribution of profit shares and productivity bonuses at §411.352(i); it may consider further revisions in subsequent rulemaking for other areas of concern.

The agency first 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 further 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” or “related to.”

a. New Special Rule for Distribution of Revenue Related to Participation in a Value-Based Enterprise

CMS proposes to add a new special rule 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. Distribution of profits from DHS that are directly attributable to a physician’s participation in a value-based enterprise would be deemed to not directly take into account the volume or value of the physician’s referrals. Thus, a group practice could 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 would include profits from DHS referred by the physician. **CMS seeks comment on whether it should permit the distribution of “revenue” from DHS instead of its proposal to permit distribution of “profits” from DHS.**

b. Other Proposed Revisions

Stakeholders expressed confusion over the definition of “overall profits” and its applicability under different circumstances. CMS proposes to revise the definition as follows:

- (ii) Overall profits means the profits derived from all the designated health services of any component of the group that consists of at least five physicians, which may include all physicians in the group. If there are fewer than five physicians in the group, overall profits means the profits derived from all the designated health services of the group.

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 could not distribute DHS profits on a service-by-service basis. **CMS seeks comment on this proposal.**

With respect to the requirements for the calculation of productivity bonuses, the deeming provision related to total physician encounters or relative value units (RVUs) would be 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 seeks comment on whether it should limit the methodology to work RVUs or whether using RVUs personally performed by the physician is an acceptable basis for calculating a productivity bonus that is deemed not to relate directly to the volume or value of referrals.**

CMS would reorganize the structure of §411.352(i) and make modifications to the language it believes will either mirror the statute more closely or clarify areas of confusion. The revisions would also remove references to Medicaid as well as substitute 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 proposes 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 contained in the physician self-referral regulations (i.e., those under 42 CFR Part 411, subpart J).

CMS notes this does 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 also explains that the proposal would not affect a party’s liability under the AKS. The agency will monitor the change (if finalized) and may propose to reinstate it for certain or all its exceptions if 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 proposes to clarify the definition with respect to inpatient hospital services. Specifically, a service furnished by a hospital to an inpatient would not constitute DHS payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare’s payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). CMS reasons that because the amount of the payment under the DRG for the admission has already been determined, additional tests ordered by a specialist would not 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 IPPS reimbursement rate.

CMS does not believe the modification should apply to hospital outpatient services. **However, it seeks comment on whether the modification should extend to outpatient hospital services or**

other categories of DHS. Further the agency seeks comment on whether, and if so how, the proposal should be extended to hospitals not paid under the IPPS for inpatient services.

b. Physician

CMS proposes a technical change to how it defines the term physician; it would cross-reference the definition of physician at section 1861(r) of the Act. This would include any limitations imposed on physicians by reason of the statute. 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 would continue to apply.

c. Referral

CMS proposes 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 would apply to such a payment.

d. Remuneration

CMS proposes to revise and clarify its policy for certain remuneration that does not constitute a compensation arrangement. The statute¹ provides an exception for items, devices, or supplies 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 reusable items may have value to physicians outside the collection of specimens.

CMS proposes revisions to the definition of remuneration in the context of the "used solely" standard. CMS now believes 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).

Further, CMS is aware that an item could theoretically be used for another purpose (e.g., a specimen lockbox could be used as a doorstep); 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.

¹ Section 1877(h)(1)(C)(ii) of the Act.

CMS proposes to insert the words “in fact” to the used solely requirement to address this concern.

However, the proposed revisions would 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.

e. Transaction

The statute enumerates an exception to the definition of compensation arrangement for isolated financial transactions.² CMS added definitions of the terms “transaction” and “isolated transaction” to §411.351. 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 consider a single payment for those multiple services 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. It proposes to separate from the definition of transaction the provisions relating to “isolated financial transaction” and create a separate definition. The proposed separate definition would clarify 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).

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 current regulations, 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.

² Section 1877(e)(6) of the Act.

CMS notes that this policy was intended to establish an outside limit on the disallowance period, and in cases of excess or insufficient compensation, the period would be determined on a case-by-case basis. CMS also clarified that it did not intend to extend the disallowance period beyond the end of the financial relationship.

CMS proposes to delete its rules on the period of disallowance entirely; it now believes they are overly prescriptive and impractical. However, this proposal would not impact parties who have relied on those regulations in the past.

CMS again acknowledges that there are no definite rules for establishing in every case when a financial relationship has ended, and it believes its current 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) §411.353(c)(1) are one way to establish the end of the period, and its proposal to delete the 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. Instead it provides some general guidance in the preamble on how to remedy compensation problems that occur during the arrangement and, when a remedy is not available, how to determine the end of the disallowance period.

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 would consider the actual arrangement between the parties and determine 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 proposed 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.

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

a. Titular Ownership or Investment Interest

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 proposes to extend the concept of titular ownership or investment to its rules governing ownership or investment interest generally. It would add 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.

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 believed that extending the exclusion to interests in other entities would run a risk of program or patient abuse.

Commenters raised concerns about physician employees in retirement plans that use a holding company; they worry that, due to the ownership relationship between the plan and the company as well as the holding company’s ownership interest in the entity that employs the physician, the physician may have an indirect ownership or investment interest in the entity which would not be protected by the §411.354(b)(3)(i) exclusion. In response, CMS proposes to add 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). The proposed exclusion for ESOPs would not be restricted to an interest in an entity that both employs the physician and sponsors the retirement plan.

CMS seeks comments on a number of issues:

- Whether existing safeguards for ESOPs under the IRC and ERISA are sufficient for purposes of the physician self-referral law; if not, what additional safeguards may be required.
- Whether it is necessary to restrict the scope or number of entities owned by an ESOP that would not be considered ownership or investment interests of physician employees.
- Whether the exclusion should apply only to an interest in an entity arising from “qualifying employer securities” offered to a physician as part of an ESOP.
- Whether the new exclusion is necessary given the current exclusion for retirement plans.

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

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 codified these policies and struck its own rule that limited use of the temporary noncompliance for signatures to once every three years.

CMS proposes to strike its existing regulations at §411.353(g) on this issue and to create a special rule for noncompliance with the signature or writing requirements of an applicable compensation arrangement. It proposes a new section §411.354(e)(3) as follows:

In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—

- (i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and
- (ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception.

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.

The special rule does not modify requirements that compensation be set in advance and other applicable requirements of an exception. However, CMS retracts a statement it made in the 2016 MPFS final rule stating that the compensation rate must be set out in writing before furnishing the service to meet the “set in advance” requirement. CMS now states that it is not necessary for the parties to put the compensation rate in writing before furnishing services; 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. CMS notes its proposed new exception for limited remuneration to a physician under §411.357(z) might be available to parties who fail to set the compensation in advance, depending on the facts and circumstances.

CMS also clarifies that a valid electronic signature (under federal or state law) satisfies the signature requirement, and documents and records used to satisfy the writing requirement may include those that are stored electronically. **CMS seeks comment on whether it should add text to the proposed regulation to codify its policy on electronic signatures and documents.**

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 proposes to clarify 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.

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 to the recruited physician (or passed on by the practice to that physician), CMS proposes to modify its requirements by eliminating 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.

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 agrees with commenters that the current exception is too restrictive, and it proposes to rewrite the requirements for the exception (which deletes much of the existing language), as follows:

(g) Remuneration provided by a hospital to a physician if the remuneration does not relate to the provision of designated health services.

Remuneration does not relate to the provision of designated health services if—

- (1) The remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals; and
- (2) The remuneration is for an item or service that is not related to the provision of patient care services.
- (3) For purposes of this this paragraph (g):
 - (i) Items that are related to the provision of patient care services include, but are not limited to, any item, supply, device, equipment, or space that is used in the diagnosis or treatment of patients and any technology that is used to communicate with patients regarding patient care services.
 - (ii) A service is deemed to be not related to the provision of patient care services if the service could be provided by a person who is not a licensed medical professional.

CMS proposes 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, under the proposal remuneration from a hospital to a physician for the provision of DHS is eligible for the exception if the item or service is not related to patient care services.

CMS removes the earlier standard which was limited to remuneration that is unrelated in any manner whatsoever and under its revised interpretation of the section 1877(e)(4) of the Act proposes a standard to except remuneration that is unrelated to the act or process of furnishing DHS. CMS notes 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. For example, payment for emergency room call coverage related to furnishing DHS even if the physician is not in fact called to the hospital to provide patient care services is still related to the provision of DHS. Similarly, CMS believes utilization review services are closely related to patient care services. Examples of direct correlations include purchasing medical devices from the physician and rental of medical equipment or medical office space.

However, administrative services of a physician that relate only to the business operations of the hospital would not relate to patient care services; for example, administrative services that are also provided by non-licensed medical personal (such as membership on the hospital's governing board) and the compensation for the services is on the same terms and conditions, would satisfy the exception. Thus in paragraph (3)(ii) of the proposed regulation text, CMS would deem a service not to be related to the provision of patient care where it can be provided legally by someone who is not a licensed medical professional and the service is of the type that is typically

furnished by someone who is not a licensed medical professional. CMS believes this would provide clarity.

CMS reiterates its earlier policy that the exception applies to rental payments made by a teaching hospital to a physician to rent his or her house in order to use the house as a residence for a visiting faculty member.

CMS seeks comments on its proposals, including other ways to distinguish between remuneration that is related to the provision of DHS and remuneration that is not. The agency wonders whether its policy should limit remuneration related to the provision of DHS to remuneration paid explicitly for a physician’s provision of DHS to the hospital’s patients.

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 response, CMS proposes to modify 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 excepted 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 proposes 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.

Finally, 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 would not apply where the exact same amount of money was exchanged between the parties, such as paying \$10 for a gift card worth \$10.

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 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 proposes to change its policy to permit the use of this exception 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 proposes to prohibit them under the proposed 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). Further, under this exception, parties could only enter into an arrangement once per year. Parties could 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.

One condition of the fair market value compensation exception is that services performed under the arrangement do not violate federal or state law (at §411.357(l)(6)). Elsewhere in the proposed rule, CMS would eliminate from its exceptions any requirements relating to the anti-kickback statute and federal or state billing and claims submissions rules. Though it does not propose to remove the condition at §411.357(l)(6), **the agency seeks comment on whether the condition is necessary or whether it should be removed; and if it were removed, what substitute safeguards should be established.**

11. Electronic Health Records (EHR) Items and Services

Current regulations at §411.357(w) provide an exception to the referral prohibition related to compensation arrangements (“the EHR exception”) for certain arrangements involving the donation of interoperable EHR software or information technology and training services. The EHR exception expires on December 31, 2021.

In this rule, CMS proposes to modify the conditions that must be met under the EHR exception. The proposals reflect CMS review of comments it received in response to the CMS RFI and comments submitted to the OIG with respect to a similar provision in the anti-kickback regulations (§1001.952(y)), along with developments related to enactment of the Cures Act.

Under the proposal, CMS would update provisions of the exception pertaining to interoperability and data lock-in, clarify that donations of certain cybersecurity software and services are permitted under the EHR exception, remove the expiration date, and modify definitions to conform to the Cures Act. In addition, the 15 percent physician contribution requirement would be modified, and certain donations of replacement technology would be permitted.

CMS notes that the OIG is considering changes to the EHR safe harbor in the OIG AKS and beneficiary inducement CMP proposed rule, and it encourages stakeholders to review and submit comments on both rules. In making the proposed changes CMS has aimed to be as consistent as possible with the OIG safe harbor proposals. CMS will consider comments submitted to the OIG on these issues, even if they did not receive similar comments on this proposed rule and may also “take additional actions” when crafting the final rule.

a. Interoperability

The Office of the National Coordinator (ONC) has previously issued a proposed rule to implement provisions of Title IV of the Cures Act (84 FR 7424), which includes proposed changes to the ONC Health Information Technology (HIT) Certification Program and provisions regarding information blocking. These provisions, if finalized, would affect provisions of §411.357(w) regarding interoperability and the “data lock-in.”

(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 proposes what it refers to as two clarifying changes to the regulatory text.

- The current requirement deems that software is interoperable if at the time it is provided to the physician it *has been certified* to an edition of the EHR certification criteria identified in the then-applicable version of 45 CFR part 170. Under the proposal, CMS would require that the software *is certified* at the time it is provided to the physician, 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 would not meet the proposed condition.
- To be consistent with ONC proposed changes to the certification program, the regulatory text would be changed to remove the reference to “an edition” of the certification criteria.

CMS notes that it is proposing to update the definition of “interoperable,” as discussed further in section II.D.11.d below. It emphasizes that any changes to the definition would be prospective only; donated software that met the definition of interoperable and met the deeming requirements at the time of the donation would continue to be protected if the proposed changes are finalized.

(2) Information Blocking and Data Lock-in

One condition of the EHR exception (§411.357(w)(3)) requires that the donor not take 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 discusses the various federal activities that have evolved related to information blocking, and the ONC NPRM proposals for implementing the information blocking provision of the Cures Act, which enacted section 3022 of the Public Health Service Act (PHSA).

Under the proposal, the text of §411.357(w)(3) would be modified to reflect the ONC proposed rule regarding information blocking. Specifically, the text would require that the donor does not engage in a practice that constitutes information blocking, as defined in section 3022 of the PHSA, in connection with the donated items or services. CMS notes that the proposed language clarifies a prohibition on both (1) engaging in conduct constituting information blocking that affects the functions of the donated items or services and (2) using the donated items or services as an instrument of information blocking.

If ONC finalizes its proposed rule, the information blocking regulations would be referenced in the regulatory text at §411.357(w)(3). **CMS specifically solicits comments on aligning the condition at §411.357(w)(3) with the PHSA and proposed ONC information blocking regulations.** It states that the current requirements already include concepts similar to the Cures Act prohibitions on information blocking and that the proposed modifications would not change the underlying purpose of the requirement.

b. Cybersecurity

CMS proposes to add a specific reference to cybersecurity in the introductory text to §411.357(w) to clarify that the exception is available to protect the donation of cybersecurity software and services and software that “protects” EHRs. Specifically, the language would clarify that the EHR exception applies to software or IT and training services, *including certain cybersecurity software and services*, necessary and used predominantly to create, maintain, transmit, receive *or protect* electronic health records if the identified conditions are met. Elsewhere in this proposed rule (see section II.E.2 below), CMS proposes a new exception to protect arrangements involving the donation of cybersecurity technology and related services.

This proposed “cybersecurity exception” is broader and includes fewer requirements than the EHR exception. The proposed expansion of 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 proposed definition of cybersecurity discussed in II.E.2 would also apply to the EHR exception. The donation of cybersecurity software and services would need to comply with only one of the two exceptions. **CMS seeks comments on its proposal and in particular on whether modification of the EHR exception is necessary if the cybersecurity exception is added.**

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.

Responding to comments on the CMS RFI and to the OIG requesting that the EHR exception be made permanent, CMS reverses its view and now proposes to eliminate the sunset date. It 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. **CMS seeks comment on whether it should select a later sunset date instead of making the exception permanent and if so, what that date should be.**

d. Definitions

CMS proposes to update the existing definitions in §411.351 of “electronic health record” and “interoperable” to reflect terms and provisions of the Cures Act. The proposed updated definitions follow:

Electronic health record means a repository that includes electronic health information that—

- (1) Is transmitted by or maintained in electronic media; and
- (2) Relates to the past, present, or future health or condition of an individual or the provision of health care to an individual.

Interoperable means—

- (1) Able to securely exchange data with and use data from other health information technology without special effort on the part of the user;
- (2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
- (3) Does not constitute information blocking as defined in section 3022 of the PHSA.

The new definitions are intended to reflect updated terminology. The proposed definition of “interoperable” is consistent with the definition of “interoperability” that appears in section 3000(9) of the PHSA (as added by the Cures Act). As a practical matter, CMS does not believe the new definition to be substantively different from the existing one.

CMS is also considering an approach that would eliminate the definition of interoperable and use instead the term “interoperability” by reference to section 3000(9) of the PHSA and 45 CFR part 170 (if finalized by the ONC). **CMS seeks comment on whether using terminology identical to the PHSA and ONC regulations would facilitate compliance with the requirements of the EHR exception and reduce regulatory burden resulting from the differences in the agencies’ terminology.**

The new definitions would be applied prospectively only, and that donations made prior to the effective date of the final rule would be governed by the definitions in effect when the donation was made.

e. Additional Proposals and Considerations

(1) 15 Percent Recipient Contribution

Currently, §411.357(w)(4) requires that as a condition to the EHR exception, the physician must pay 15 percent of the donor's cost of the item or service. After reviewing comments made on the CMS RFI and to the OIG about the burden on the 15 percent contribution, particularly on small and rural practices, **CMS is considering and solicits comments on the following two alternatives.** (It acknowledges that no changes to regulatory text regarding the 15 percent contribution are proposed.)

- Eliminating or reducing the 15 percent contribution requirement for small or rural physician organizations. Comments are specifically solicited on how “small or rural physician organization” should be defined and whether “rural physician organization” should be defined as a physician organization located in a rural area, as that term is defined at §411.351, or defined in line with the definition of a rural provider at §411.356(c)(1). Comments are also solicited on other subsets of potential physician recipients for which the 15 percent contribution is a particular burden.
- Reducing or eliminating the 15 percent contribution requirement in the EHR exception for all physician recipients. Comments are sought on the potential impact of this approach on adoption of EHR technology, and any attendant risks of fraud and abuse. Specific examples are sought of any prohibitive costs associated with the 15 percent contribution requirement, both for the initial donation of EHR technology, and subsequent updates and upgrades.

As a separate issue, CMS is also considering modifying or eliminating the 15 percent contribution requirement for updates to previously donated EHR software or technology. **Comments are sought on alternatives.** For example, CMS is considering requiring a contribution for the initial investment and any new modules but not for any software updates. It says other alternatives might still require some contribution but could reduce the uncertainty and administrative burden associated with assessing a contribution for each update.

(2) Replacement Technology

CMS states that it is proposing to allow donations of replacement EHR technology, and **seeks comments on the types of situations in which the donation of replacement technology would be appropriate.** CMS is interested in how it might safeguard against situations where donors inappropriately offer, or a physician inappropriately solicits unnecessary technology instead of an upgrade to existing technology.

CMS notes the rapid pace of advancement in EHR technology, and makes this proposal in response to comments stating that in some situations, replacement technology is appropriate but prohibitively expensive.

[Note: Although this proposal is discussed in the preamble to the proposed rules and comments are sought, no reference to striking or changing regulatory text is made. Current §411.357(w)(8) prohibits the donation of equivalent technology or services. That provision is not identified in the proposed rule for modification or removal.]

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 is 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.

To address confusion, CMS proposes to create a new term “NPP patient care services” that would mean direct patient care services furnished by an NPP that addresses 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. It would substitute that term for patient care services throughout the exception. Similarly, CMS proposes to substitute 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 proposes a similar clarifying revision to the term “referral” as defined in §411.357(x)(4); CMS proposes to use the term “NPP referral” in this exception.

The exception is silent on the timing of the compensation arrangement. CMS proposes to add 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 proposes a technical change to the language of §411.355(c)(5); it proposes to insert “Medicare Advantage” 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. **CMS seeks comment on whether the current language of the exception is broad enough to encompass the full range of Medicare Advantage plans that exist today and that do not pose a risk of program or patient abuse. It also seeks input on which, if any, additional Medicare Advantage plans should be included in this exception.**

CMS also proposes to change “Web site” 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.

CMS proposes a new exception at §411.357(z) for remuneration that does not exceed an aggregate of \$3,500 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:

- 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.
- The compensation does not exceed the fair market value of the items or services.
- The arrangement is commercially reasonable.
- The 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.
- Compensation for the use of premises, equipment, personnel, items, supplies, or services 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, equipment, personnel, items, supplies, or services 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, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

The exception would apply even in the absence of documentation for the arrangement and when the amount or formula for calculating the remuneration is not set out in advance. CMS would not count toward the \$3,500 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 would consider 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 \$3,500 during the year to qualify for protection under this exception. On the other hand, CMS notes that this proposed exception could be used in conjunction with other exceptions.

This exception would 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. 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 proposed exception would neither affect a party's obligation to comply with that statute nor ensure compliance with that statute.

CMS seeks comment on whether the \$3,500 limit is appropriate to accommodate nonabusive compensation arrangements. It also seeks input on whether it is necessary to limit the applicability of the exception to items and services that are personally furnished by the physician. CMS also seek comment on whether it should include a condition 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 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. **CMS seeks comment on whether it should modify it proposed regulation text to explicitly state this policy.**

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

A new exception to the referral prohibition related to compensation arrangements is proposed for certain arrangements involving donation of certain cybersecurity technology and related services (“the cybersecurity exception”). It would appear as a new §411.357(bb). A related proposal is included in the OIG AKS proposed rule.

The proposal is made in response to stakeholder comments and suggestions, and CMS 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 2017³ 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 proposed cybersecurity exception would promote increased security without protecting potentially abusive arrangements.

Under the proposal, nonmonetary remuneration in the form of certain types of cybersecurity technology and services would be protected if certain conditions are met. The proposed conditions for the exception are:

- The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.
- 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.
- The physician does not make receipt of or amount or nature of the technology or services a condition of doing business with the donor.
- The arrangement is documented in writing.

a. Definitions

CMS proposes to define “cybersecurity” as the process of protecting information by preventing, detecting, and responding to cyberattacks. The definition would be placed in §411.351 and would apply to this proposed cybersecurity exception and the proposed modified EHR exception at §411.357(w). This broad definition is derived from the National Institute for Standards and Technology (NIST) Framework for Improving Critical Information, which is not specific to the health care industry. CMS wants to avoid a narrow definition that might become obsolete over time. **CMS seeks comment on whether a definition tailored to the health care industry would be more appropriate.**

“Technology” would be defined in §411.357(bb) as any software or other type of information technology other than hardware. The proposed definition would capture Application

³ The report is available at <https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf>

Programming Interface technology, which is neither software nor a service. While it recognizes that cybersecurity may require certain hardware, CMS is concerned that donations of valuable, multifunctional hardware may pose a risk of program or patient abuse, and would not be used predominantly to implement, maintain or establish effective cybersecurity, which would be a general requirement for the exception. CMS offers the example that the proposed exception would not protect a laptop computer or tablet used by a physician to enter information into an EHR, but it would protect encryption software for the laptop or tablet. A similar exclusion of hardware applies in the current EHR exception at §411.457(w).

Two alternative policies are discussed, and comments are sought. Under the first alternative, the exception would cover specific hardware necessary for cybersecurity if the hardware is stand-alone, meaning it is not integrated within multifunctional equipment and serves only cybersecurity purposes. A two-factor authentication dongle is offered as an example. Comments are specifically sought on what types of hardware might qualify and whether they should be protected under the cybersecurity provision. The second alternative is discussed below in II.E.2.e.

CMS notes that the proposed exception does not extend to donation of cybersecurity measures that are outside of technology or services, such as installation, improvement or repair of infrastructure related to physical safeguards that could improve cybersecurity. For example, upgraded wiring or high security doors would not be protected donations. CMS considers these as extremely valuable and having multiple benefits in addition to cybersecurity and therefore pose a risk that the donation would be intended to influence physician referrals to the donating entity.

b. Conditions on Donation and Protected Donors

Technology and services must be necessary and used predominantly for cybersecurity. One condition of the proposed cybersecurity exception is that the technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity. Therefore, the proposed exception would not protect donations of technology or services that are otherwise used in the normal course of the recipient's business. **CMS seeks comment on whether this proposed limitation would prohibit the donation of cybersecurity technology and services that are vital to improving the cybersecurity of the health care industry.**

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. Examples offered of software considered necessary and predominantly used for cybersecurity include malware prevention software; software security measures to protect endpoints that allow for network access control; business continuity software; data protection and encryption; and email traffic filtering. Examples offered of protected services include services associated with developing, installing, and updating cybersecurity software; cybersecurity training services; cybersecurity services for business continuity and data recovery services; models that rely on third-party service providers to manage, monitor or operate cybersecurity of a recipient and services associated with performing cybersecurity risk assessment or analysis. **Comments are solicited on the proposed breadth of protected technology and services and whether CMS should**

include or exclude certain technology, categories of technology, services or categories of services in the proposed exception. CMS emphasizes that in all cases, the donation of services must be nonmonetary. For example, if an entity experienced a cyberattack that involved ransomware, payment of the ransom amount for a recipient would not be protected.

CMS is considering whether to deem certain arrangements to satisfy the requirement that the technology or services be *necessary to* implement, maintain or reestablish cybersecurity. Parties would still have to show on a case-by-case basis that the requirement for the technology or services to be *used predominantly* for these purposes is met. The possible provision would deem donors and recipients to 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 widely-recognized cybersecurity framework or set of standards such as those developed or endorsed by NIST, or other national or international standards bodies. That is, the provision would allow donors to use these standards to demonstrate compliance with the “necessary to” requirement. **CMS seeks comments on this approach, including on what qualifies as a widely recognized cybersecurity framework or set of standards and whether the parties could demonstrate that the deeming provision is met through documentation, certification, or other methods “not proscribed by regulation.”**

Donors may not condition donations on referrals. Another condition of the proposed cybersecurity exception is 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 would provide cybersecurity technology and services only to physicians that connect to its systems, but the condition would prohibit the donor from conditioning the donation on referrals or other business generated. It notes that even a low-referring physician practice poses a cybersecurity risk to a connected system.

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.

Unlike the EHR exception, CMS does not propose to include a list of selection criteria which would be deemed to meet this requirement. It intends to remove obstacles to adoption of cybersecurity to address the growing threat of cyberattacks on the health care industry, and 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. **CMS solicits comments on whether it should include deeming provisions in the cybersecurity exception that are similar to those in the EHR exception at §411.357(w)(6),⁴ and any other conditions or permitted conduct that it should enumerate.**

⁴ §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

Based on comments to the OIG suggesting that referral sources may become beholden to donors, CMS is considering narrowing the scope of entities that may provide remuneration under the exception, as it has for the EHR exception. **It solicits comments on whether particular types of entities should be excluded from donating cybersecurity technology and related services, and if so, why.** CMS has previously distinguished between individuals and entities with direct and primary patient care relationships that have a central role in the health care delivery infrastructure (such as hospitals and physician practices) and suppliers of ancillary services and manufacturers or vendors that indirectly furnish items and services used in the care of patients. (Readers are referred to 78 FR 78757 through 78762.) CMS asks whether its historical concerns and other considerations regarding direct and indirect patient care apply in the context of cybersecurity donations.

c. Conditions for Recipients

The proposal would prohibit a potential recipient or the potential recipient's practice 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.

CMS is not proposing to require a recipient contribution under the cybersecurity exception because it 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 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 across recipients, contribution requirements may become a barrier to adoption of improvements because of the costs allocated to each recipient. Finally, CMS says that not imposing a minimum contribution would free up physician resources to contribute to cybersecurity by protecting hardware that is core to their business that may pose a cybersecurity risk. Despite not proposing a federal minimum contribution, CMS states that donors would be free to require recipients to contribute to the cost and such contributions would be excepted under the proposal if all other conditions of the cybersecurity exception were met.

d. Written Documentation

Under the proposed cybersecurity exception, the arrangement between a donor and recipient would have to be documented in writing. CMS expects that this documentation would identify

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.

the recipient, provide a general description of the cybersecurity technology and services provided, the timeframe for the arrangement, a reasonable estimate of the value, and any financial responsibility to be borne by the recipient. A signed contract would not be 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. **Comments are sought on whether regulations should specify the items that must be included in the written documentation of the arrangement, and whether a signed writing should be required of the parties.**

e. Alternative Proposal for Inclusion of Cybersecurity Hardware Donations

As described above, for purposes of the proposed cybersecurity exception CMS would define “technology” to specifically exclude hardware. **Comments are sought on an alternative approach that would allow the donation of cybersecurity hardware.** CMS believes that this alternative would bolster cybersecurity without creating a risk of program or patient abuse.

Under the alternative, a protected donation could include cybersecurity hardware that the donor has determined is reasonably necessary based on cybersecurity assessments of its own organization and the recipient that are based on industry standards. The donor would be required to have risk assessment that identifies the recipient as a risk to the donor’s cybersecurity, and the recipient would have to have a cybersecurity risk assessment to provide a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat.

CMS based this approach on existing legal requirements and best practices related to information security, citing NIST Special Publication 800-30, which is a guide to conducting risk assessments,⁵ and the Office of Civil Rights guidance related to the Health Information Technology for Economic and Clinical Health (HITECH) Act⁶. CMS believes that a cybersecurity risk assessment consistent with industry standards would provide a reasonable basis for donors to identify risk and threats to their IT systems that could be mitigated by donating hardware to physicians who connect with their systems. The alternative proposal would define risk assessment consistent with NIST Special Publication 800-30.

Regarding this alternative proposal, comments are specifically sought on:

- Whether a definition of risk assessment based on NIST Special Publication 800-30 would be sufficient for the proposed exception and alternative proposal to allow donations of hardware.
- Whether CMS should include specific standards for cybersecurity risk assessment as an independent requirement of the cybersecurity exception if this alternative is finalized.
- Whether the requirement that donated cybersecurity hardware be necessary and used predominantly for cybersecurity obviates the need for requiring a risk assessment.

⁵ NIST Special Publication 800-30 Revision 1, *Guide for Conducting Risk Assessments* (Sept. 2012), available at <https://nvlpubs.nist.gov/nistpubs/legacy/sp/nistspecialpublication800-30r1.pdf>.

⁶ HHS Guidance on Risk Analysis at <https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html?language=es>.

- Whether the requirement that both donor and recipient have cybersecurity risk assessments
 - is needed in light of other laws and regulations requiring similar assessment, and
 - would inhibit donations of cybersecurity technology and services by diverting resources to risk assessments that could be used to improve cybersecurity of the parties.
- Descriptions of existing practices of potential donors and recipients with respect to risk assessments that would provide a basis to determine whether a donation of cybersecurity hardware is reasonable and necessary.
- Explanations of the types of hardware necessary for effective cybersecurity. CMS is considering additional safeguards if this alternative proposal is finalized, such as limits on the type of cybersecurity hardware permitted through a definition of hardware. It notes that even if it finalizes this proposal, multifunctional hardware would still be prohibited because it would not meet the requirement to be necessary and predominantly used to implement and maintain cybersecurity.
- Whether a 15 percent financial contribution should be required from the recipient similar to that in the EHR exception, whether this would be sufficient to ensure that the recipient would use the hardware to improve its cybersecurity posture, and whether a different financial contribution would be appropriate, and if so, why.
 - CMS proposes to exempt small and rural providers if this alternative is finalized with a financial contribution requirement, and seeks comments on the exemption.

Whether under this alternative there should be a cap on the value of donated hardware, in lieu of or in conjunction with a 15 percent financial contribution requirement.

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 that would be required of value-based arrangements exempted from physician self-referral requirements under this proposed rule would not increase burden and so would be exempt from ICR requirements. CMS states that the documentation that would be necessary under these proposed rules are necessary for normal business operations to enforce the legal obligations of the parties so there would be no increase in burden.

IV. Regulatory Impact Statement

CMS examined the impact of the proposed 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 determined that the rule would not have a significant economic impact on a substantial number of small entities. Instead, CMS asserts that it would be likely to reduce, not increase, regulatory burden.
- CMS does not provide an analysis of the proposed rule's potential impact on a substantial number of small rural hospitals because it is expected to have a minimal impact on such facilities.
- The proposed rule changes would 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 with proposals to eliminate prior regulations.

CMS estimates the total costs of review of the proposed rule by all directly affected entities during the first year after it is finalized to be \$31.7 million. Other budgetary effects are not estimated although CMS expects many of the proposed changes will reduce compliance burden for impacted providers. CMS requests comment on those impacts.

Alternatives considered. CMS considered maintaining the status quo but believes that a transition to a value-based system is urgently needed so it sees these additional flexibilities as critical to that transition.

CMS also considered limiting proposed 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 notes that it is considering whether to exclude laboratories and DMEPOS suppliers from the definition of VBE participant because labs and DMS suppliers do not have direct patient contact of the type that warrant protections to advance value-based and patient centered care.