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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 411

[CMS-1720-P]

RIN 0938-AT64

Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would address any undue regulatory impact and burden of the physician self-referral law. This proposed rule is being issued in conjunction with the Centers for Medicare & Medicaid Services' (CMS) Patients over Paperwork initiative and the Department of Health and Human Services' (the Department or HHS) Regulatory Sprint to Coordinated Care. This proposed rule proposes exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It would also create a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; create a new

exception for donations of cybersecurity technology and related services; and amend the existing exception for electronic health records (EHR) items and services. This proposed rule also provides critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 75 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1720-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1720-P,

P.O. Box 8013

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1720-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW,
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the
"SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Lisa O. Wilson, (410) 786-8852.

Matthew Edgar, (410) 786-0698.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

ACO	Accountable care organization
API	Application programming interface
ASC	Ambulatory surgical center
CEC	Comprehensive ESRD Care Model
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CISA	Cybersecurity Information Sharing Act of 2015 (Pub. L. 114-113, enacted on December 18, 2015)
CJR	Comprehensive Care for Joint Replacement Model
CMP	Civil monetary penalty
CMS RFI	Request for Information Regarding the Physician Self-Referral Law (83 FR 29524)
CY	Calendar year
DHS	Designated health services
DMEPOS	Durable medical equipment, prosthetics, orthotics & supplies
DRA	Deficit Reduction Act of 2005 (Pub. L. 109-171, enacted on February 8, 2006)
DRG	Diagnosis-related group
EHR	Electronic health records

EKG	Electrocardiogram
EMTALA	Emergency Medical Treatment and Labor Act (Pub. L. 99-272, enacted on April 7, 1986)
ERISA	Employee Retirement Income Security Act of 1974 (Pub. L. 93–406, enacted on September 2, 1974)
ESOP	Employee stock ownership plan
ESRD	End-stage renal disease
FFS	Fee-for-service
FQHC	Federally qualified health center
FR	Federal Register
FY	Fiscal year
HCIC	Health care industry cybersecurity
HHS	[Department of] Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191, enacted August 21, 1996)
IPA	Independent practice association
IPPS	Acute Care Hospital Inpatient Prospective Payment System
IRS	Internal Revenue Service
IT	Information technology
MA	Medicare Advantage
MIPPA	Medicare Improvements for Patients and Providers Act (Pub. L. 110-275, enacted on July 15, 2008)

MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003)
NIST	National Institute of Standards and Technology
NPP	Nonphysician practitioner
NPRM	Notice of proposed rulemaking
OBRA 89	Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239, enacted on December 19, 1989)
OBRA 90	Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101- 508, enacted on November 5, 1990)
OBRA 93	Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66, enacted on August 10, 1993)
OCM	Oncology Care Model
OIG	[HHS] Office of Inspector General
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
OPPS	Hospital Outpatient Prospective Payment System
PFS	Physician Fee Schedule
PHI	Protected health information
PHSA	Public Health Service Act (Pub. L. 178-410, enacted on July 1, 1944)
PPS	Prospective payment system
RFI	Request for information
RHC	Rural health clinic
RVU	Relative value unit

SNF Skilled nursing facility

SRDP CMS Voluntary Physician Self-Referral Disclosure Protocol

I. Background

A. Statutory and Regulatory History

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. A financial relationship is an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority 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. For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.

This rulemaking follows a history of rulemakings related to the physician self-referral law. The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health

services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the **Federal Register** on January 4, 2001 as a final rule with comment period (66 FR 856). The second final rulemaking (Phase II) was published in the **Federal Register** on March 26, 2004 as an interim final rule with comment period (69 FR 16054). Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the **Federal Register** on September 5, 2007 as a final rule (72 FR 51012).

In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the Fiscal Year (FY) 2009 Inpatient Prospective Payment System final rule with comment period (73 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) revisions to the “stand in the shoes” provisions; (2) establishment of provisions regarding the period of disallowance and temporary noncompliance with signature requirements; (3) prohibitions on per unit of service (“per-click”) and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of “entity.”

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) (Affordable Care Act), we issued final regulations on November 29, 2010 in the Calendar Year (CY) 2011 Physician Fee Schedule (PFS) final rule with comment period

that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). We also issued final regulations on November 24, 2010 in the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66987) that established or revised certain regulatory provisions concerning physician-owned hospitals to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act. On November 16, 2015, in the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to physician-owned hospitals. On November 15, 2016, we included in the CY 2017 PFS final rule, at §411.357(a)(5)(ii)(B), (b)(4)(ii)(B), (l)(3)(ii), and (p)(1)(ii)(B), requirements identical to regulations that have been in effect since October 1, 2009 that the rental charges for the lease of office space or equipment are not determined using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (81 FR 80534).

On November 23, 2018, in our most recent update, the CY 2019 PFS final rule (83 FR 59715 through 59717), we incorporated into our regulations provisions at sections 1877(h)(1)(D) and (E) of the Act that were added by section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123). Specifically, we codified in regulations our longstanding policy that the writing requirement in various compensation arrangement

exceptions in §411.357 can be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. We also amended the special rule for temporary noncompliance with signature requirements at §411.353(g), removing the limitation on the use of the rule to once every 3 years with respect to the same physician and making other changes to conform the regulatory provision to section 1877(h)(1)(E) of the Act.

B. Health Care Delivery and Payment Reform: Transition to Value-Based Care

1. The Regulatory Sprint to Coordinated Care

The Department has identified the broad reach of the physician self-referral law, as well as the Federal anti-kickback statute and beneficiary inducements civil monetary penalty (CMP) law, sections 1128B(b) and 1128A(a)(5) of the Act, respectively, as potentially inhibiting beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors. Industry stakeholders have informed us that, because the consequences of noncompliance with the physician self-referral law (and the anti-kickback statute) are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth). To address these concerns, and to help accelerate the transformation of the health care system into one that better pays for value and promotes care coordination, HHS launched a Regulatory Sprint to Coordinated Care (the Regulatory Sprint), led by the Deputy Secretary of HHS. This Regulatory Sprint aims to remove potential regulatory barriers to care coordination and value-based care created by four key Federal health care laws and

associated regulations: (1) the physician self-referral law; (2) the anti-kickback statute; (3) the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA); and (4) the rules under 42 CFR Part 2 related to opioid and substance use disorder treatment. Through the Regulatory Sprint, HHS aims to encourage and improve—

- A patient’s ability to understand treatment plans and make empowered decisions;
- Providers’ alignment on an end-to-end treatment approach (that is, coordination among providers along the patient’s full care journey);
- Incentives for providers to coordinate, collaborate, and provide patients with tools to be more involved; and
- Information-sharing among providers, facilities, and other stakeholders in a manner that facilitates efficient care while preserving and protecting patient access to data.

The Department believes that the realization of these goals would meaningfully improve the quality of care received by all American patients. As part of the Regulatory Sprint, CMS, the HHS Office of Inspector General (OIG), and the HHS Office for Civil Rights (OCR) each issued requests for information to solicit comments that may help to inform the Department’s approach to achieving the goals of the Regulatory Sprint (83 FR 29524, 83 FR 43607, and 83 FR 64302, respectively). We discuss our request for information (the CMS RFI) in this section of this proposed rule, including the specific information we requested from commenters, and how we used the information shared by commenters to inform this proposed rulemaking.

2. Policy Considerations and Other Information Relevant to the Development of this Proposed Rule

a. Medicare Payment was Volume-Based when the Physician Self-Referral Statute was Enacted

When the physician self-referral statute was enacted in 1989, under traditional fee-for-service (FFS) Medicare (that is, Parts A and B), the vast majority of covered services were paid based on volume. Although some services were “bundled” into a single payment, such as inpatient hospital services that were paid on the basis of the diagnosis-related group (DRG) that corresponded to the patient’s diagnosis and the services provided (known as the Hospital Inpatient Prospective Payment System, or IPPS), in general, Medicare made a payment each time a provider or supplier furnished a service to a beneficiary. Thus, the more services a provider or supplier furnished, the more Medicare payments it would receive. Importantly, these bundled payments typically covered services furnished by a single provider or supplier, directly or by contract; payments were not bundled across multiple providers, each billing independently. This volume-based reimbursement system continues to apply under traditional Medicare to both services paid under a prospective payment system (PPS) and services paid under a retrospective FFS system.

As described in this proposed rule, the physician self-referral statute was enacted to address concerns that arose in Medicare’s volume-based reimbursement system where the more designated health services that a physician ordered, the more payments Medicare would make to the entity that furnished the designated health services. If the referring physician had an ownership or investment interest in the entity furnishing the

designated health services, he or she could increase the entity's revenue by referring patients for more or higher value services, potentially increasing the profit distributions tied to the physician's ownership interest. Similarly, a physician who had a service or other compensation arrangement with an entity might increase his or her aggregate compensation if he or she made referrals that resulted in more Medicare payments to the entity. The physician self-referral statute was enacted to combat the potential that financial self-interest would affect a physician's medical decision making and ensure that patients have options for quality care. The law's prohibitions were intended to prevent a patient from being referred for services that are not needed or steered to less convenient, lower quality, or more expensive health care providers because the patient's physician can improve his or her financial standing through those referrals. This statutory structure was designed for and made sense in Medicare's then largely volume-based reimbursement system.

b. The Medicare Shared Savings Program, the Center for Medicare and Medicaid Innovation, and Medicare's Transition to Value-Based Payment

Since the enactment of the physician self-referral statute in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and for non-Federal payors and patients. For some time, we have engaged in efforts to align payment under the Medicare program with the quality of the care provided to our beneficiaries. Laws such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA), the Deficit Reduction Act of 2005 (Pub. L. 109-171) (DRA), and the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275)

(MIPPA) guided our early efforts to move toward health care delivery and payment reform. More recently, the Affordable Care Act required significant changes to the Medicare program's payment systems and provides the Secretary with broad authority to test innovative payment and service delivery models.

Section 3022 of the Affordable Care Act established the Medicare Shared Savings Program (Shared Savings Program). The Congress created the Shared Savings Program to promote accountability for a patient population and coordinate items and services under Medicare Parts A and B and encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. In essence, the Shared Savings Program would facilitate coordination among providers to improve the quality of care for Medicare FFS beneficiaries and reduce unnecessary costs. Physicians, hospitals, and other eligible providers and suppliers may participate in the Shared Savings Program by creating or participating in an accountable care organization (ACO) that agrees to be held accountable for the quality, cost, and experience of care of an assigned Medicare FFS beneficiary population. ACOs that successfully meet quality and savings requirements share a percentage of the achieved savings with Medicare. Since enactment, we have issued numerous regulations to implement and update the Shared Savings Program.

In keeping with the Secretary's vision for achieving value-based transformation by pioneering bold new payment models, we recently finalized changes to the Shared Savings Program that allow us to take an important step forward in how Medicare pays for value. In the December 31, 2018, final rule entitled "Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success" (the 2018 Shared

Savings Program final rule) (83 FR 67816), we recognized Shared Savings Program ACOs as an important innovation for moving our payment systems away from paying for volume and toward paying for value and outcomes, as ACOs are held accountable for the total cost of care and quality outcomes for the assigned beneficiary patient populations they serve. We made significant design changes to the Shared Savings Program that are intended to put the program on a path toward achieving a more measurable move to value, demonstrate savings to the Medicare program, and promote a competitive and accountable marketplace (83 FR 68050). Specifically, we finalized a significant redesign of the participation options available under the Shared Savings Program to encourage ACOs to transition to two-sided risk models (in which they may share in savings and are accountable for repaying shared losses), increase savings and mitigate losses for the Medicare Trust Funds, and increase program integrity. For more information about the Shared Savings Program, see <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html>.

Section 1115A of the Act, as added by section 3021 of the Affordable Care Act, established the Center for Medicare and Medicaid Innovation (the Innovation Center) within CMS. The purpose of the Innovation Center is to test innovative payment and service delivery models to reduce expenditures for the care furnished to patients in the Medicare and Medicaid programs and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of that care. Using its authority in section 1115A of the Act, the Innovation Center has tested numerous health care delivery and payment models in which providers, suppliers, and individual practitioners participate. Most Innovation Center models generally fall into three categories: accountable care

models, episode-based payment models, and primary care transformation models. The Innovation Center also tests initiatives targeted to the Medicaid and CHIP population and to Medicare-Medicaid (dual eligible) enrollees, and is focused on other initiatives to accelerate the development and testing of new payment and service delivery models, as well as to speed the adoption of best practices. We describe a few representative Innovation Center models in this section of the proposed rule.

The Innovation Center recently released financial and quality results for the second year of another of its ACO models, the Next Generation ACO model, which requires participants to assume the highest level of risk out of all CMS ACO programs and models, and in exchange for this level of risk, rewards participants with greater regulatory flexibility. The Next Generation ACO model actuarial results show that net savings to the Medicare Trust Funds from the model in 2017 were more than \$164 million across 44 ACOs. The model is also showing strong performance on quality metrics. See <https://www.cms.gov/newsroom/press-releases/cms-finalizes-pathways-success-overhaul-medicare-national-aco-program>.

The Innovation Center is also testing several episode-based payment models, including the Oncology Care Model (OCM) and the Comprehensive Care for Joint Replacement (CJR) Model. The goal of OCM is to utilize appropriately aligned financial incentives to enable improved care coordination, appropriateness of care, and access to care for beneficiaries undergoing chemotherapy. Under this model, physician practices have entered into payment arrangements that include financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients. The OCM encourages participating practices to improve care and lower costs

through an episode-based payment model that financially incentivizes high-quality, coordinated care. The practices participating in OCM have committed to providing enhanced services to Medicare beneficiaries such as care coordination, navigation, and national treatment guidelines for care. The OCM provides an incentive to participating physician practices to comprehensively and appropriately address the complex care needs of the beneficiary population receiving chemotherapy treatment and heighten their focus on furnishing services that specifically improve the patient experience or health outcomes. Fourteen commercial payors are participating in OCM in alignment with Medicare to create broader incentives for care transformation at the physician practice level. Aligned financial incentives that result from engaging multiple payors leverage the opportunity to transform care for oncology patients across a broader population. Other payors benefit from savings, better outcomes for their enrollees, and greater information around care quality. Participating payors have the flexibility to design their own payment incentives to support their enrollees while aligning with the Innovation Center's specific goals for OCM of care improvement and efficiency.

In addition to the Innovation Center's overarching goal of reduced program expenditures while preserving or enhancing quality of care, like OCM, the goal of the CJR Model is to transform care delivery with the result of better and more efficient care for patients undergoing the most common inpatient surgeries for Medicare beneficiaries: hip and knee replacements (also called lower extremity joint replacements). This model tests bundled payment and quality measurement for an episode of care associated with hip and knee replacements to encourage hospitals, physicians, and post-acute care providers to work together to improve the quality and coordination of care from the initial

hospitalization through recovery.

For more information about the Innovation Center's innovative health care payment and service delivery models, see <https://innovation.cms.gov/>. Importantly, the Congress granted the Secretary broad authority to waive provisions of section 1877 of the Act and certain other Federal fraud and abuse laws when he determines it is necessary to implement the Shared Savings Program (see section 1899(f) of the Act) or test models under the Innovation Center's authority (see section 1115A(d)(1) of the Act). For more information about waivers issued using these authorities and guidance documents related to specific waivers, see <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>.

c. Commercial Payor and Provider-Driven Activity

Although payments directly from a payor to a physician generally do not implicate the physician self-referral law unless the payor is itself an entity that furnishes designated health services, remuneration between physicians and other health care providers that provide care to a payor's enrolled patients (or subscribers) likely does implicate the physician self-referral law. Commercial payors and health care providers have implemented and continue to develop numerous innovative health care payment and care delivery models that do not include or specifically relate to CMS. Even though the physicians and health care providers who participate in these initiatives do not necessarily provide designated health services payable by Medicare as part of the initiatives, financial relationships between them may nonetheless implicate the physician self-referral law, which, in turn, may restrict referrals of Medicare patients. In considering the policies proposed in this proposed rule, we examined the value-based care delivery and

payment models developed by commercial payors, as well as those developed directly by health care providers, to better understand the need for exceptions to the physician self-referral law that would permit financial relationships among health care providers who provide services to patients outside the Medicare program.

CMS is aware of developments by payors, including the development of value-based care delivery and payment initiatives, that are intended to achieve the same population health goals as ACOs: better health, affordability, and experience. The approach of these payment initiatives is to reward health care professionals for value rather than volume and promote higher quality of care and lower total medical costs. CMS is aware of numerous initiative arrangements with primary care physician groups in over 30 states. One particular program encompassed more than 2 million commercial subscribers and more than 140,000 primary care physicians and specialists. The initiative expanded on prior initiatives involving large physician groups and integrated delivery systems, which showed successes, including better-than-market quality performance, and total medical cost; 50 percent fewer unnecessary emergency room visits; better compliance with diabetes measures; and closure of 21 percent more gaps in care.

Also of note, another payor has developed plans that promote care coordination measures by providing financial incentives to their hospital networks for reaching Integrated Care Certification from The Joint Commission. This payor's initiative was developed to evaluate the ability of identified health care settings to provide collaborative, coordinated services. The certification is a 3-year recognition of an organization's ability to provide clinically integrated care. (See https://www.jointcommission.org/assets/1/18/ICC_eligibility_12-14.pdf.) This type of

care coordination is similar to the goals set forth in CMS' ACO programs and models, as well as our Bundled Payments for Care Improvement initiatives.

In response to the CMS RFI mentioned in section I.B.1. of this proposed rule and in more detail in section I.B.2.d. of this proposed rule, commenters shared information regarding alternative payment models and other innovative programs sponsored by commercial payors. One commenter described its value-based contracting with physicians and health care providers as a move away from traditional volume-driven practices. This payor reimburses physicians for care coordination activities with incentive payments to facilitate better care; shares savings with physicians where their efforts helped achieve the cost savings; pays bundled rates for surgical procedures performed in ambulatory surgical centers (ASCs); and makes incentive payments to encourage the use of certain sites of service for particular cases. This commenter also noted that pharmaceutical manufacturers and other service providers are part of its value-based models. According to this commenter, its efforts will help align financial incentives with patient health outcomes and help prepare physicians and other providers to deliver care that improves patient outcomes but at lower cost, all while assuming greater financial risk. Other commenters described the breadth of their involvement in value-based health care delivery and payment. One of these commenters noted that 61 million (60 percent) of its subscribers have access to value-based providers and, in 2017, its value-based reimbursement accounted for 31 percent of total claims spending. Another commenter stated that it has 1,000 ACOs, with 15 million subscribers who access care from over 110,000 physicians and 1,100 hospitals participating in this value-based care program. These commenters stressed that their achievements in programs

where the physician self-referral law is not implicated or does not impose an absolute prohibition on physician referrals could be expanded to benefit the Medicare program and its beneficiaries with meaningful reform of the physician self-referral regulations.

d. Request for Information Regarding the Physician Self-Referral Law (CMS-1720-NC)

As described previously, the Secretary identified four priorities for HHS, the first of which is transforming our health care system into one that pays for value.

Dramatically different from the system that existed when the physician self-referral statute was enacted, a value-driven health care system pays for health and outcomes rather than sickness and procedures. We believe that a successful value-based system requires integration and coordination among physicians and other health care providers and suppliers. The Secretary has laid out four areas of emphasis for building a system that delivers value: maximizing the promise of health information technology (IT), improving transparency in price and quality, pioneering bold new models in Medicare and Medicaid, and removing government burdens that impede care coordination. This proposed rule focuses primarily on the final two areas of emphasis for value-based transformation—pioneering new models in Medicare and Medicaid and removing regulatory barriers that impede care coordination.

As the Secretary and the Administrator of CMS (the Administrator) have made clear, we are well aware of the burden that regulations, including the physician self-referral regulations, place on health care professionals and organizations, especially with respect to care coordination. In 2017, through the annual payment rules, CMS requested comments on improvements that could be made to the health care delivery system that would reduce unnecessary burdens for clinicians, other providers, and

patients and their families. In response, commenters shared information regarding the barriers to participation in health care delivery and payment reform efforts, both public and private, as well as the burdens of compliance with the physician self-referral statute and regulations as they exist today. As a result of our review of these comments, and with a goal of reducing regulatory burden and dismantling barriers to value-based care transformation while also protecting the integrity of the Medicare program, on June 25, 2018, we published in the **Federal Register** a Request for Information Regarding the Physician Self-Referral Law (as noted previously, the CMS RFI) seeking recommendations and input from the public on how to address any undue impact and burden of the physician self-referral statute and regulations (83 FR 29524). In the CMS RFI, we stated that we are particularly interested in input on issues that include the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements, the need for revisions or additions to exceptions to the physician self-referral regulations, and terminology related to alternative payment models and the physician self-referral statute and regulations in general (83 FR 29525).

We received approximately 375 comments in response to the CMS RFI. A wide range of stakeholders, including physicians and associations representing physicians, hospitals and associations representing hospitals, integrated health care delivery systems, non-Federal payors, individuals, rural stakeholders, and other components of the health care industry submitted comments. Commenters indicated that they appreciated the opportunity to submit feedback and recognized that the health care system is moving away from paying based on volume and toward payments based on value. Although most commenters believed that changes to the physician self-referral regulations are

needed to support the move to a value-based payment system, many recognized that the potential for program integrity vulnerability or other abuses continues to be a significant threat that CMS should not ignore. We received comments on most of the issues for which we requested information. We appreciate the detailed comments submitted, and found them extremely informative and helpful in developing our proposals.

Comments fell within five general themes. First, commenters requested new exceptions to the physician self-referral law to protect a variety of compensation arrangements between and among parties in CMS-sponsored alternative payment models and also those models that are sponsored by other payors. Commenters also requested protection for care coordination arrangements. Generally, commenters recognized the need for appropriate safeguards. Second, commenters requested a new exception to permit entities to donate cybersecurity technology and services to physicians. Third, commenters provided helpful feedback on terminology and concepts critical to the physician self-referral law, such as commercial reasonableness, fair market value, and compensation that “takes into account” the volume or value of referrals and is “set in advance.” Fourth, some commenters expressed concerns that new exceptions or easing current restrictions could exacerbate overutilization and other harms. For example, some commenters indicated that financial gain should never be permitted to influence medical decision making, and some expressed concern that value-based payment systems drive industry consolidation and reduce competition. Finally, a few commenters provided feedback on issues that were not covered by the CMS RFI, such as requests to eliminate or keep the statutory restrictions for physician-owned hospitals and requests to eliminate, expand, or limit the scope and availability of the in-office ancillary services exception.

C. Application and Scope of the Physician Self-Referral Law—Generally

Our intent in interpreting and implementing section 1877 of the Act has always been “to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory language and intent,” and we have not vacillated from this position (66 FR 860). Our 1998 proposed rule was informed by our review of the legislative history of section 1877 of the Act, consultation with our law enforcement partners about their experience implementing and enforcing the Federal fraud and abuse laws, and empirical studies of physicians’ referral patterns and practices, which concluded that a physician’s financial relationship with an entity can affect a physician’s medical decision-making and lead to overutilization. At the time of our earliest rulemakings, we did not have as much experience in administering the physician self-referral law or working with our law enforcement partners on investigations and actions involving violations of the physician self-referral law. Thus, despite our stated intention to interpret the law’s prohibitions narrowly and the exceptions broadly, we proceeded with great caution when designing exceptions.

Over the past decade, in particular, we have vastly expanded our knowledge of the aspects of financial relationships that result in Medicare program or patient abuse. Our administration of the CMS Voluntary Self-Referral Disclosure Protocol (SRDP), which has received over 1100 submissions since its inception in 2010, has provided us insight into thousands of financial relationships—most of which were compensation arrangements—that ran afoul of the physician self-referral law but posed no real risk of Medicare program or patient abuse. We made revisions to our regulations and shared policy clarifications in the CY 2016 and 2019 PFS rulemakings to address many issues

related to the documentation requirements in the statutory and regulatory exceptions to the physician self-referral law, but we have not, to date, addressed other requirements in the regulatory exceptions that stakeholders, including CMS RFI commenters, have identified as adding unnecessary complexity without increasing safeguards for program integrity. In this proposed rule, we are proposing to delete certain requirements in our regulatory exceptions that may be unnecessary at this time. We are also proposing to revise existing exceptions or propose new exceptions for nonabusive arrangements that we identified through our administration of the SRDP and the CMS RFI comments, and for which there is currently no applicable exception to the physician self-referral law's referral and billing prohibitions. In sections II.D. and E. of this proposed rule, we describe our specific proposals.

D. Purpose of the Proposed Rule

In 2017, CMS launched the Patients over Paperwork initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience. This effort emphasizes a commitment to removing regulatory obstacles to providers spending time with patients. Reducing unnecessary burden generally is a shared goal of the Patients over Paperwork initiative and the Regulatory Sprint. The Regulatory Sprint is focused specifically on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care. As requested by the Administrator and the Deputy Secretary, we reexamined the

physician self-referral statute and our regulations in order to identify ways to address any undue impact and burden of the law. Informed by the responses to the CMS RFI and our own experience in administering the physician self-referral law, we are proposing numerous revisions to modernize and clarify the physician self-referral regulations.

The proposals set forth in section II.A. of this proposed rule are intended to alleviate the undue impact of the physician self-referral statute and regulations on parties that participate in alternative payment models and other novel financial arrangements and to facilitate care coordination among such parties. As part of the Regulatory Sprint, OIG is concurrently developing proposals under the anti-kickback statute and CMP law to address similar concerns. Because many of the compensation arrangements between parties that participate in alternative payment models and other novel financial arrangements implicate both the physician self-referral law and the anti-kickback statute, we coordinated closely with OIG in developing some of the proposals in this proposed rule. Where appropriate, our aim is to promote alignment across our agencies' proposed rules to ease the compliance burden on the regulated industry. In some cases, CMS' proposals may be different in application or potentially more restrictive than OIG's comparable proposals, in recognition of the differences in statutory structures, authorities, and penalties. In other cases, OIG's proposals may be more restrictive. For some arrangements, it may be appropriate for the anti-kickback statute, which is an intent-based criminal law, to serve as "backstop" protection for arrangements that might be protected by an exception to the strict liability physician self-referral law. Given the close nexus between our proposals and OIG's proposals, we encourage stakeholders to review and submit comments on both proposed rules. However, we may consider

comments received only by OIG on its proposed rule if the comments address issues relevant to our proposals.

Our proposals that do not directly address value-based arrangements are set forth in sections II.B., C., D., and E. of this proposed rule and seek to balance genuine program integrity concerns against the considerable burden of the physician self-referral law's billing and claims submission prohibitions by reassessing the appropriate scope of the statute's reach; establishing exceptions for common nonabusive compensation arrangements between physicians and the entities to which they refer Medicare beneficiaries for designated health services; and providing critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.

II. Provisions of the Proposed Regulations

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

1. Background

Transforming our health care system into one that pays for value is one of the Secretary's priorities. Based on the comments to the CMS RFI, it is clear that there is broad consensus throughout the health care industry regarding the urgent need for a movement away from legacy systems that pay for care on a FFS basis. Identifying and dismantling regulatory barriers to value-based care transformation is a critical step in this movement. We are aware of the effect the physician self-referral law may have on parties participating or considering participation in integrated care delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost, and we share the optimism of commenters that the changes to the

physician self-referral regulations proposed here will unlock innovation and enable HHS to realize its goal of transforming the health care system into one that pays for value.

The health care landscape when the physician self-referral law was enacted bears little resemblance to the landscape of today. As some CMS RFI commenters highlighted, the physician self-referral law was enacted at a time when the goals of the various components of the health care system were not merely unaligned but often in conflict, with each component competing for a bigger share of the health care dollar without regard to the inefficiencies that resulted for the system as a whole—in other words, a volume-based system. According to several commenters, the current physician self-referral regulations—intended to combat overutilization in a volume-based world—are outmoded because, by their nature, integrated care models protect against overutilization by aligning clinical and economic performance as the benchmarks for value. And, in general, the greater the economic risk that providers assume, the greater the economic disincentive to overutilize services. According to more than one of these commenters, the current prohibitions are even antithetical to the stated goals of policy makers both in the Congress and within HHS for health care delivery and payment reform. Although we agree in concept, we continue to operate substantially in a volume-based payment system. Thus, we must proceed with caution, even as we propose the significant changes outlined in this proposed rule.

The vast majority of CMS RFI commenters requested that CMS revise existing exceptions or develop one or more new exceptions to the physician self-referral law to address the concerns noted previously. (We consider commenters’ requests for “waivers” of the physician self-referral law’s prohibitions to be requests for new exceptions, as they

have the same result; that is, if the conditions of the waiver or exception are met, the arrangement will be outside the ambit of the physician self-referral law's prohibitions.) Commenters urged us to exercise our authority to the broadest extent possible and focus on how the physician self-referral law should apply to the emerging models likely to dominate in the near future and beyond. Commenters also urged us not to limit the application of new policies to Medicare-sponsored models and payment methodologies. We intend for our proposals to facilitate an evolving health care delivery system, and endeavor here to strike the appropriate balance between ensuring program integrity and designing policies that will stand the test of time.

A few commenters stressed that a multi-faceted approach that establishes multiple new exceptions would only add more burden and complexity to the law. These commenters requested that we establish a single exception, similar to the Shared Savings Program Participation Waiver (80 FR 66726), that would apply to any compensation arrangement, regardless of the type of arrangement, payment model, or level of risk undertaken by the parties to the arrangement. Although we appreciate the commenters' concerns about complexity, we are cognizant of the need to ensure the integrity of the Medicare program and believe that the approach advocated by the commenters would not adequately protect the program and its beneficiaries. We believe that the proposals described in this section of the rule achieve the right balance between ensuring program integrity, making compliance with the physician self-referral law readily achievable, and providing the flexibility required by participants in value-based health care delivery and payment systems. As noted previously, in developing the proposed exceptions, definitions, and related policies, we coordinated closely with OIG. Where possible and

feasible, we have aligned with OIG's proposals to ease the compliance burden on the regulated industry.

2. Proposed Definitions and Exceptions

We are proposing at §411.357(aa) new exceptions to the physician self-referral law for compensation arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk undertaken by the parties to the arrangement or the value-based enterprise of which they are participants. The exceptions would apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients, or a combination of both. Although we believe that revisions to the physician self-referral regulations are crucial to facilitating the transition to a value-based health care delivery and payment system, nothing in our proposals is intended to suggest that many value-based arrangements, such as pay-for-performance arrangements or certain risk-sharing arrangements, do not satisfy the requirements of existing exceptions to the physician self-referral law.

For purposes of applying the proposed exceptions, we are proposing new definitions at §411.351 for the following terms: value-based activity; value-based arrangement; value-based enterprise; value-based purpose; VBE participant; and target patient population. The definitions are essential to the application of the exceptions. The proposed exceptions apply only to compensation arrangements that qualify as value-based arrangements. Thus, the exceptions may be accessed only by those parties that qualify as VBE participants in the same value-based enterprise. We intend for the definitions and exceptions together to create the set of requirements for protection from the physician self-referral law's referral and claims submission prohibitions.

To facilitate readers' review of our proposals, we discuss the proposed definitions first.

a. Proposed Definitions

The proposed "value-based" definitions are interconnected and, for the best understanding, should be read together. For purposes of applying the proposed exceptions at §411.357(aa), we are proposing the following definitions at §411.351:

- *Value-based activity* would mean any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise: (1) the provision of an item or service; (2) the taking of an action; or (3) the refraining from taking an action. The making of a referral is not a value-based activity.
- *Value-based arrangement* would mean an arrangement for the provision of at least one value-based activity for a target patient population between or among: (1) the value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.
- *Value-based enterprise* would mean two or more VBE participants: (1) collaborating to achieve at least one value-based purpose; (2) each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise; (3) that have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and (4) that have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

- *Value-based purpose* would mean: (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* would mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

- *Target patient population* would mean an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s).

The activities that serve as the basis for the compensation arrangements are key to qualifying as a value-based arrangement to which the proposed exceptions at §411.357(aa) would apply. We are proposing to identify these activities as “value-based activities” and propose at §411.351 to define “value-based activity” to include the provision of an item, the provision of a service, the taking of an action, or the refraining from taking an action, provided that the value-based activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which the parties are participants. Sometimes value-based activities are easily identifiable as the provision of items or services to a patient; other times, identifying a specific activity responsible for an outcome in a value-based health care system can be difficult. We

appreciate that remuneration paid in furtherance of the objectives of a value-based health care system does not always involve one-to-one payments for items or services provided by a party to an arrangement. For example, a shared savings payment distributed by an entity to a downstream physician who joined with other providers and suppliers to achieve the savings represents the physician's agreed upon share of such savings rather than a payment for specific items or services furnished by the physician to the entity (or on the entity's behalf). And, when payments are made to encourage a physician to adhere to a redesigned care protocol, such payments are made, in part, in consideration of the physician refraining from following his or her past patient care practices rather than for direct patient care items or services furnished by the physician. On the other hand, the act of referring patients for designated health services is itself not a value-based activity. As a general matter, referrals are not items or services for which a physician may be compensated under the physician self-referral law, and payments for referrals are antithetical to the purpose of the statute (69 FR 16096). We discuss this in further detail in section II.D.2.c. of this proposed rule.

Value-based activities must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise. For example, if the value-based purpose of the enterprise is to coordinate and manage the care of patients who undergo lower extremity joint replacement procedures, a value-based arrangement might require routine post-discharge meetings between a hospital and the physician primarily responsible for the care of the patient following discharge from the hospital. However, if the value-based purpose of the enterprise is to reduce costs to, or growth in expenditures of, payors while improving or maintaining the improved quality of care for the target patient population,

providing patient care services (the purported value-based activity) without monitoring their utilization would not appear to be reasonably designed to achieve that purpose.

The definition of “value-based arrangement” is key to our proposals aimed at facilitating the transition to value-based care and fostering care coordination, as the proposed exceptions apply only to arrangements that qualify as value-based arrangements. Under our proposal, an arrangement between a value-based enterprise and one or more of its VBE participants (if the enterprise is an “entity” as defined at §411.351 and the VBE participants are physicians), or between VBE participants in the same value-based enterprise, for the provision of at least one value-based activity for a target patient population would qualify as a value-based arrangement. Because our proposed exceptions at §411.357(aa) would apply only to compensation arrangements (as defined at §411.354(c)), the value-based arrangement must be a compensation arrangement and not another type of financial relationship to which the physician self-referral law applies. Effectively, the parties to a value-based arrangement would be an entity furnishing designated health services and a physician; otherwise, the physician self-referral law’s prohibitions would not be implicated. We discuss the other terminology used in the proposed definition of “value-based arrangement” in this section of the proposed rule.

Patient care coordination and management are the foundation of a value-based health care delivery system. Reform of the delivery of health care through better care coordination—including more efficient transitions for patients moving between and across care settings and providers,¹ reduction of orders for duplicative items and services,

¹ For purposes of this section, the term “providers” includes both providers and suppliers as those terms are defined in 42 CFR 400.202, as well as other components of the health care system. The term is used generically unless otherwise noted.

and open sharing of medical records and other important health data across care settings and among a patient's providers (consistent with privacy and security rules)—is integrally connected to reforming health care payment systems to shift from volume-driven to value-driven payment models. We expect that most value-based arrangements would involve activities that coordinate and manage the care of a target patient population, but have not proposed to limit the universe of compensation arrangements that would qualify as value-based arrangements to those arrangements specifically for the coordination and management of patient care. We seek comment regarding whether this approach—designed to provide needed flexibility for parties participating in alternative payment models (including those sponsored by CMS) to succeed in the transition to value-based payment—poses a risk of program or patient abuse that should be addressed through a revised definition of “value-based arrangement” that requires care coordination and management in order to qualify as a value-based arrangement.

The exceptions proposed at §411.357(aa) apply only to value-based arrangements, which, as described previously, must be between a value-based enterprise and one or more of its VBE participants or between parties in the same value-based enterprise. We intend the definition of “value-based enterprise” to include only organized groups of health care providers, suppliers, and other components of the health care system collaborating to achieve the goals of a value-based health care system. An “enterprise” may be a distinct legal entity—such as an ACO—with a formal governing body, operating agreement or bylaws, and the ability to receive payment on behalf of its affiliated health care providers. An “enterprise” may also consist only of the two parties to a value-based arrangement with the written documentation recording the arrangement

serving as the required governing document that describes the enterprise and how the parties intend to achieve its value-based purpose(s). (We note, as described below, that a value-based arrangement need not be reduced to writing to satisfy the requirements of the exceptions proposed at §411.357(aa)(1) and (2).) Whatever its size and structure, a value-based enterprise is essentially a network of participants (such as clinicians, providers, and suppliers) that have agreed to collaborate with regard to a target patient population to put the patient at the center of care through care coordination, increase efficiencies in the delivery of care, and improve outcomes for patients. We have proposed our definition of “value-based enterprise” in terms of the functions of the enterprise as it is not our intention to dictate or limit the appropriate legal structures for qualifying as a value-based enterprise.

To qualify as a value-based enterprise, among other things, each participant in the network, whom we refer to as VBE participants, must be a party to at least one value-based arrangement with at least one other participant in the network or with the value-based enterprise (if the enterprise is an “entity” as defined at §411.351). (If the network is comprised of only two VBE participants, they must have at least one value-based arrangement with each other in order for the network to qualify as a value-based enterprise.) We describe the proposed definition of VBE participant in more detail in this section of the proposed rule. In addition, the network seeking to qualify as a value-based enterprise must have an accountable body or person that is responsible for the financial and operational oversight of the enterprise. This may be the governing board, a committee of the governing board, or a corporate officer of the legal entity that is the value-based enterprise, or this may be the party to a value-based arrangement that is

designated as being responsible for the financial and operational oversight of the arrangement between the parties (if the “enterprise” is a network consisting of just the two parties). Finally, the network must have a governing document that describes the network (that is, the value-based enterprise) and how the VBE participants intend to achieve its value-based purpose(s). Implicit in this definition is that the value-based enterprise must have at least one value-based purpose.

Also critical to qualifying as a value-based arrangement is the purpose of the arrangement. As noted previously, only arrangements reasonably designed to achieve at least one value-based purpose may potentially qualify as a value-based arrangement to which the exceptions proposed at §411.357(aa) would apply. Our proposed definition of “value-based purpose” identifies four core goals related to a target patient population. These are: coordinating and managing the care of the target patient population; improving the quality of care for the target patient population; appropriately reducing the costs to, or the growth in expenditures of, payors without reducing the quality of care for the target patient population; and 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 the target patient population. One or more of these purposes must anchor every compensation arrangement that qualifies as a value-based arrangement to which our proposed new exceptions would apply. Some of these goals are recognizable as part of the successor frameworks to the “triple aim” that are integral to CMS’ value-based programs and our larger quality strategy to reform how health care is delivered and reimbursed. Although we expect that stakeholders will be familiar with these concepts, we seek comment regarding whether additional

interpretation is necessary. Specifically, with respect to the value-based purpose of appropriately reducing the costs to, or the growth in expenditures of, payors without reducing the quality of care for the target patient population, we are considering whether to require that the purpose of the value-based enterprise is to improve quality or maintain the already-improved quality of care for the target patient population (in addition to appropriately reducing the costs to or the growth of expenditures of payors). That is, the value-based purpose identified at proposed §411.351 (definition of value-based purpose, paragraph (3)) would state: appropriately reducing the costs to, or the growth in expenditures of, payors while improving or maintaining the improved quality of care for the target patient population. If we adopt such a policy, a value-based enterprise could not select this value-based purpose until after it has already achieved some improvement in the quality of care for the target patient population that is the subject of the value-based arrangement. We seek comment regarding this proposal.

We are seeking comment whether it is desirable or necessary to express in regulation text what is meant by “coordinating and managing care” and, if so, whether “coordinating and managing care” should be defined to mean 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. We note that this would align closely with the definition of “coordinating and managing care” under consideration by OIG. We also seek comment regarding 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. The transitioning from volume-based to value-based health care delivery and payment mechanisms is the fourth goal identified in our proposed definition of value-based purpose. We interpret “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 the target patient population” as a category that includes the integration of VBE participants in team-based coordinated care models; establishing the infrastructure necessary to provide patient-centered coordinated care; and accepting (or preparing to accept) increased levels of financial risk from payors or other VBE participants in value-based arrangements. We are cognizant that this goal may lack the precision desired in the physician self-referral regulations. Specifically, without clear boundaries as to what qualifies as “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 the target patient population,” it may be difficult to know whether the underlying purpose of an arrangement qualifies as a value-based purpose that triggers the availability of the proposed new exceptions at §411.357(aa). We seek comment with respect to this concern and the proposed definition of value-based purpose generally. We believe that reducing costs to patients is a laudable objective of a value-based arrangement when the reduction in costs relates to services that are unnecessary for the patient and does not inappropriately shift costs to the payor or another participant in the health care system. Due to our concerns about gaming and the inappropriate shifting of costs, we did not

propose to include the reduction of costs to patients as a value-based purpose. We seek comment on this policy determination.

As noted previously, we proposed to define VBE participant (that is, a participant in a value-based enterprise) to mean an individual or entity that engages in at least one value-based activity as part of a value-based enterprise, as described in this section II.A.2.a. We note that the word “entity,” as used in the proposed definition of “VBE participant,” is not limited to non-natural persons that qualify as “entities” as defined at current §411.351. Our proposed definition of “VBE participant” is intended to align with the definition under consideration by OIG. We seek comment regarding whether the use of the word “entity” in this definition would cause confusion due to the fact that the universe of non-natural persons (that is, entities) that could qualify as VBE participants is greater than the universe of non-natural persons that qualify as “entities” as defined at current §411.351 and, if so, alternatives for defining “VBE participant” for purposes of section 1877 of the Act and the physician self-referral regulations.

Based on the experience of our law enforcement partners, including their oversight experience, we are also concerned about protecting potentially abusive arrangements between certain types of entities that furnish designated health services for purposes of the physician self-referral law. Specifically, we are concerned about compensation arrangements between physicians and laboratories or suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that may be intended to improperly influence or capture referrals without contributing to the better coordination of care for patients. (See the 2013 EHR final rule (78 FR 78751), issued on December 27, 2013, for a discussion of our concerns regarding the donation of EHR

items and services by laboratories (78 FR 78757 through 78762).) We are considering whether to also exclude laboratories and DMEPOS suppliers from the definition of VBE participant or, in the alternative, whether to include in the exceptions at §411.357(aa), if finalized, a requirement that the arrangement is not between a physician (or immediate family member of a physician) and a laboratory or DMEPOS supplier. In particular, it is not clear to us that laboratories and DMEPOS suppliers have the direct patient contacts that would justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system. We solicit public comment on the role laboratories and DMEPOS suppliers play in care coordination for patients and value-based delivery and payment models. We are interested in learning more about how laboratories or DMEPOS suppliers may be important or necessary to foster care coordination for patients, as well as roles they may play that raise an undue risk of program or patient abuse. We note that, regardless of whether we exclude these suppliers (or any other providers or suppliers) from the definition of “VBE participant,” they may nevertheless be part of a value-based enterprise.

Due to our (and our law enforcement partners’) ongoing program integrity concerns with certain other components of the health care system and to maintain consistency with policies under consideration by OIG, we are also considering whether to exclude the following providers, suppliers, and other persons from the definition of “VBE participant”: pharmaceutical manufacturers; manufacturers and distributors of DMEPOS; pharmacy benefit managers (PBMs); wholesalers; and distributors. We believe that aligning our policies, if finalized, would minimize complexity for parties whose

arrangements implicate both the physician self-referral law and the anti-kickback statute. The exclusion from the definition of “VBE participant” would, in operation, serve to exclude a compensation arrangement between a physician and the party that is not a VBE participant from the application of the proposed exceptions for value-based arrangements. Therefore, in the alternative, we are considering whether to include in the exceptions at §411.357(aa) for value-based arrangements, if finalized, a requirement that the arrangement is not between a physician (or immediate family member of a physician) and a: pharmaceutical manufacturer; manufacturer or distributor of DMEPOS; pharmacy benefit manager; wholesaler; or distributor. We note that pharmacy benefit managers, manufacturers, and distributors usually are not entities furnishing designated health services for purposes of the physician self-referral law and, for the most part, serve only as persons in unbroken chains of financial relationships that may establish an indirect ownership or investment interest or an indirect compensation arrangement under the regulations at §411.354(b) and (c). Finally, even if we exclude pharmaceutical manufacturers, manufacturers and distributors of DMEPOS, pharmacy benefit managers, wholesalers, distributors, or other parties from the definition of “VBE participant,” no person, whether or not a provider or supplier in the Medicare program, would be precluded from participating in and contributing to a value-based enterprise. We seek comment on which persons and entities should qualify as VBE participants; our alternative proposals regarding protection for arrangements involving physicians (or their immediate family members) and the specified persons or organizations; and, in particular, whether other providers or suppliers, such as health technology companies, should be excluded from the definition of VBE participant or the application of the proposed

exceptions due to similar program integrity concerns. We note that we intend to align our policies with policies under consideration by OIG where possible and appropriate, and will consider comments submitted to OIG regarding its proposed definition of “VBE participant” as we develop policies in any final rule.

We are proposing to define the target patient population for which VBE participants undertake value-based activities to mean the identified patient population selected by a value-based enterprise or its VBE participants using legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise’s value-based purpose(s). Legitimate and verifiable criteria may include medical or health characteristics (for example, patients undergoing knee replacement surgery or patients with newly diagnosed type 2 diabetes), geographic characteristics (for example, all patients in an identified county or set of zip codes), payor status (for example, all patients with a particular health insurance plan or payor), or other defining characteristics. Selecting a target patient population consisting of only lucrative or adherent patients (cherry-picking) and avoiding costly or noncompliant patients (lemon-dropping) would not be permissible under most circumstances, as we would not consider the selection criteria to be legitimate (even if verifiable). Generally speaking, choosing a target patient population in a manner driven primarily by a profit motive or purely financial concerns would not be legitimate. We seek comment regarding the requirement that selection criteria be legitimate and verifiable, as well as any additional or substitute criteria that we might include in the definition of target patient population. We also seek comment on additional selection criteria that should or should not be considered “legitimate and verifiable” and on

whether we should specify in regulation text a non-exhaustive list of selection criteria that would or would not be “legitimate and verifiable.”

b. Proposed Exceptions

The physician self-referral law (along with other Federal fraud and abuse laws) provides critical protection against a range of troubling patient and program abuses that may result from volume-driven, FFS payment. These abuses include unnecessary utilization, increased costs to payors and patients, inappropriate steering of patients, corruption of medical decision making, and competition based on buying referrals instead of delivering quality, convenient care. While value-based payment models hold promise for addressing these abuses, they may pose risks of their own, including risks of stinting on care (underutilization), cherry-picking, lemon-dropping, and manipulation or falsification of data used to verify outcomes. Moreover, during the transformation to value-based payment, many new delivery and payment models include both FFS and value-based payment mechanisms in the same model, subjecting providers to mixed incentives, and presenting the possibility of arrangements that pose both traditional FFS risk and emerging value-based payment risks.

In removing regulatory barriers to innovative care coordination and value-based arrangements, we are faced with the challenge of designing protection for emerging health care arrangements, the optimal form, design, and efficacy of which remains unknown or unproven. This is a fundamental challenge of regulating during a period of innovation and experimentation. In addition, the health care industry is experiencing very rapid change, and there is a lack of predictability of desired future arrangements. Matters are further complicated by the substantial variation in care coordination and

value-based arrangements contemplated by the health care industry, variation among patient populations and providers, emerging health technologies and data capabilities, and our desire not to chill beneficial innovations. Thus, the one-size-fits-all approach to protection from the physician self-referral law's prohibitions that was recommended by many commenters may be less than optimal.

The design and structure of our proposed exceptions are intended to further several complementary goals. First, we have endeavored to remove regulatory barriers, real or perceived, to create space and flexibility for industry-led innovation in the delivery of better and more efficient coordinated health care for patients and improved health outcomes. Second, consistent with the Secretary's priorities, the historical trend toward improving health care through better care coordination, and the increasing adoption of value-based models in the health care industry, we are proposing a set of exceptions that, as a whole, may create additional incentives for the industry to move away from volume-based health care delivery and payment and toward population health and other non-FFS payment models. In this regard, our proposed exception structure incorporates additional flexibilities for compensation arrangements between parties that have increased their participation in mature value-based payment models and their assumption of downside financial risk under such models. As discussed in more detail in this section of the proposed rule, our expectation is that meaningful assumption of downside financial risk would not only serve the overall transformation of industry payment systems, but could also curb, at least to some degree, FFS incentives to order medically unnecessary or overly costly items and services, key patient and program harms addressed by the physician self-referral law (and other Federal fraud and abuse

laws).

As described in this proposed rule and in the CMS RFI, the current exceptions to the physician self-referral law include requirements that may create significant challenges for parties that wish to develop novel financial arrangements to facilitate their successful participation in health care delivery and payment reform efforts. Most of the commonly relied upon exceptions to the physician self-referral law include requirements related to compensation that may be difficult to satisfy where the arrangement is designed to foster the behavior shaping necessary for the provision of high-quality patient care that is not reimbursed on a traditional FFS basis. Requirements that compensation be set in advance, fair market value, and not take into account the volume or value of a physician's referrals or the other business generated between the parties may inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures (or reduced growth in expenditures). For example, depending on their structure, arrangements for the distribution of shared savings or repayment of shared losses, gainsharing arrangements, and pay-for-performance arrangements that provide for payments to refrain from ordering unnecessary care, among others, may be unable to satisfy the requirements of an existing exception to the physician self-referral law. According to one commenter, a typical shared savings payment inherently takes into account the volume or value of referrals for hospital services and other designated health services, but does so by creating an inverse correlation between the volume or value of referrals and the amount of the shared savings payment. As another commenter suggested, many stakeholders simply do not possess a degree of risk tolerance sufficient to participate in new models of health care delivery and payment if they have to apply the

requirements of the existing exceptions to their financial arrangements, even when such arrangements do not have the characteristics that the physician self-referral law was intended to constrain. Thus, rather than being a check on bad actors, in the context of value-based care models, the physician self-referral law may actually be having a chilling effect on models and arrangements designed to “bend the cost curve and improve quality of care to patients.”

We have carefully considered the CMS RFI comments and anecdotal information shared by stakeholders regarding the impact of the specific requirements that compensation be set in advance, fair market value, and not 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, law enforcement and judicial activity related to these requirements, and our own observations from our work (including our work on fraud and abuse waivers for CMS accountable care and other models). We are concerned that the inclusion of such requirements in the exceptions for value-based arrangements proposed at §411.357(aa) would conflict with our goal of addressing regulatory barriers to value-based care transformation. As one commenter stated, these requirements simply may not be suited to the collaborative models that reward value and outcomes.

We note that two of the exceptions for value-based arrangements that we are proposing are available to protect arrangements even when payments from the payor are made on a FFS basis. Even so, we are not proposing to require that remuneration is consistent with fair market value and not determined in any manner that takes into account the volume or value of a physician’s referrals or the other business generated by the physician for the entity. Instead, we are proposing a carefully woven fabric of

safeguards, including requirements incorporated through the applicable value-based definitions. We believe that the disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address that are built into the proposed value-based definitions will operate in tandem with the requirements included in the proposed exceptions and be sufficient to protect against program and patient abuse. This is especially true where full or meaningful downside financial risk is assumed. We are, however, including in two of the proposed exceptions for value-based arrangements that the methodology used to determine the amount of the remuneration—but not the actual amount of the remuneration itself—is set in advance of the undertaking of value-based activities for which the remuneration is provided. We seek comment on our approach. We are especially interested in comments regarding whether the safeguards provided by the combination of the proposed definitions and the requirements of the proposed exceptions would be adequate to protect against program or patient abuse and, if not, whether it would be appropriate or necessary to include requirements in any final exceptions that remuneration: (1) not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity; and (2) is consistent with the fair market value of the value-based activities provided under the arrangement. We are also interested in comments regarding whether we should include a requirement that the value-based arrangement is commercially reasonable as defined in our alternative proposals described in section II.B.2. of this proposed rule.

Because the proposed exceptions for value-based arrangements do not include a requirement that the remuneration is not determined in any manner that takes into account the volume or value of referrals, the special rule at current §411.354(d)(4) would

not apply to arrangements protected under the exceptions. (See section II.B. of this proposed rule for a more fulsome discussion of the history of the special rule at §411.354(d)(4).) This special rule permits the entity of which the physician is a *bona fide* employee, independent contractor, or party to a managed care contract to direct the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets specified conditions designed to preserve the physician's judgment as to the patient's best medical interests, avoid interfering in an insurer's operations, and, importantly, protect patient choice.

The right to freedom of choice of providers is expressed and reinforced in almost every aspect of the Medicare program. We believe that a patient's control over who provides his or her care directly contributes to improved health outcomes and patient satisfaction, enhanced quality of care and efficiency in the delivery of care, increased competition among providers, and reduced medical costs, all of which are aims of the Medicare program. Protection of patient choice is especially critical in the context of referrals made by a physician to an entity with which the physician has a financial relationship, as the physician's financial self-interest may impact, if not infringe on, a patient's right to control who furnishes his or her care. For this reason, we are proposing to make compliance with §411.354(d)(4)(iv) a requirement of the exceptions that apply to employment arrangements, personal service arrangements, or managed care contracts that purport to restrict or direct physician referrals, including the proposed exceptions at §411.357(aa) for value-based arrangements. (We are not proposing to include this requirement in the exception for group practice arrangements with a hospital at §411.357(g) because the statute does not authorize the Secretary to impose additional

requirements by regulation beyond those included in the statute at section 1877(e)(7) of the Act.) As described in section II.B. of this proposed rule, we are also proposing clarifying revisions to current §411.354(d)(4). In the alternative, rather than reference §411.354(d)(4)(iv), we are proposing to include at §411.357(aa) a separate requirement applicable specifically to value-based arrangements 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 health care provider, the physician's medical judgment, and the ability of health insurers to efficiently provide care to their members. We seek comment on the best approach to address our concerns.

Finally, we have endeavored to be as neutral as possible with respect to the types of value-based enterprises and value-based arrangements the proposed exceptions would cover in order to allow for innovation and experimentation in the health care marketplace and so that compliance with the physician self-referral law is not the driver of innovation or the barrier to innovation. One CMS RFI commenter asserted that, in their current state, the physician self-referral regulations discourage the development and adoption of rewards that encourage change on a broad scale, across all patient populations and payor types, and over indefinite periods of time. It is for this reason also that we are not proposing to limit the exceptions to CMS-sponsored models or establish separate exceptions with different criteria for arrangements that exist outside of CMS-sponsored models.

When the physician self-referral law was expanded in 1993 to apply to designated health services beyond the clinical laboratory services to which the original 1989 law applied, according to the sponsor of the legislation, the Honorable Fortney "Pete" Stark,

the physician self-referral law was intended to address physician referrals that drive up health care costs and result in unnecessary utilization of services. (See Opening Statement of the Honorable Pete Stark, Physician Ownership and Referral Arrangements and H.R. 345, “The Comprehensive Physician Ownership and Referral Act of 1993,” House of Representatives, Committee on Ways and Means, Subcommittee on Health, April 20, 1993, p. 144.) Mr. Stark went on to emphasize the importance of a physician’s ability to offer patients neutral advice about whether or not services are necessary, which services are preferable, and who should provide them. He noted that the physician self-referral law would improve consumers’ confidence in their physicians and the health care system generally. In other words, the legislation was proposed (and the law ultimately enacted) to counter the effects of physician decision making driven by financial self-interest—overutilization of health care services, the suppression of patient choice, and the impact on the medical marketplace.

As discussed previously in this proposed rule, in 1989 and 1993, the vast majority of Medicare services were reimbursed based on volume under a retrospective FFS system. The statutory exceptions to the physician self-referral law’s referral and billing prohibitions were developed during this time of FFS, volume-based payment, with conditions which, if met, would allow the physician’s ownership or investment interest or compensation arrangement to proceed without triggering the ban on the physician’s referrals or the entity’s claims submission. We believe that the exceptions in section 1877 of the Act indicate the Congress’ stance on what safeguards are necessary to protect against program or patient abuse in a system where Medicare payment is available for each service referred by a physician and furnished by a provider or supplier. To date, the

exceptions for compensation arrangements issued under section 1877(b)(4) of the Act, which grants the Secretary authority to establish exceptions for financial relationships that the Secretary determines do not pose a risk of program or patient abuse, have generally followed the blueprint established by the Congress for compensation arrangements that exist in a FFS system.

Value-based health care delivery and payment shifts the paradigm of our analysis under section 1877(b)(4) of the Act. When no longer operating in a volume-based system, or operating in a system that reduces the amount of FFS payment by combining it with some level of value-based payment, we believe that our exceptions need fewer “traditional” requirements to ensure the arrangements they protect do not pose a risk of program or patient abuse. This is because a value-based health care delivery and payment system itself provides safeguards against harms such as overutilization, care stinting, patient steering, and negative impacts on the medical marketplace. Using the Secretary’s authority under section 1877(b)(4) of the Act, we are proposing three exceptions for compensation arrangements that we believe do not pose a risk of program or patient abuse when considered in concert with: (1) the program integrity and other requirements integrated in the proposed definitions used to apply the exceptions only to compensation arrangements that qualify as “value-based arrangements;” and (2) the disincentives to perpetrate the harms the physician self-referral law was intended to deter that are intrinsic in the assumption of substantial downside financial risk and meaningful participation in value-based health care delivery and payment models. Specifically, at proposed §411.357(aa)(1), we are proposing an exception that would apply to a value-based arrangement where a value-based enterprise has, during the entire term of the

arrangement, assumed full financial risk from a payor for patient care services for a target patient population. At proposed §411.357(aa)(2), we are proposing an exception that would apply to a value-based arrangement under which the physician is at meaningful downside financial risk for failure to achieve the value-based purposes of the value-based enterprise during the entire term of the arrangement. Finally, at proposed §411.357(aa)(3), we are proposing an exception that would apply to any value-based arrangement, provided that the arrangement satisfies specified requirements. The proposed exceptions include fewer requirements where a value-based enterprise has assumed full financial risk for the cost of the target patient population's health care (that is, the value-based enterprise and its VBE participants receive no FFS payments in addition to the capitated payments or global budget payment made to the value-based enterprise from the payor), with the requirements increasing and changing as the level of financial risk in the value-based arrangement diminishes.

The exceptions proposed at §411.357(aa) and described in detail in this section of the proposed rule would be applicable to the compensation arrangements between parties in a CMS-sponsored model, program, or other initiative (provided that the compensation arrangement at issue qualifies as "value-based arrangement"), and we believe that compensation arrangements between parties in a CMS-sponsored model, program, or other initiative can be structured to satisfy the requirements of at least one of the proposed exceptions at §411.357(aa). We intend that this suite of value-based exceptions, if finalized, would eliminate the need for any new waivers of section 1877 of the Act for value-based arrangements. (We note that, even if the proposed exceptions are finalized, parties may elect to use the waivers applicable to the CMS-sponsored models,

programs, or initiatives in which they participate.) Even so, we are interested in learning whether stakeholders view our proposals as leaving gaps in protection from the physician self-referral law's prohibitions for certain arrangements that are permissible under a CMS-sponsored model, program, or other initiative. We are soliciting comments regarding the structure and scope of our proposed exceptions; specific compensation arrangements that are permissible under a CMS-sponsored model, program, or other initiative but might not be able to satisfy the requirements of one of the proposed value-based exceptions; and suggested modifications to our proposals that would bridge any perceived or actual gaps in the protection of the exceptions at proposed §411.357(aa)(1), (2) and (3). We are also interested in comments that address what safeguards would be appropriate to include in such a "gap-filler" exception in order to protect against program or patient abuse. We remind potential commenters that an exception issued using the authority at section 1877(b)(4) of the Act may protect only those financial relationships that the Secretary determines do not pose a risk of program or patient abuse.

We are mindful that value-based enterprises and parties to value-based arrangements may assume other types of risk, including operational risk, contractual risk, and investment risk. For example, the adopter of EHR technology and the developer of a medical office building assume business risk that the investment in the EHR technology and the buildout of office space, respectively, does not result in profit. For our purposes, we are focused on the financial risk because we believe such risk can directly influence the incentives physicians and other providers have to order items and services for patients, the conduct at the core of the physician self-referral law (and other Federal fraud and abuse laws). We are not persuaded other types of risk would operate similarly to

counter volume-based payment incentives; however, we solicit comments on this issue.

Several CMS RFI commenters requested that we keep in place existing exceptions that may protect certain value-based arrangements, regardless of any proposed new exceptions and policies. We are not at this time proposing any substantive changes to the exception at §411.355(c) for services furnished by an organization (or its contractors or subcontractors) to enrollees or the exception at §411.357(n) for risk-sharing arrangements. However, see section II.D.13. of this proposed rule for our proposal to update the exception at §411.355(c) to eliminate an out-of-date reference. Many commenters discussed the difficulty specialty physicians have in participating in alternative payment models, especially advanced alternative payment models, and requested that we deem certain financial relationships to qualify as alternative payment models. Our proposals do not turn on whether the parties to an arrangement are participating in alternative payment models or whether arrangements themselves qualify as alternative payment models. We believe that the approach discussed in this proposed rule, under which the proposed exceptions are available for compensation arrangements designed to achieve the value-based purpose(s) of an enterprise consisting of at least the physician and the entity to which he or she refers designated health services, is the better approach. Physician self-referral law policy is not the appropriate place to define or identify alternative payment models. Our focus here is to remove the regulatory barriers that inhibit the transformation to value-based care.

(1) Full Financial Risk (Proposed §411.357(aa)(1))

We are proposing at §411.357(aa)(1) an exception to the physician self-referral law (the “full financial risk exception”) that would apply to value-based arrangements

between VBE participants in a value-based enterprise that has assumed “full financial risk” 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; that is, the value-based enterprise is financially responsible (or is contractually obligated to be financially responsible within the 6 months following the commencement date of the value-based arrangement) on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For Medicare beneficiaries, we would interpret this requirement to mean that the value-based enterprise, at a minimum, is responsible for all items and services covered under Parts A and B. We seek comments regarding the proposed definition of “full financial risk” described here and in proposed §411.357(aa)(1)(viii). Specifically, we seek comment regarding whether a value-based enterprise should be considered to be at full financial risk if it is responsible for the cost of only a defined set of patient care services for a target patient population and whether we should require a minimum period of time during which the value-based enterprise is at full financial risk (for example, 1 year).

Full financial risk may take the form of capitation payments (that is, a predetermined payment per patient per month or other period of time) or global budget payment from a payor that compensates the value-based enterprise for providing all patient care items and services for a target patient population for a predetermined period of time. The proposed exception would not prohibit other approaches to full financial risk, and we seek comment regarding other types of full financial risk payment models that may exist currently or that stakeholders anticipate as the transition to a value-based

health care delivery and payment system progresses. As described elsewhere in this section, a value-based enterprise need not be a separate legal entity with the power to contract on its own. Rather, networks of physicians, entities furnishing designated health services, and other components of the health care system collaborating to achieve the goals of a value-based health care system, organized with legal formality or not, may qualify as a value-based enterprise. A value-based enterprise may assume legal obligations in any number of ways. For example, all VBE participants in a value-based enterprise could each sign the contract for the value-based enterprise to assume full financial risk from a payor. Or, the VBE participants in a value-based enterprise could have contractual arrangements among themselves that assign risk jointly and severally. Or, similar to physicians in an independent practice association (IPA), VBE participants could vest the authority to bind all VBE participants in the value-based enterprise with a designated person who contracts for the assumption of full financial risk on behalf of the value-based enterprise and its VBE participants. We do not purport to prescribe in this proposal a specific manner for the assumption of full financial risk.

The financial risk must be prospective; that is, the contract between the value-based enterprise and the payor may not allow for any additional payment to compensate for costs incurred by the value-based enterprise in providing specific patient care items and services to the target patient population, nor may any VBE participant claim payment from the payor for such items or services. Our proposed definition of “full financial risk” would not prohibit a payor from making payments to a value-based enterprise to offset losses incurred by the enterprise above those prospectively agreed to by the parties. The payment of shared savings or other incentive payments for achieving quality,

performance, or other benchmarks also would not be prohibited. We are proposing to also protect value-based arrangements entered into in preparation for the implementation of the value-based enterprise's full financial risk payor contract where such arrangements begin after the value-based enterprise is contractually obligated to assume full financial risk for the cost of patient care items and services for the target patient population but prior to the date the provision of patient care items and services under the contract begin. We are proposing to limit this period to the 6 months prior to the effective date of the full financial risk payor contract. In other words, the value-based enterprise must be at full financial risk within the 6 months following the commencement of the value-based arrangement. We seek comment whether this is a sufficient period of time for parties to construct arrangements and begin preparations for the implementation of the value-based enterprise's full financial risk payor contract.

We believe that full financial risk is one defining characteristic of a mature value-based payment system. When a value-based enterprise is at full financial risk for the cost of all patient care services, the incentives to order unnecessary services or steer patients to higher-cost sites of service are diminished. Even when downstream contractors are paid on something other than a full-risk basis, the value-based enterprise itself is incented to monitor for appropriate utilization, referral patterns, and quality performance, which we believe helps to reduce the risk of program or patient abuse. As one CMS RFI commenter noted, where there is a finite amount of payment, if costs go up, participating providers may incur direct financial losses. According to the commenter, these kinds of payment limitations provide stronger and more effective guardrails against increases in the volume and costs of services than the fraud and abuse laws ever placed on the FFS

system. As a precaution, we are including several important safeguards in the proposed exception.

One requirement of the proposed exception is that the value-based enterprise must be at full financial risk during the entire duration of the value-based arrangement for which the parties to the arrangement seek protection. The proposed exception would not protect arrangements that begin at some point during a period when the safeguards intrinsic to full-risk value-based payment are in place, but that continue into a timeframe when such safeguards no longer exist. However, one or both of the other proposed exceptions at §411.357(aa) may be available to protect value-based arrangements that exist during a period when the value-based enterprise is not at full financial risk for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population.

As described throughout this proposed rule, we believe that well-coordinated and managed patient care is the cornerstone of a value-based health care system. We are soliciting comments regarding whether it is necessary to include in the full financial risk exception, as well as the other exceptions for value-based arrangements at §411.357(aa), a requirement that the parties to a value-based arrangement engage in value-based activities that include, at a minimum, the coordination and management of the care of the target patient population or that the value-based arrangement be reasonably designed, at a minimum, to coordinate and manage the care of the target patient population. We believe that such a requirement would be the most direct way to further the goals of the Regulatory Sprint. On the other hand, we also believe that, by their nature, arrangements that qualify as “value-based arrangements” would have care coordination and

management at their heart, and we question whether an explicit requirement is necessary. Moreover, we are concerned that requiring every value-based arrangement to include the coordination and management of care of the target patient population could leave beneficial value-based arrangements that do not directly coordinate or manage the care of the target patient population without access to any of the exceptions at proposed §411.357(aa) and potentially unable to meet the requirements of any existing exception to the physician self-referral law.

We are also proposing a requirement that the remuneration under the value-based arrangement is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population. We recognize that payments under certain incentive payment arrangements, such as gainsharing arrangements, may be difficult to tie to specific items or services furnished by a VBE participant. We would not interpret the requirement at proposed §411.357(aa)(1)(ii) as mandating a one-to-one payment for an item or service (or other value-based activity). Gainsharing payments, shared savings distributions, and similar payments may result from value-based activities undertaken by the recipient of the payment for patients in the target patient population. We believe that the requirement that the remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population adequately addresses this issue; however, we are considering whether to require that the remuneration also or instead relates to the value-based purpose(s) of the value-based enterprise or value-based arrangement. Also, we intend for this to be an objective standard; that is, the remuneration must, in fact, be for or result from value-based activities undertaken by the recipient of the remuneration for

patients in the target patient population. The proposed exception, therefore, would not protect payments for referrals or any other actions or business unrelated to the target patient population, such as general marketing or sales arrangements. With respect to in-kind remuneration, essentially, the remuneration must be necessary and not simply duplicate technology or other infrastructure that the recipient already has. Finally, although the remuneration must be for or result from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, parties would not be prohibited from using the remuneration for the benefit of patients who are not part of the target patient population.

Integrated into most of the CMS-sponsored models is a requirement that any remuneration between parties to an allowable financial arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient in the assigned patient population. We believe this is an important safeguard for patient safety and quality of care, regardless of whether Medicare is the ultimate payor for the services, and propose to include it in the full financial risk exception by requiring at proposed §411.357(aa)(1)(iii) that remuneration is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not. Remuneration that leads to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act.

In addition, we are proposing to protect only those value-based arrangements under which 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. Although this requirement is similar to the requirement that remuneration is for or results

from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population, it is intended to address a different concern. The exception would not protect arrangements where one or both parties have made referrals or other business not covered by the value-based arrangement a condition of the remuneration. By way of example, if the value-based enterprise is at full financial risk for the total cost of care for all of a commercial payor's enrollees in a particular county, the exception would not protect a value-based arrangement between an entity and a physician that are VBE participants in the value-based enterprise if the entity required the physician to refer Medicare patients who are not part of the target patient population for designated health services furnished by the entity. Similarly, the exception would not protect a value-based arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement required that the physician perform all his or her other orthopedic surgeries at the hospital. (Our examples relate to value-based arrangements between entities furnishing designated health services and physicians because the physician self-referral law's prohibitions would not be implicated if the arrangement was not between an entity furnishing designated health services and a physician (or the physician organization in whose shoes the physician stands under §411.354(c)(2).)

We are also proposing requirements at §411.357(aa)(1)(v) and (vi) related to requiring a physician to refer to a particular provider, practitioner, or supplier and price transparency. We refer to our description of these requirements in sections II.B.4. and II.A.2.b., of this proposed rule, respectively.

Finally, we are proposing to require that records of the methodology for determining and the actual amount of remuneration paid under the value-based

arrangement be maintained for a period of at least 6 years and made available to the Secretary upon request. Requirements similar to this are found in our existing regulations in the group practice rules at §411.352(d)(2) and (i), the exception for physician recruitment at §411.357(4)(iv), and the exception for assistance to compensate a nonphysician practitioner at §411.357(x)(2). We expect that parties are familiar with these requirements and that the maintenance of such records is part of their routine business practices.

We consider the exception at proposed §411.357(aa)(1) comparable, in some respects, to the exception at §411.357(n) for risk-sharing arrangements, which is intended to be a broad exception with maximum flexibility, covering all risk-sharing compensation paid to a physician by an entity downstream of any type of health plan, insurance company, or health maintenance organization (that is, any “managed care organization”) or independent practice association, provided the arrangement relates to enrollees and meets the conditions set forth in the exception (69 FR 16114). All downstream entities are included within the scope of the exception for risk-sharing arrangements. We endeavored to structure a similar exception here, given the underlying parallels between a managed care organization and a value-based enterprise at full financial risk for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population. Although the proposed exception at §411.357(aa)(1) is not limited to “risk-sharing compensation” paid to a physician, but, rather, covers any type of remuneration paid under a value-based arrangement that is for or results from value-based activities undertaken by the recipient of the remuneration, for the reasons discussed throughout this section II.A. of this proposed rule, we believe that the type of flexibility

provided in the exception for risk-sharing arrangements is also warranted here. Finally, like the exception at §411.357(n) for risk-sharing arrangements, there are no documentation requirements proposed for the full financial risk exception. Nevertheless, we believe that reducing to writing any arrangement between referral sources is a good business practice that allows the parties to monitor and confirm that the arrangement is operating as intended.

(2) Value-Based Arrangements with Meaningful Downside Financial Risk to the Physician (Proposed §411.357(aa)(2))

A few CMS RFI commenters opined that the health care industry is in the infancy of its transition to value-based health care delivery and payment. Although we believe that our efforts described in section I.B.2. of this proposed rule, as well as those of non-Federal payors and a significant segment of the health care industry, have advanced us beyond “infancy,” we acknowledge that most physicians and providers are not yet prepared or willing to be responsible for the total cost of patient care services for a target patient population. However, some physicians are participating in or considering participating in alternative payment models that provide for potential financial gain in exchange for the undertaking of downside financial risk.

We believe that financial risk assumed directly by a physician will affect his or her practice and referral patterns in a way that curbs the influence of traditional FFS, volume-based payment. When that financial risk is tied to the failure to achieve value-based purposes, we believe there is great potential for the type of behavior-shaping necessary to transform our health care delivery system into one that improves patient outcomes, eliminates waste and inefficiencies, and reduces costs to or the growth in

expenditures of payors. Arrangements under which a physician is at meaningful downside financial risk for failure to achieve predetermined cost, quality, or other performance benchmarks contain certain inherent protections against program or patient abuse.

We are proposing an exception at §411.357(aa)(2) that would protect remuneration paid under a value-based arrangement where the physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise (the “meaningful downside financial risk exception”). (As noted previously, for purposes of our proposed exceptions, the parties to a value-based arrangement would be an entity furnishing designated health services and a physician; otherwise, the physician self-referral law’s prohibitions would not be implicated.) Although the physician must be at meaningful downside financial risk for the entire term of the value-based arrangement, the remuneration could be paid to or from the physician. We seek comment regarding whether the physician would have the same incentive to modify his or her practice and referral patterns in a manner designed to achieve the important goals described in this proposed rule if the party that has assumed the meaningful downside financial risk and is paying remuneration under the arrangement is the entity furnishing designated health services. We expect that, in such a case, the entity would be appropriately motivated to monitor and respond to a physician’s practice and referral patterns if such patterns could negatively impact the entity’s financial position, but we are not convinced that such motivation to monitor would be sufficient to safeguard against program or patient abuse.

For purposes of the exception, we are proposing to define “meaningful downside

financial risk” to mean that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement. We believe that this level of financial risk is high enough to curb the influence of traditional FFS, volume-based payment and achieve the type of behavior-shaping necessary to facilitate achievement of the goals set forth in this proposed rule. Defining meaningful downside financial risk in this way would establish consistency with the 25 percent threshold determined by the Secretary for the statutory and regulatory exceptions for physician incentive plans at section 1877(e)(3)(B) of the Act and §411.357(d)(2), respectively, which reference “substantial financial risk” to a physician (or physician group). For purposes of those exceptions, the Secretary has defined “substantial financial risk” to mean the risk for referral services that exceeds the risk threshold, which is currently set at 25 percent (see §422.208). We have proposed to require that the financial risk be “downside” risk for clarity. Because we are not proposing to limit the type of remuneration that may be provided, we require the risk of repayment to be for no less than 25 percent of the value of the remuneration to account for remuneration that may be provided in-kind, such as infrastructure or care coordination services.

Meaningful downside financial risk would also include full financial risk. That is, for purposes of the meaningful downside financial risk exception, we are proposing to define “meaningful downside financial risk” to also mean that the physician is financially responsible to the payor or the entity on a prospective basis for the cost of all or a defined set of items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. Thus, a physician would be at

meaningful downside financial risk when he or she is at “full” financial risk; that is, when the physician is paid a capitated payment, global budget payment, or some other payment for all or a defined set of patient care services for the target patient population. We are, however, concerned about the potential for gaming if the parties established too narrow a set of patient care services for which the physician is at meaningful downside financial risk. We are considering an approach that defines meaningful downside financial risk only to mean that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement and exclude a specific reference to total cost of care. We seek comment on our approaches as to how we might appropriately define meaningful downside financial risk for purposes of proposed §411.357(aa)(2). Specifically, we seek comment on whether the proposed 25 percent threshold is appropriate, and whether downside risk for 25 percent of only a nominal amount of remuneration would be sufficient to curb the influence of traditional FFS, volume-based payment.

As we discussed previously, under the full financial risk exception, we are proposing to protect value-based arrangements entered into in preparation for the implementation of the value-based enterprise’s full financial risk payor contract where such arrangements begin after the value-based enterprise is contractually obligated to assume full financial risk for the cost of patient care items and services for the target patient population but prior to the date the provision of patient care items and services under the contract begin. We are proposing to limit this period to the 6 months prior to the effective date of the full financial risk payor contract. We seek comment whether we should include an analogous provision in the meaningful downside financial risk

exception and, if so, whether 6 months is an appropriate period of time for parties to construct arrangements and begin preparations for the physician's assumption of meaningful downside financial risk.

Because the exception proposed at §411.357(aa)(2) does not require the type of global risk to the value-based enterprise as our proposed full financial risk exception, we believe that additional or different requirements are necessary to protect against program or patient abuse. We are proposing a requirement at §411.357(aa)(2)(i) that the physician must be at meaningful downside financial risk for the entire term of the value-based arrangement. We believe this is important to curtail any gaming that could occur by adding meaningful downside financial risk to a physician during only a short portion of the term of an arrangement.

To buttress our oversight ability and that of our law enforcement partners, we are proposing at §411.357(aa)(2)(ii) a requirement that the nature and extent of the physician's financial risk is set forth in writing. This is also, of course, a good business practice that allows the parties to monitor their value-based arrangements and ensure that they are operating as intended. For similar reasons, but also as a safeguard against manipulating a value-based arrangement to reward referrals, we are proposing a requirement that the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided. The special rule on compensation at §411.354(d)(1) that deems compensation to be set in advance when certain conditions are met would apply. However, that provision is merely a deeming provision and parties would be free to confirm satisfaction of the proposed requirement another way.

Integrated into most of the CMS-sponsored models is a requirement that any remuneration between parties to an allowable financial arrangement is not provided as an inducement to reduce or limit medically necessary items or services to any patient in the assigned patient population. We believe this is an important safeguard for patient safety and quality of care, regardless of whether Medicare is the ultimate payor for the services, and propose to include it in the meaningful downside financial risk exception by requiring at proposed §411.357(aa)(2)(v) that remuneration is not provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not. Remuneration that leads to a reduction in medically necessary services would be inherently suspect and could implicate sections 1128A(b)(1) and (2) of the Act.

For the reasons discussed in section II.A.2.b.(1). of this proposed rule, we are also proposing to include in the meaningful downside financial risk exception requirements that the 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 provided as an inducement to reduce or limit medically necessary items or services to any patient, whether in the target patient population or not; 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; and that 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. We would interpret these requirements as described in section II.A.2.b.(1). of this proposed rule and seek comments as requested.

We are also proposing requirements at §411.357(aa)(2)(vii) and (viii) related to requiring a physician to refer to a particular provider, practitioner, or supplier and price transparency.

(3) Value-Based Arrangements (Proposed §411.357(aa)(3))

One CMS RFI commenter stated that, because physician decisions drive the overwhelming majority of all health care spending and patient outcomes, it is not possible to transform health care without a strong, aligned shared partnership between entities furnishing designated health services and physicians. According to other commenters, alignment of parties' financial interests is key to the behavior shaping necessary to succeed in a value-based payment system. Another commenter, a commercial payor, asserted that permitting physicians and physician groups (especially smaller practices that are not used to risk-sharing or are too small to absorb downside financial risk) to assume only upside risk—or, for that matter, no financial risk—would encourage more physicians to participate in care coordination activities now while they continue to build towards being able to enter into two-sided risk-sharing arrangements. In consideration of these and similar comments, as well as our belief that bold reforms to the physician self-referral regulations are necessary to foster the delivery of coordinated patient care and achieve the Secretary's vision of transitioning to a truly value-based health care delivery and payment system, we are proposing an exception at §411.357(aa)(3) for compensation arrangements that qualify as value-based arrangements, regardless of the level of risk undertaken by the value-based enterprise or any of its VBE participants (the "value-based arrangement exception"). As proposed, the exception would permit both monetary and nonmonetary remuneration between the parties. We are considering whether to limit the

scope of the proposed exception to nonmonetary remuneration only and seek comment regarding the impact such a limitation may have on the transition to a value-based health care delivery and payment system.

We are proposing to include in the value-based arrangement exception certain requirements that are included in the proposed meaningful downside financial risk exception, some of which are also included in the proposed full financial risk exception. We would interpret these requirements as described in section II.A.2.b.(1). of this proposed rule, and include them in the value-based arrangement exception for the same reasons articulated with respect to our other proposed exceptions. We also seek comments as requested previously in sections II.A.2.b.(1). and II.A.2.b.(2). of this proposed rule. These requirements are: the 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 provided as an inducement to reduce or limit medically necessary items or services to a patient in the target patient population; remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement; the methodology used to determine the amount of the remuneration is set in advance of the furnishing of the items or services for which the remuneration is provided; and 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. We are also proposing requirements at §411.357(aa)(2)(vii) and (viii) related to requiring a physician to refer to a particular provider, practitioner, or supplier and price transparency.

Because the exception proposed at §411.357(aa)(3) would be applicable even to value-based arrangements where neither party, but especially not the physician, has undertaken any downside financial risk, we believe that safeguards beyond those included in the proposed meaningful downside financial risk exception are necessary to protect against program or patient abuse. Specifically, we are proposing, as an alternative to the requirement that remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered by the value-based arrangement, a requirement that remuneration is not conditioned on the volume or value of referrals of any patients to the entity or the volume or value of any other business generated by the physician for the entity. We note that, as described in section II.A.2.b. of this proposed rule, we are not proposing to include in the value-based arrangement exception a requirement that the remuneration is not determined in any manner that takes into account the volume or value of a physician's referrals or the other business generated by the physician. The alternative proposal described here would prohibit remuneration that is conditioned on the volume or value of referrals of any patients to the entity or the volume or value of any other business generated by the physician for the entity. We seek comments regarding this alternative proposal; the interplay of the proposed alternative requirement with our longstanding policy that the entity of which the physician is a *bona fide* employee or independent contractor, or that is a party to a managed care contract with the physician, may direct the physician's referrals to a particular provider, practitioner, or supplier, as long as the compensation arrangement meets specified conditions designed to preserve the physician's judgment as to the patient's best medical interests, avoid interfering in an insurer's operations, and protect patient choice; and

whether including such an alternative requirement would impede parties' ability to achieve the value-based purposes on which their value-based arrangement is premised if the entity cannot direct referrals as historically permitted.

In addition, we are proposing additional requirements in the exception proposed at §411.357(aa)(3) that the value-based arrangement is set forth in writing and signed by the parties, and that the writing includes a description of: the value-based activities to be undertaken under the arrangement; how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; the target patient population for the arrangement; the type or nature of the remuneration; the methodology used to determine the amount of the remuneration; and the performance or quality standards against which the recipient of the remuneration will be measured, if any. We believe that the documentation requirements are self-explanatory. Although we expect that parties would plan to satisfy the writing requirement in advance of the commencement of the value-based arrangement, the special rule at proposed §411.354(e)(3) (modified, in part, from existing §411.353(g)(1)(ii)) would apply. We highlight that we intend that the value-based purpose of the arrangement must relate to the value-based enterprise as a whole (which, as noted previously in section II.A.2.a. of this proposed rule, may be the two parties to the value-based arrangement). The exception would not protect a "side" arrangement between two VBE participants that is unrelated to the goals and objectives (that is, the value-based purposes) of the value-based enterprise of which they are participants, even if the arrangement itself serves a value-based purpose, as defined at proposed §411.351. We seek comment whether we should specifically include this policy in the proposed value-based arrangement exception as a requirement separate from

the writing requirement.

In addition, we are proposing to require that the performance or quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable. Such standards must be determined prospectively, and any changes to the performance or quality standards must be set forth in writing and apply only prospectively. We recognize that performance or quality standards may not be applicable to all value-based arrangements—for example, an arrangement under which a hospital provides needed infrastructure to a physician in the same value-based enterprise may not require the physician to achieve specific performance or quality goals in order to receive or keep the infrastructure items or services. However, if the value-based arrangement does include performance or quality standards that relate to the receipt of the remuneration—for example, an arrangement to share the internal cost savings achieved if the physician meaningfully participates in the hospital’s quality and outcomes improvement program and reaches or exceeds predetermined benchmarks for his or her personal performance or quality measurement—such performance or quality standards must be determined in advance of their implementation. The exception would not protect arrangements where the performance or quality standards are set retrospectively. Moreover, any performance or quality standards against which the recipient of the remuneration will be measured should not simply reflect the status quo. We are considering whether to require that performance or quality standards be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery. We seek comment regarding whether we should include this as a requirement of the proposed value-based arrangement exception and the burden or

cost of including such a requirement.

We expect that, as a prudent business practice, parties would monitor their arrangements to determine whether they are operating as intended and serving their intended purposes, regardless of whether the arrangements are value-based, and have in place mechanisms to address identified deficiencies, as appropriate. In fact, there is an implicit ongoing obligation for an entity to monitor its financial relationship with a physician for compliance with an applicable exception.

In general, if a physician has a financial relationship with an entity that does not satisfy all requirements of an applicable exception (after applying any special rules), section 1877(a)(1)(A) of the Act prohibits the physician from making a referral to the entity for the furnishing of designated health services for which payment may otherwise be made under Medicare, section 1877(a)(1)(B) of the Act prohibits the entity from presenting or causing to present a claim under Medicare for the designated health services furnished pursuant to a prohibited referral, and section 1877(g)(1) of the Act prohibits Medicare from making payment for a designated health service that is provided pursuant to a prohibited referral. Parties must ensure the compliance of their financial relationship with an applicable exception at the time the physician makes a referral for designated health service(s).

To illustrate, assume a hospital donates EHR items and services to Physician A, including ongoing software upgrades, maintenance, and services, for which the vendor charges the hospital monthly in advance of providing the EHR items and services. The regulation at §411.357(w)(4) requires that, before the receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The parties

agree that Physician A will pay 15 percent of the monthly cost of the EHR items and services prior to the beginning of each month. If Physician A fails to make the July 31st payment as scheduled, the arrangement would no longer satisfy the requirements of §411.357(w)(4), and Physician A would be prohibited from making referrals for designated health services to the hospital as of August 1st and the hospital would be prohibited from submitting claims to the Medicare program for any improperly referred designated health services. If the arrangement is later brought back into compliance with the requirements of the exception, the physician would again be permitted to make referrals for designated health services to the hospital, and the hospital could submit claims for such designated health services (but not the designated health services referred during the period of noncompliance). The hospital has an obligation to ensure that the claims it submits to Medicare for designated health services referred by a physician are permissible and, in fact, explicitly certifies compliance with the physician self-referral law on each claim form and cost report it submits. We note that the arrangement described would also implicate the Federal anti-kickback statute, and the parties must also ensure compliance with that statute.

With respect to arrangements that would qualify for protection under the exception for value-based arrangements as proposed at §411.357(aa)(3), there would also exist an implicit ongoing obligation to monitor for compliance with the exception. To illustrate, assume a hospital revised its care protocol for screening for a certain type of cancer to incorporate newly issued guidelines from a nationally recognized organization. The new guidelines, and the revised protocol, no longer support a single screening modality for the disease. Instead, the organization recommends screening by combining

two modalities to achieve more accurate results. The revised guidelines and hospital care protocol are intended to improve the quality of care for patients by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results (which can be frequent for single-modality screening for the disease). The hospital observes that most community physicians continue to refer patients to the hospital for single-modality screening. To align referring physician practices with the hospital's revised care protocol, the hospital offers to pay physicians \$10 for each instance that they order dual-modality screening in accordance with the revised care protocol during a 2-year period. The hospital expects that it would take approximately 2 years to shape physician behavior to always follow the recommended care protocol (except when not medically appropriate for the particular patient). Assume that both single-modality and dual-modality screening are designated health services payable by Medicare.

The exception at proposed §411.357(aa)(3) is applicable only to arrangements that qualify as "value-based arrangements," as proposed at §411.351. The arrangement must be for the provision of at least one value-based activity for a target patient population and must be between a value-based enterprise and one or more of its VBE participants or between VBE participants in the same value-based enterprise. The value-based activity must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise that is a party to the arrangement or is the value-based enterprise in which the parties to the arrangement are each VBE participants. In this illustration, the value-based enterprise is the hospital and identified community physicians. (The hospital and the community physicians could also be part of a larger value-based enterprise.) The target patient population is patients in the hospital's service

area that receive screening for the particular disease. The value-based activity is adherence with the hospital's revised care protocol by ordering dual-modality screening instead of single-modality screening. The value-based purpose of the value-based enterprise is to improve the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results.

At its inception, provided that an arrangement between the hospital and Physician B satisfies all requirements of proposed §411.357(aa)(3), Physician B's referrals of designated health services to the hospital and the hospital's submission of claims to Medicare for the designated health services referred by Physician B would not violate the physician self-referral law. However, assume that one year into the arrangement, the hospital's data analysis indicates that the use of dual-modality screening not only does not result in earlier detection of cancer, but results in more false positive results, invasive biopsies, and unnecessary treatment than single-modality screening. As a result, the hospital determines that the use of dual-modality screening, despite the nationally-recognized recommendations, will not achieve its goal to improve the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results. At that point, because the value-based activities under the arrangement would no longer be reasonably designed to achieve the value-based purpose of improving the quality of care for patients in the hospital's service area by detecting more cancers and avoiding potential unnecessary overtreatment of false positive results, the arrangement would no longer qualify as a "value-based arrangement" and would no longer qualify for protection under the

exception at proposed §411.357(aa)(3). Absent modification of the arrangement to ensure qualification as a “value-based arrangement” and compliance with the requirements of the exception at proposed §411.357(aa)(3), Physician B would be prohibited from making future referrals of any designated health services to the hospital unless the arrangement satisfies the requirements of another applicable exception to the physician self-referral law (which it likely would not). In addition, the hospital would be prohibited from submitting claims to Medicare for any improperly referred designated health services.

As described previously, parties must ensure the compliance of their financial relationship with an applicable exception at the time of the physician’s referral for the designated health service(s). The failure to monitor for or a lack of knowledge of such compliance does not nullify the prohibition. If the hospital did not monitor the arrangement for progress toward the value-based purpose of the value-based enterprise, Physician B’s future referrals would nevertheless be prohibited due to the fact that adherence to the revised care protocol could not, in fact, achieve the value-based purpose of the value-based enterprise and would no longer be a “value-based activity” as that term is defined at proposed §411.351. In turn, the arrangement would not qualify as a “value-based arrangement” and the exception at proposed §411.357(aa)(3) would no longer be available to protect Physician B’s referrals.

As illustrated, implicit in the physician self-referral law, as applied, is a requirement that one or both parties monitor the compliance of their value-based arrangement with an applicable exception, including whether the value-based activities under the arrangement are furthering (or could further) the value-based purpose(s) of the

value-based enterprise. Even so, as additional program integrity safeguards, we are considering whether to require that: (1) the value-based enterprise or the VBE participant providing the remuneration must monitor to determine whether the value-based activities under the arrangement are furthering the value-based purpose(s) of the value-based enterprise; and (2) 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 the determination that the value-based purpose(s) will not be achieved through the value-based activities or within 60 days of such determination. We seek comment regarding whether we should include these as requirements of the proposed value-based arrangement exception, how parties could monitor for achievement of value-based purposes, and the burden or cost of including such a requirement. Specifically, we seek comment regarding whether we should require that monitoring should occur at specified intervals and, if so, what the intervals should be. Recognizing that cost savings, in particular, may take an extended period of time to achieve, we also seek comment regarding whether to impose time limits with respect to a value-based enterprise's or VBE participant's determination that the value-based purpose of the enterprise will not be achieved through the value-based activities required under the arrangement; that is, require that the value-based purpose must be achieved within a certain timeframe, such as 3 years and, if it is not, the value-based purpose would be deemed not achievable through the value-based activities requirement under the arrangement. We also seek comment regarding the types of monitoring activities that parties to value-based arrangements are currently performing.

We are also considering 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 the nonmonetary remuneration. We would require that the 15 percent contribution is made: (1) within 90 calendar days of the donation of the nonmonetary remuneration if the donation is a one-time cost to the donor; and (2) at reasonable, regular intervals if the donation of the nonmonetary remuneration is an ongoing cost to the donor. As we stated with respect to the 15 percent contribution required under the current exception at §411.357(w) for EHR items and services, parties should use a reasonable and verifiable method for allocating costs and are strongly encouraged to maintain contemporaneous and accurate documentation (71 FR 45161 through 45162).

Requiring financial participation by a recipient of nonmonetary remuneration under a value-based arrangement would help ensure that the nonmonetary remuneration is appropriate and beneficial for the achievement the value-based purpose(s) of the value-based enterprise, as well as that the recipient will actually use the nonmonetary remuneration. However, we are concerned that such a requirement could inhibit the adoption of value-based arrangements. As discussed in section II.D.11.d.(1) of this proposed rule, many commenters to the CMS RFI expressed that the 15 percent contribution requirement under the existing exception for EHR items and services is burdensome to some recipients and acts as a barrier to adoption of EHR technology. We are concerned that the burden of a 15 percent contribution requirement would prove similarly burdensome under value-based arrangements, particularly with respect to small and rural physicians, providers, and suppliers that cannot afford the contribution. We seek comment regarding whether we should include a recipient contribution requirement in the proposed value-based arrangement exception and the burden or cost of including

such a requirement. Specifically, we seek comment regarding the appropriate level for any required contribution (if 15 percent is not an appropriate level) and whether certain recipients (for example, small or rural physicians, providers, and suppliers) should be exempt from compliance with the requirement.

Finally, as discussed throughout sections I. and II.A. of this proposed rule, where possible and feasible, we aim to align our policies with those under consideration by OIG to ease the compliance burden on the regulated industry by minimizing complexity for parties whose arrangements implicate both the physician self-referral law and the anti-kickback statute. For this reason, we are considering whether to adopt any other requirements included in the safe harbor at proposed §1001.952(ee) and not specifically proposed in this section II.A.2.b.(3). We will consider comments received by OIG on its proposals when developing any final policies for the value-based arrangement exception to the physician self-referral law.

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

The prohibitions of section 1877 of the Act apply if a physician (or an immediate family member of a physician) has an ownership or investment interest in an entity or a compensation arrangement with an entity. For purposes of the physician self-referral law, a compensation arrangement is any arrangement involving direct or indirect remuneration between a physician (or an immediate family member of the physician) and an entity, and remuneration means any payment or other benefit made directly, indirectly, overtly, covertly, in cash, or in kind. (See §§411.351 and 411.354(c).) In Phase I, we finalized regulations that define when an indirect compensation arrangement exists

between a physician and the entity to which he or she refers designated health services. For purposes of applying these regulations, in the FY 2008 IPPS final rule, we finalized additional regulations that deem a physician to stand in the shoes of his or her physician organization if the physician has an ownership or investment interest in the physician organization that is not merely a titular interest. These regulations are found at §411.354(c)(2) and (3).

Under our current regulations, if an indirect compensation arrangement exists, the exception for indirect compensation arrangements at §411.357(p) is available to protect the compensation arrangement. If all of the requirements of the exception are satisfied, the physician would not be barred from referring patients to the entity for designated health services and the entity would not be barred from submitting claims for the referred services. No other exception in §411.357 is applicable to indirect compensation arrangements. However, the parties may elect to protect individual referrals of and claims for designated health services using an applicable exception in §411.355 of our regulations.

We anticipate that an unbroken chain of financial relationships described in current §411.354(c)(2)(i) may include a value-based arrangement, as that term is proposed to be defined at §411.351. Thus, an unbroken chain of financial relationships that includes a value-based arrangement could form an “indirect compensation arrangement” for purposes of the physician self-referral law if the circumstances described in §411.354(c)(2)(ii) and (iii) also exist. In such an event, despite the existence of the value-based arrangement in the unbroken chain of financial relationships, under our current regulations, the only exception available to ensure the permissibility of all the

physician's referrals to the entity (assuming no other financial relationships exist between the parties) would be the exception for indirect compensation arrangements at §411.357(p), which includes requirements not found in the proposed exceptions for value-based arrangements at §411.357(aa). (If the parties elect to utilize a "services" exception at §411.355, designated health services are protected only on a service-by-service basis and satisfaction of the requirements of an applicable exception permits only the referral of and claim submission for the particular designated health service that satisfied the requirements of the exception.) For the reasons discussed previously in this section II.A.2.b. of this proposed rule, it is possible that an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships that forms the indirect compensation arrangement could not satisfy the requirements of §411.357(p) because the compensation to the physician could take into account the volume or value of referrals or other business generated by the physician for the entity or may not be fair market value for specific items or services provided by the physician to the entity.

In this section II.A.2.b. of this proposed rule, we are proposing exceptions available only to compensation arrangements that qualify as value-based arrangements. Although our proposals do not limit the applicability of the exceptions to value-based arrangements directly between a physician and the entity to which he or she refers designated health services, the definition of "value-based arrangement" proposed at §411.351 requires that the compensation arrangement is "between" (or "among," if there are more than two parties to the arrangement) specified parties. We are proposing here to identify the circumstances under which the proposed exceptions at §411.357(aa) would

apply to an indirect compensation arrangement that includes a value-based arrangement in the unbroken chain of financial relationships described in §411.354(c)(2)(i).

Specifically, we are proposing that, when the value-based arrangement is the link in the chain closest to the physician—that is, the physician is a direct party to the value-based arrangement—the indirect compensation arrangement would qualify as a “value-based arrangement” for purposes of applying the proposed exceptions at §411.357(aa). To be clear, the link closest to the physician may not be an ownership interest; it must be a compensation arrangement that meets the definition of value-based arrangement at proposed §411.351. For purposes of determining whether the indirect compensation arrangement satisfies the requirements of an applicable exception at proposed §411.357(aa), we would look at the value-based arrangement to which the physician is a party. For the reasons described in section II.A.2.a. of this proposed rule, we are considering whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of “indirect value-based arrangement” if the link closest to the physician (that is, the value-based arrangement to which the physician is a party) is a compensation arrangement between the physician and a: pharmaceutical manufacturer; manufacturer, distributor, or supplier of DMEPOS; laboratory; pharmacy benefit manager; wholesaler; or distributor. In the alternative, we are considering whether to exclude an unbroken chain of financial relationships between an entity and a physician from the definition of “indirect value-based arrangement” if one of these persons or organizations is a party to any financial relationship in the chain of financial relationships. We are also considering whether to include health technology companies in any such exclusion in order to align our policies with policies under consideration by

OIG where possible and appropriate. We seek comment on these approaches and their effectiveness in enhancing program integrity.

Under this proposal, parties would first determine if an indirect compensation arrangement exists and, if it does, determine whether the compensation arrangement to which the physician is a direct party qualifies as a value-based arrangement. If so, the exceptions at proposed §411.357(aa) for value-based arrangements would be applicable. To illustrate, assume an unbroken chain of financial relationships between a hospital and a physician that runs: hospital—(owned by)—parent organization—(owns)—physician practice—(employs)—physician. Thus, the links in the unbroken chain are ownership or investment interest—ownership or investment interest—compensation arrangement. For purposes of determining whether an indirect compensation exists between the physician and the hospital, under §411.354(c)(2)(ii), we analyze the compensation arrangement between the physician practice and the physician. Assume also that the compensation paid to the physician under her employment arrangement varies with the volume or value of her referrals to the hospital because she is paid a bonus for each referral for designated health services furnished by the hospital provided that she adheres to redesigned care protocols intended to further one or more value-based purposes (as defined at proposed §411.351). Finally, assume that the hospital has actual knowledge that the physician receives aggregate compensation that varies with the volume or value of her referrals to the hospital. The unbroken chain of financial relationships establishes an indirect compensation arrangement; therefore, in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services, the indirect compensation arrangement must

satisfy the requirements of an applicable exception. Under this alternative proposal, if the compensation arrangement between the physician practice and the physician qualifies as a value-based arrangement (as defined at proposed §411.351), the exceptions at proposed §411.357(aa) would be available to protect the value-based arrangement (that is, the indirect compensation arrangement) between the hospital and the physician. (The parties could also utilize an applicable exception in §411.355 to protect individual referrals for designated health services or the exception at §411.357(p) to protect the indirect compensation arrangement between the hospital and the physician, but it is unlikely that all requirements of §411.357(p) would be satisfied in this hypothetical fact pattern.)

In the alternative, we are proposing to define “indirect value-based arrangement” and specify in regulation that the exceptions proposed at §411.357(aa) would be available to protect the arrangement. Under this alternate proposal, an indirect value-based arrangement would exist if: (1) between the physician and the entity there exists 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). Under our alternative proposal, if an unbroken chain of financial relationships between a physician and an entity qualifies as an “indirect value-based

arrangement,” the three exceptions proposed at §411.357(aa) would be applicable and the requirements of at least one of the applicable exceptions must be satisfied in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services. For purposes of determining whether the indirect value-based arrangement satisfies the requirements of an applicable exception at proposed §411.357(aa), we would look at the value-based arrangement to which the physician is a party. (The parties could also utilize an applicable exception in §411.355 to protect individual referrals for designated health services or the exception at §411.357(p) to protect the indirect compensation arrangement between the hospital and the physician, but it is unlikely that all requirements of §411.357(p) would be satisfied in this hypothetical fact pattern.)

To illustrate this alternative proposal, assume the same unbroken chain of financial relationships. The first step in the analysis would be to determine whether the compensation arrangement between the physician practice and the physician is a value-based arrangement (irrespective of whether the compensation to the physician varies with the volume or value of her referrals to the hospital). If so, and the hospital has actual knowledge of the value-based arrangement, the unbroken chain of financial relationships would constitute an indirect value-based arrangement that must satisfy the requirements of an applicable exception at proposed §411.357(aa) in order for the physician to refer patients to the hospital for designated health services and for the hospital to submit claims to Medicare for the referred designated health services. (The parties could also utilize an applicable exception in §411.355 to protect individual referrals for designated health services.)

We seek 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. Specifically, we are interested in whether one of the approaches described here is preferable. We are also soliciting comments on whether it is necessary to establish new regulations at all; that is, whether we should simply apply our existing regulations at §411.354(c) to determine whether an unbroken chain of financial relationships that includes a value-based arrangement establishes an indirect compensation arrangement. If so, the parties could rely on the exception at current §411.357(p) for indirect compensation arrangements or any applicable exception in §411.355 to protect individual referrals from the physician to the entity and claims for the referred designated health services.

(5) Price Transparency

Price transparency is a critical component of a health care system that pays for value and aligns with our desire to reinforce and support patient freedom of choice. We believe that transparency in pricing can empower consumers of health care services to make more informed decisions about their care and lower the rate of growth in health care costs. Health care consumers today lack meaningful and timely access to pricing information that could, if available, help them choose a lower-cost setting or a higher-value provider. Patients are often unaware of site-of-care cost differentials until it is too late (see Aparna Higgins & German Veselovskiy, *Does the Site of Care Change the Cost of Care*, Health Affairs (June 2, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160602.055132/full/>). Multiple surveys and studies have revealed that patients want their health care providers to engage

in cost discussions, and one recent national survey found that a majority of physicians want to have cost of care discussions with their patients (see Caroline E. Sloan, MD & Peter A. Ubel, MD, *The 7 Habits of Highly Effective Cost-of-Care Conversations*, *Annals of Internal Medicine* (May 7, 2019), <https://annals.org/aim/issue/937992>, and *Let's Talk About Money*, The University of Utah (2018), <https://uofuhealth.utah.edu/value/lets-talk-about-money.php>). The point of referral presents an ideal opportunity to have such cost-of-care discussions.

In the CMS RFI, we solicited comment on the role of transparency in the context of the physician self-referral law. In particular, we solicited comment on whether, if provided by the referring physician to a beneficiary, transparency about a physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing (such as data about quality of services provided) would reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address. Many commenters replied that making a physician's financial relationships and cost of care information available could be useful. One commenter suggested that providing clear and transparent information was vital in the health care industry where patients are often vulnerable, confused, and unsure of their options. This commenter further opined that informed patients are empowered to take charge of their health care and better assist their providers in fulfilling their health care needs. Several commenters shared similar support for transparency efforts. Another commenter stated that transparency of a physician's financial relationships along with price and quality of care information would be valuable to patients in choosing providers and care pathways. This commenter maintained that these actions would also engage

patients in protecting against possible unintended consequences of value-based arrangements. Other commenters raised concerns that information on price transparency and a physician's financial relationships with other health care providers, in combination with already-required disclosures under HIPAA, informed consent information and forms, insurance payment authorization forms, and other paperwork that patients receive or must complete would serve only to inundate patients with paperwork that they will find confusing or simply not read. These commenters contended that, although transparency is an appealing concept, requiring additional disclosures would result in more burden than benefit.

The June 24, 2019 Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First recognizes the importance of price transparency. The executive order directs Federal agencies to take historic steps toward getting patients the information they need and when they need it to make well-informed decisions about their health care. CMS has already acted on the Executive Order through its proposals in the CY 2020 OPPS proposed rule to improve the availability of meaningful pricing information to the public. We believe that all consumers need price and quality information in advance to make an informed decision when they choose a good or service, including at the point of a referral for such goods or services. By making meaningful price and quality information more broadly available, we can protect patients and increase competition, innovation, and value in the health care system.

As discussed elsewhere in this section of the proposed rule, we are committed to ensuring that physician self-referral law policies do not infringe on patient choice and the ability of physicians and patients to make health care decisions that are in the patient's

best interest. We believe it is important for patients to have timely access to information about all aspects of their care, including information about the factors that may affect the cost of services for which they are referred. A patient who is made aware, for example, that costs may differ based on the site of service where the referred services are furnished, may become a more conscious consumer of health care services. Access to such information may also spark important conversations between patients and their physicians, promoting patient choice and the ability of physicians and patients to make health care decisions that are in the patient's best interest. In conjunction with their physicians' determination of the need for recommended health care services and the urgency of that need, information on the factors that may affect the cost of such services could ensure that patients have the information they need to shop and seek out high-quality care at the lowest possible cost.

We seek to establish policies that facilitate consumers' ability to participate actively and meaningfully in decisions relating to their care. At the same time, we are cognizant that including requirements regarding price transparency in the exceptions to the physician self-referral law raises certain challenges for the regulated industry. We seek comments on how to pursue our price transparency objectives in the context of the physician self-referral law, both in the context of a value-based health care system and otherwise, and how to overcome the technical, operational, legal, cultural, and other challenges to including price transparency requirements in the physician self-referral regulations. Specifically, we are interested in comments regarding 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. Finally, we seek comment 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.

In furtherance of our goal of price transparency for all patients, we are considering whether to include a requirement related to price transparency in every exception for value-based arrangements at proposed §411.357(aa). For instance, we are considering whether to require 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. Because of limits on currently available pricing data, we believe such a requirement could be an important first step in breaking down barriers to cost-of-care discussions that play a beneficial role in a value-based health care system. The public notice provided or reflected in the policy could be made in any form or manner that is accessible to patients. For example, a notice on the physician's website, a poster on the wall in the physician's office, or a notice in a patient portal used by the physician's patients would all be acceptable. We expect that any notice would be written in plain language that would be

understood by the general public. We refer readers to the Plain Writing Act of 2010 (Pub. L. 111-274, enacted on October 13, 2010) for further information. We seek comment on whether, if we finalize such a requirement, it would be helpful for CMS to provide a sample notice and, if we provide a sample notice, whether we should deem such a notice to satisfy the requirement described. We note that we would not require public notice in advance of referrals for emergency hospital services to avoid delays in urgently needed care. We seek comment on other options for price transparency requirements in the value-based exceptions to the physician self-referral law that we are proposing in this proposed rule, as well as whether we should consider for a future rulemaking the inclusion of price transparency requirements in exceptions to the physician self-referral law included in our existing regulations.

B. Fundamental Terminology and Requirements

1. Background

As described in greater detail in this section of the proposed rule, many of the statutory and regulatory exceptions to the physician self-referral law include one, two, or all of the following requirements: the compensation arrangement itself is commercially reasonable; the amount of the compensation is fair market value; and the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals (or, in some cases, other business generated between the parties). These requirements are presented in various ways within the statutory and regulatory exceptions, but it is clear that they are separate and distinct requirements, each of which must be satisfied when present in an exception. Nonetheless, the regulated industry and its complementary parts, such as the health care valuation community,

continue to seek additional guidance from CMS. For example, many CMS RFI commenters shared a common belief that, if compensation is not fair market value, CMS would automatically consider it to take into account the volume or value of referrals. Or, under the current definition of fair market value at §411.351, if compensation takes into account the volume or value of referrals, it cannot be fair market value. (Although this is not the case, we note that failure to meet even a single requirement of an applicable exception leaves a compensation arrangement subject to the physician self-referral law's referral and claims submission prohibitions; failure to satisfy multiple requirements of an exception does not result in "additional" noncompliance with the law's prohibitions.) We provide examples of such guidance below in sections II.B.3 and II.B.5. Moreover, although commercial reasonableness is a core requirement of many exceptions to the physician self-referral law, the only guidance we have provided to date is in a proposed rule (63 FR 1700). False Claims Act case law has exacerbated the challenge of complying with these three fundamental requirements, according to commenters.

Over the years, stakeholders have approached CMS with requests for clarification on our policy with respect to when an arrangement is considered 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 light of the current Regulatory Sprint, we included in the CMS RFI specific questions regarding these issues. A large number of commenters responded to these specific requests. Although the commenters suggested varying ways we could provide clearer guidance, uniformly, they requested that we establish bright-line, objective regulations for each of these fundamental

requirements. Our overall intention in this proposed rule is to reduce the burden of compliance with the physician self-referral law, provide clarification where possible, and revise regulations as necessary to achieve these goals and the goals of the Regulatory Sprint. We reviewed the statute and our regulations in a fresh light, and believe that clear, bright-line rules would enhance both stakeholder compliance efforts and our enforcement capability. We have endeavored here to provide the clarity that will benefit the regulated industry, CMS, and our law enforcement partners.

In developing our proposals for guidance on the fundamental terminology and requirements described previously, we considered three basic questions—

- Does the arrangement make sense as a means to accomplish the parties' goals?
- How did the parties calculate the remuneration?
- Did the calculation result in compensation that is fair market value for the asset, item, service, or rental property?

These questions relate, respectively, to the definition of commercial reasonableness, the volume or value standard and the other business generated standard, and the definition of fair market value. In this section of the proposed rule, we provide detailed descriptions of our proposed definitions and special rules. Importantly, our proposals relate only to the application of section 1877 of the Act and our physician self-referral regulations.

Although other laws and regulations, including the anti-kickback statute and CMP law, may utilize the same or similar terminology, the interpretations proposed here would not affect OIG's (or any other governmental agency's) interpretation or ability to interpret such terms for purposes of laws or regulations other than the physician self-referral law. In addition, our interpretation of these key terms does not relate to and in no way binds

the Internal Revenue Service with respect to its rulings and interpretation of the Internal Revenue Code or State agencies with respect to any State law or regulation that may utilize the same or similar terminology. We note further that, to the extent terminology is the same as or similar to terminology used in the Quality Payment Program within the PFS, our proposals would not affect or apply to the Quality Payment Program.

2. Commercially Reasonable (§411.351)

We are proposing to include at §411.351 a definition for the term “commercially reasonable.” As described previously, many of the statutory and regulatory exceptions to the physician self-referral law include a requirement that the compensation arrangement is commercially reasonable. For example, the exception at section 1877(e)(2) of the Act for *bona fide* employment relationships requires that the remuneration provided to the physician is pursuant to an arrangement that would be commercially reasonable (even if no referrals were made to the employer). The exception at section 1877(e)(3)(A) of the Act for personal service arrangements uses slightly different language to describe this general concept, and requires that the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement. The exception at §411.357(l) for fair market value compensation, which the Secretary established in regulation using his authority at section 1877(b)(4) of the Act, requires that the arrangement is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties. Despite the prevalence of this requirement (in one form or another), we addressed the concept of commercial reasonableness only once—in our 1998 proposed rule—where we stated that we are interpreting “commercially reasonable” to mean that

an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals (63 FR 1700). The physician self-referral regulations themselves lack a codified definition for the term commercially reasonable.

As discussed previously, we believe that the key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement makes sense as a means to accomplish the parties' goals. We continue to believe that this determination should be made from the perspective of the particular parties involved in the arrangement. The determination of commercial reasonableness is not one of valuation. Nor does the determination that an arrangement is commercially reasonable turn on whether the arrangement is profitable. It is apparent from our review of the CMS RFI comments that there is a widespread misconception about our position on the nexus between the commercial reasonableness of an arrangement and its profitability. We wish to clarify that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable.

CMS RFI commenters shared numerous examples of compensation arrangements that they believed would be commercially reasonable despite the fact that the party paying the remuneration does not recognize an equivalent or greater financial benefit from the items or services purchased in the transaction, or that the party receiving the remuneration incurs costs in furnishing the items or services that are greater than the amount of the remuneration received. Commenters also explained that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement. These

commenters explained some of the reasons why parties would enter into such transactions, such as community need, timely access to health care services, fulfillment of licensure or regulatory obligations, including those under the Emergency Medical Treatment and Labor Act (EMTALA), the provision of charity care, and the improvement of quality and health outcomes. One commenter suggested that entire hospital service lines, with their needed management and other physician-provided services, are illustrative for operating at a loss and identified psychiatric and burn units as examples of such service lines. According to this commenter, with changes in reimbursement, more service lines will operate at a loss in the future. The commenter urged that these services are of vital need to communities and, unless CMS addresses the definition of “commercial reasonableness,” health care providers may be prohibited from providing these services to their communities as a result of a fear of violating the commercial reasonableness standard. We find these comments and the concerns they highlight compelling.

We are proposing two alternative definitions for the term “commercially reasonable.” First, we are proposing to define “commercially reasonable” to mean that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. In the alternative, we are proposing to define “commercially reasonable” to mean that 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. We seek comment on each of these proposed definitions as well as input from stakeholders regarding other possible definitions that would provide clear guidance to enable parties to structure their arrangements in a

manner that ensures compliance with the requirement that their particular arrangement is commercially reasonable. We are also proposing to clarify in regulation text that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

In developing our proposals, we reviewed the Internal Revenue Service (IRS) Revenue Ruling 97-21, which considered whether a hospital violates the requirements for exemption from federal income tax as an organization described in section 501(c)(3) of the Internal Revenue Code (Title 26 of the United States Code) when it provides incentives to recruit private practice physicians to join its medical staff or to provide medical services in the community. The IRS identified several activities that would support a hospital's charitable purposes, all of which were mentioned in the CMS RFI comments. As described previously, the arrangements identified by commenters on the CMS RFI may further a legitimate business purpose of the parties or make commercial sense as well. However, arrangements that, on their face, appear to further a legitimate business purpose of the parties may not be commercially reasonable if they merely duplicate other facially legitimate arrangements. For example, a hospital may enter into an arrangement for the personal services of a physician to oversee its oncology department. If the hospital needs only one medical director for the oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement merely duplicates the already-obtained medical directorship services and may not be commercially reasonable. Although the evaluation of compliance with the physician self-referral law always requires a review of the facts and circumstances of the financial relationship between the parties, the commercial

reasonableness of multiple arrangements for the same services is questionable.

Also important to our consideration of the best way to define and interpret “commercially reasonable” was the IRS’s conclusion that a hospital may not engage in substantial unlawful activities and maintain its tax-exempt status because the conduct of an unlawful activity is inconsistent with charitable purposes. The IRS explained that an organization conducts an activity that is unlawful, and therefore not in furtherance of a charitable purpose, if the organization’s property is to be used for an objective that is in violation of the criminal law. We are similarly taking the position that an activity that is in violation of criminal law would not be a legitimate business purpose of the parties, nor would it make commercial sense, and, therefore, would not be commercially reasonable for purposes of the physician self-referral law. We note that the absence of a criminal violation would not, in and of itself, establish that an arrangement is commercially reasonable. We seek comment on our alternate proposals for the definition of “commercially reasonable” and its interpretation, including how parties could determine whether an arrangement is on similar terms and conditions as like arrangements.

We note that many of the exceptions to the physician self-referral law require that an arrangement is commercially reasonable “even if no referrals were made between the parties” or “even if no referrals were made to the employer.” The exceptions use varying phrasing to describe this requirement and we do not repeat each iteration here. We are not proposing to eliminate this requirement from the exceptions where it appears. For example, under our first alternative proposal, an employment arrangement must further a legitimate business purpose of the parties and be on similar terms and conditions as like arrangements, even if no referrals were made to the employer, as well as satisfy the other

requirements of the exception, in order for the physician to refer patients to the employing entity for designated health services and for the employing entity to submit claims to Medicare for the referred designated health services. Under our second alternative proposal, an employment arrangement must make commercial sense and be entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if no referrals were made to the employer, as well as satisfy the other requirements of the exception. To emphasize, a compensation arrangement must satisfy the “even if no referrals were made” requirement if it is included as a requirement of the relevant exception under which the parties seek protection from the physician self-referral law’s referral and claims submission prohibitions.

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

Many of the exceptions at section 1877(e) of the Act (“Exceptions Relating to Other Compensation Arrangements”) and in our regulations include a requirement that the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement, and some exceptions also include a requirement that the compensation is not determined in a manner that takes into account other business generated between the parties. We refer to these as the “volume or value standard” and the “other business generated standard,” respectively. Throughout the regulatory history of the physician self-referral law, we have shared our interpretation of these standards and responded to comments as they arose. Despite our attempt at establishing clear guidance regarding the

application of the volume or value standard and the other business generated standard, commenters to several requests for information, including the CMS RFI, identified their lack of a clear understanding as to when compensation will be considered to take into account the volume or value of referrals or other business generated by the physician as one of the greatest risks they face when structuring arrangements between entities furnishing designated health services and the physicians who refer to them. They stated that, not only do they face the risk of penalties under the physician self-referral law, but, because a violation of the physician self-referral law may be the predicate for liability under the Federal False Claims Act (31 U.S.C. 3729 through 3733), entities are susceptible to both government and whistleblower actions that can result in significant penalties through litigation or settlement. Commenters and other stakeholders have long expressed frustration that, from their perspective, the guidance from CMS has been too limited and left them without an objective standard against which to judge their financial relationships. Our proposals here are intended to provide objective tests for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician. Before describing our proposals, we provide a brief history of the guidance to date on the volume or value standard and the other business generated standard.

In the 1998 proposed rule, we discussed the volume or value standard as it pertains to the criteria that a physician practice must meet to qualify as a “group practice” (63 FR 1690). We also stated that we would apply this interpretation of the volume or value standard throughout our regulations (63 FR 1699). In the discussion of group practices, we stated that we believe that the volume or value standard precludes a group

practice from paying physician members for each referral they personally make or based on the volume or value of the referred services (63 FR 1690). We went on to state that the most straightforward way for a physician practice to demonstrate that it is meeting the requirements for group practices would be for the practice to avoid a link between physician compensation and the volume or value of any referrals, regardless of whether the referrals involve Medicare or Medicaid patients (63 FR 1690). However, because our definition of “referral” at §411.351 includes only referrals for designated health services, we also noted that a physician practice that wants to compensate its members on the basis of non-Medicare and non-Medicaid referrals would be required to separately account for revenues and distributions related to referrals for designated health services for Medicare and Medicaid patients (63 FR 1690). (See section II.C. of this proposed rule for a discussion of the inclusion of Medicaid referrals in the existing regulation and our proposed revisions to the group practice rules.) Outside of the group practice context, these principles apply generally to compensation from an entity to a physician. We also addressed the other business generated standard in the 1998 proposed rule, stating that we believe that the Congress may not have wished to except arrangements that include additional compensation for other business dealings and that, if a party’s compensation contains payment for other business generated between the parties, we would expect the parties to separately determine if this extra payment falls within one of the exceptions (63 FR 1700).

In Phase I, we finalized our policy regarding the volume or value standard and the other business generated standard, responding to comments on our proposals in the 1998 proposed rule. Most importantly, we revised the scope of the volume or value standard to

permit time-based or unit of service-based compensation formulas (66 FR 876). We also stated that the phrase “does not take into account other business generated between the parties” means that the fixed, fair market value payment cannot take into account, or vary with, referrals of designated health services payable by Medicare or Medicaid or any other business generated by the referring physician, including other Federal and private pay business (66 FR 877), noting that the phrase “generated between the parties” means business generated by the referring physician for purposes of the physician self-referral law (66 FR 876). We stated that section 1877 of the Act establishes a straightforward test that compensation should be at fair market value for the work or service performed or the equipment or [office] space leased—not inflated to compensate for the physician’s ability to generate other revenue (66 FR 877). Finally, in response to an inquiry about whether the compensation paid to a physician for the purchase of his or her practice could include the value of the physician’s referrals of designated health services to the practice, we stated that compensation may include the value of designated health services made by the physician to his or her practice if the designated health services referred by the selling physician satisfied the requirements of an applicable exception, such as the in-office ancillary services exception, and the purchase arrangement is not contingent on future referrals (66 FR 877). This policy would apply also to the value of the physician’s referrals of designated health services to his or her practice if the compensation arrangement between the physician and the practice satisfied the requirements of an applicable exception.

Also in Phase I, we established special rules on compensation at §411.354(d)(2) and (3) that deem compensation not to take into account the volume or value of referrals

or other business generated between the parties if certain conditions are met (66 FR 876 through 877). These rules state that compensation will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of designated health services. Compensation will be deemed not to take into account the volume or value of other business generated between the parties to a compensation arrangement if the compensation is fair market value and does not vary during the term of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business. Both special rules apply to time-based or per-unit of service-based (“per-click”) compensation formulas. However, as we noted later in Phase II, the special rules on compensation are intended to be safe harbors, and there may be some situations not described in §411.354(d)(2) or (3) where an arrangement does not take into account the volume or value of referrals or other business generated between the parties (69 FR 16070).

In Phase II, we clarified that personally performed services are not considered other business generated by the referring physician (69 FR 16068). We also stated that fixed compensation (that is, one lump payment or several individual payments aggregated together) can take into account or otherwise reflect the volume or value of referrals (for example, if the payment exceeds the fair market value for the items or services provided) (69 FR 16059). We noted that whether the compensation does, in fact, take into account or otherwise reflect the volume or value of referrals will require a case-by-case

determination based on the facts and circumstances. (We note that the language “otherwise reflects” was considered superfluous and removed from our regulation text in Phase III (72 FR 51027).)

To date, we have not codified any regulations defining or otherwise interpreting the volume or value standard or the other business generated standard. In this proposed rule, we are proposing to do so. The proposed special rules at §411.354(d)(5) and (6), if finalized, will supersede our previous guidance, including guidance with which they may be (or appear to be) inconsistent. We note that, unless finalized, the proposed special rules and the policies they effect are not applicable to the determination of whether compensation takes into account the volume or value of referrals or the volume or value of other business generated between the parties (that is, by the physician).

In the CMS RFI, we solicited comments on when, in the context of the physician self-referral law and, specifically, within the context of alternative payment models and other novel financial arrangements, compensation should be considered to “take into account the volume or value of referrals” by a physician or “take into account other business generated” between parties to an arrangement (83 FR 29526). We requested that commenters share with us, by way of example or otherwise, compensation formulas that do not take into account the volume or value of referrals by a physician or other business generated between the parties. We discussed the comments related to the inclusion of the volume or value standard or the other business generated standard in new exceptions for value-based arrangements in section II.A.2.b. of this proposed rule. Our discussion in this section II.B.3. of this proposed rule relates only to these standards as they apply outside of the context of value-based arrangements; specifically, as they apply

to the definition of remuneration at section 1877(h)(1)(C) of the Act and §411.351 of our regulations, the definition of indirect compensation arrangement at §411.354(c)(2), the special rule on compensation that is considered set in advance at §411.354(d)(1), the special rules for per-unit compensation at §411.354(d)(2) and (3), the exception for academic medical centers at §411.355(e)(1)(ii), and various exceptions for compensation arrangements at section 1877(e) of the Act and in §411.357 of our regulations (including the proposed exceptions for limited remuneration to a physician at §411.357(z) and cybersecurity technology and related services at §411.357(bb), if finalized). As discussed previously, the proposed exceptions for value-based arrangements do not include the volume or value standards as requirements for the remuneration between the parties.

CMS RFI commenters uniformly requested that we provide objective benchmarks for determining when compensation is considered to take into account the volume or value of referrals or take into account other business generated between the parties. Many commenters stated their belief that a provider's subjective intent is potentially relevant in determining whether the manner in which the compensation was established took into account the volume or value of referrals or other business generated. These and many other commenters requested that the regulations make clear that the volume or value standard and the other business generated standard are bright-line, objective tests; that is, by the plain terms of an arrangement, the test is whether the methodology used to set physician compensation utilizes as a variable the volume or value of the physician's referrals or the volume or value of other business generated by the physician. Other commenters shared their concerns that, under the current guidance and the position taken by the government in certain of its enforcement actions, parties can never be sure that

their determination of the compensation to be paid under an arrangement with a referring physician will be insulated from scrutiny.

We believe there is great value in having an objective test for determining whether the compensation is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between the parties. Our proposals are intended to establish such a test. We are proposing an approach that, rather than deeming compensation under certain circumstances not to have been determined in a manner that takes into account the volume or value of referrals or takes into account other business generated between the parties, defines exactly 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 our proposed approach, which we believe creates the bright-line rule sought by commenters and other stakeholders, outside of the circumstances at proposed §411.354(d)(5) and (6), compensation would not be considered to take into account the volume or value of referrals or take into account other business generated between the parties, respectively. In other words, only when the mathematical formula used to calculate the amount of the compensation includes as a variable referrals or other business generated, and the amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity, is the compensation considered to take into account the volume or value of referrals or take into account the volume or value of other business generated. We believe our proposed approach is consistent with the position we articulated in Phase I where we stated that, in general, we believe that a compensation structure does not directly take into account the volume or value of

referrals if there is no direct correlation between the total amount of a physician's compensation and the volume or value of the physician's referrals of designated health services (66 FR 908).

Although we are proposing nonsubstantive changes to standardize where possible the language used to describe the volume or value standard and the other business generated standard in our regulations, due to the varying language used throughout the statutory scheme and the language that will remain in the regulatory scheme even if our proposed changes are finalized, we find it impossible to establish a single definition for each standard. Therefore, instead of a definition at §411.351, we are proposing special rules for compensation arrangements that will apply regardless of the exact language used to describe the standards. Also, because section 1877 of the Act defines a compensation arrangement as any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity, we believe it is necessary that the tests address circumstances where the compensation is from the entity to the physician, as well as where the compensation is from the physician to the entity. Therefore, we are proposing two separate special rules for the volume or value standard (proposed §411.354(d)(5)(i) and (6)(i)) and two special rules for the other business generated standard (proposed §411.354(d)(5)(ii) and (6)(ii)). Our proposals apply only for purposes of section 1877 of the Act and the physician self-referral regulations.

Under the policy proposed at §411.354(d)(5)(i)(A), compensation from an entity to a physician (or immediate family member of the physician) takes into account the volume or value of referrals only if the formula used to calculate the 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. For example, if the physician (or immediate family member) *receives additional compensation* as the number or value of the physician's referrals to the entity increase, the physician's (or immediate family member's) compensation would positively correlate with the number or value of the physician's referrals. Unless the special rule at §411.354(d)(2) for unit-based compensation applies and its conditions are met, the physician's (or immediate family member's) compensation would take into account the volume or value of referrals. To illustrate, assume that a physician practice does not qualify as a group practice under §411.352 of the physician self-referral regulations. The practice pays its physicians a percentage of collections attributed to the physician, including personally performed services and services furnished by the practice (the physician's "pool"). If the physician's pool includes amounts collected for designated health services furnished by the practice that he ordered but did not personally perform, under proposed §411.354(d)(5)(i), the physician's compensation would take into account the volume or value of his referrals to the practice. Assuming the physician is paid 50 percent of the amount in his pool, the mathematical formula that illustrates the physician's compensation would be: $\text{compensation} = (.50 \times \text{collections from personally performed services}) + (.50 \times \text{collections from referred designated health services}) + (.50 \times \text{collections from non-designated health services referrals})$. The policy proposed at §411.354(d)(5)(ii)(A) with respect to when compensation from an entity to a physician (or immediate family member of the physician) takes into account other business generated would operate in the same manner.

Analogously, under the policy proposed at §411.354(d)(6)(i)(A), compensation from a physician (or immediate family member of the physician) to an entity takes into account the volume or value of referrals only if the formula used to calculate the compensation paid by the physician includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the compensation that negatively correlates with the number or value of the physician's referrals to the entity. For example, if the physician (or immediate family member) *pays less compensation* as the number or value of the physician's referrals to the entity increase, the compensation from the physician to the entity would negatively correlate with the number or value of the physician's referrals. Unless the special rule at §411.354(d)(2) for unit-based compensation applies and its requirements are met (which seems unlikely), the compensation would take into account the volume or value of referrals. To illustrate, assume a physician leases medical office space from a hospital. Assume also that the rental charges are \$5000 per month and the arrangement provides that the monthly rental charges will be reduced by \$5 for each diagnostic test ordered by the physician and furnished in one of the hospital's outpatient departments. Under proposed §411.354(d)(6)(i), the compensation (that is, the rental charges) would take into account the volume or value of the physician's referrals to the hospital. The mathematical formula that illustrates the rental charges paid by the physician to the hospital would be: $\text{compensation} = \$5000 - (\$5 \times \text{the number of designated health services referrals})$. The policy proposed at §411.354(d)(6)(ii)(A) with respect to when compensation from a physician (or immediate family member of the physician) to an entity takes into account other business generated would operate in the same manner.

We are also proposing at §411.354(d)(5)(i)(B) and (ii)(B), and at §411.354(d)(6)(i)(B) and (ii)(B), additional policies outlining the narrowly-defined circumstances under which we would consider fixed-rate compensation (for example, a fixed annual salary or an unvarying per-unit rate of compensation) to be determined in a manner that takes into account the volume or value of referrals or other business generated by a physician for the entity paying the compensation. Under this approach, compensation would take into account the volume or value of referrals where the parties utilize a predetermined tiered approach to compensation under which the volume or value of a physician's prior referrals is the basis for determining the unvarying rate of compensation from an entity to a physician (or an immediate family member of a physician) or the unvarying rate of compensation that a physician (or an immediate family member of a physician) must pay an entity over the entire duration of the arrangement. The policy would operate analogously with respect to other business previously generated by the physician for the entity. Under this approach, the compensation need not be determined based on a mathematical formula, but there must be a predetermined, direct positive or negative correlation between the volume or value of the physician's prior referrals (or other business previously generated for the entity) and the exact rate of compensation paid to or by the physician (or an immediate family member of the physician) in order for the compensation to violate the volume or value standard or the other business generated standard. Put another way, there must be a predetermined, direct, and meaningful "if X, then Y" correlation between the volume or value of the physician's prior referrals (or the other business previously generated by the physician for the entity) and the prospective rate of compensation to be paid over the

entire duration of the arrangement for which the compensation is determined. Merely hoping for or even anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals or the other business generated by the physician for the entity.

We note that an “if X, then Y” compensation methodology is capable of reproduction in a mathematical formula that positively or negatively correlates with the number or value of the physicians’ referrals to the entity. (In Boolean algebra, the formula $p \rightarrow q$ represents this type of compensation methodology.) To illustrate, assume that a hospital-employed physician is paid on the basis of her personally performed professional services (in this example, the physician is paid a predetermined rate per physician work relative value unit (wRVU)). The hospital has a predetermined tiered system for determining physician compensation when entering into renewal employment arrangements under which a physician is paid \$30 per wRVU if she ordered 300 or fewer outpatient diagnostic tests per year during the prior term of employment and \$35 per wRVU if she ordered more than 300 outpatient diagnostic tests per year during the prior term of employment. Because the physician ordered 250 outpatient diagnostic tests per year during the prior term of her employment, her compensation for the duration of the renewal arrangement is \$30 per wRVU. Even though the physician is paid an unvarying rate of \$30 per wRVU regardless of whether she makes zero, 10, or 1,000 referrals to the entity during the term of the renewal arrangement, her compensation would nonetheless take into account the volume or value of her referrals and other business generated for the entity. As another example, assume that a physician leases medical office space from a hospital and the rental charges are as follows: \$2000 per month if the physician is in the

top 25 percent of admitting physicians at the hospital (measured by the gross charges per inpatient admission); \$2500 per month if the physician is in the second quartile of admitting physicians on the hospital's medical staff (measured by the gross charges per inpatient admission); and \$3500 per month if the physician is in the bottom half of admitting physicians at the hospital (measured by the gross charges per inpatient admission). Under our proposed additional approach to the volume or value standard and other business generated standard, the compensation (that is, the rental charges) would be determined in a manner that takes into account the value of the physician's referrals and other business generated for the hospital. We seek comment on this additional proposal. We are particularly interested in comments regarding whether this approach would achieve our goal of establishing sufficiently objective tests for determining whether the compensation is determined in any manner that takes into account the volume or value of referrals or takes into account other business generated between the parties.

Although our proposals would establish "special rules" on compensation, we would interpret them in the same manner as definitions. That is, the special rules are intended to 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. If the methodology used to determine the physician's compensation or the payment from the physician does not fall squarely within the defined circumstances, the compensation would not take into account the volume or value of the physician's referrals or the other business generated by the physician, as appropriate, for purposes of applying the exceptions to the physician self-referral law.

We do not believe that it is necessary to include the modifier "directly or

indirectly” in the proposed special rules interpreting the volume or value standard and the other business generated standard or in the definitions and exceptions where these standards appear. We believe that the modifier “directly or indirectly” is implicit in the requirements that compensation is not determined in any manner that takes into account the volume or value of referrals or the volume or value of other business generated. For this reason, and in the interest of having uniform language throughout our regulations that describes the volume or value standard and the other business generated standard, we are proposing to remove the modifier from the regulations where it appears in connection with the standards and the related requirements. We also believe that leaving the modifying language in the regulations might create confusion if the proposed special rules interpreting the volume or value standard and other business generated standard are finalized. Where the statute or regulations specifically allow parties to determine compensation in a manner that only indirectly takes into account the volume or value of referrals (for example, in the exception for EHR items and services at §411.357(w)(6) and the rules for a group practice’s distribution of profit shares and payment of productivity bonuses at section 1877(h)(4)(B) of the Act and §411.352(i)), our regulations include guidance regarding direct versus indirect manners of determining compensation. We solicit comment on whether additional guidance is necessary in light of our proposed interpretation of the volume or value standard and the other business generated standard included in this proposed rule. We note that the proposed exception for donations of cybersecurity technology and related services discussed in section II.E.2. of this proposed rule would also permit certain remuneration that indirectly takes into account the volume or value of referrals but does not include specific deeming provisions

or other guidance regarding direct versus indirect manners of determining remuneration. We seek comment in section II.E.2. regarding the need for additional guidance or regulation text that includes deeming provisions related to the volume or value standard in the proposed exception.

Finally, a large number of the CMS RFI commenters that addressed the volume or value and other business generated standards requested that we confirm, if not codify, related guidance in our Phase II regulation (69 FR 16088 through 16089). In Phase II, a commenter presented a scenario under which a hospital employs a physician at an outpatient clinic and pays the physician for each patient seen at the clinic; the physician reassigns his or her right to payment to the hospital, and the hospital bills for the Part B physician service (with a site-of-service reduction); and the hospital also bills for the hospital outpatient services, which may include some procedures furnished as “incident to” services in a hospital setting. The Phase II commenter’s concern was that the payment to the physician is inevitably linked to a facility fee, which is a designated health service (that is, a hospital service). Accordingly, the commenter wondered whether the payment to the physician would be considered an improper productivity bonus based on a referral of designated health services (that is, the facility fee). In response, we stated that the fact that corresponding hospital services are billed would not invalidate an employed physician’s personally performed work, for which the physician may be paid a productivity bonus (subject to the fair market value requirement). The CMS RFI commenters expressed concern that, following the July 2, 2015 opinion of the United States Court of Appeals for the Fourth Circuit in *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, CMS may no longer endorse this policy.

We believe that the proposed objective tests for determining when compensation takes into account the volume or value of referrals or the volume or value of other business generated may address the CMS RFI commenters' concerns. However, for clarity, we reaffirm the position we took in the Phase II regulation. With respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service. We are also clarifying that our 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 in the special rule at §411.354(d)(2). That is, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula—even when the entity bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals if the compensation meets the conditions of the special rule at §411.354(d)(2) (see 69 FR 16067).

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

When the conditions of the special rule at existing §411.354(d)(4) are met, compensation from a *bona fide* employer, under a managed care contract, or under a personal services arrangement is deemed not to take into account the volume or value of referrals, even if the physician's compensation was predicated, either expressly or

otherwise, on the physician making referrals to a particular provider, practitioner, or supplier. This special rule was established in Phase I after many commenters objected to our statement in the 1998 proposed rule that fixed payments to a physician could be considered to take into account the volume or value of referrals if a condition or requirement for receiving the payment was that the physician refer designated health services to a given entity, such as an employer or an affiliated entity (63 FR 1700). In Phase I, we acknowledged that the proposed interpretation could have had far-reaching effects, especially for managed care arrangements and group practices. We determined to permit directed referrals without considering the physician's compensation to take into account the volume or value of his or her referrals, but only if the referral requirement does not apply if a patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment. In addition, the referral requirement must be set out in writing and signed by the parties, and the compensation to the physician must be: (1) set in advance for the term of the compensation arrangement; and (2) consistent with fair market value for the services performed. Finally, the compensation arrangement must otherwise comply with an applicable exception in §411.355 or §411.357 (66 FR 878).

We continue to believe in the importance of preserving patient choice, protecting the physician's professional medical judgment, and avoiding interference in the operations of a managed care organization. However, given our proposed interpretation of the volume or value standard, we are concerned that current §411.354(d)(4) may apply in fewer instances, if at all, to serve these important goals. Therefore, to reiterate how

critical these protections are, we are proposing to include in the exceptions applicable to the types of contracts or arrangements to which the special rule has historically applied an affirmative requirement that the compensation arrangement meet the conditions of the special rule at §411.354(d)(4) (as modified in accordance with the proposal set forth in this section of the proposed rule). To that end, we are proposing to include in the exceptions at §411.355(e) for academic medical centers, §411.357(c) for *bona fide* employment relationships, §411.357(d)(1) for personal service arrangements, §411.357(d)(2) for physician incentive plans, §411.357(h) for group practice arrangements with a hospital, §411.357(l) for fair market value compensation, and §411.357(p) for indirect compensation arrangements, a requirement that, in addition to satisfying the other requirements of the exception, the relevant arrangement must comply with the revised special rule at §411.354(d)(4). In making this proposal, we are relying on the authority granted to the Secretary under sections 1877(b)(4), (e)(2)(D), (e)(3)(A)(vii), (e)(3)(B)(i)(II), and (e)(7)(vii) of the Act. We solicit comment as to whether, given the nature of academic medical centers, the proposed requirement at revised §411.354(d)(4) is necessary.

We are also proposing to revise §411.354(d)(4) to eliminate certain language regarding: (1) whether the “set in advance” and “fair market value” conditions of the special rule apply to the compensation arrangement (as stated in the regulation) or to the compensation itself; and (2) when compensation is considered fair market value. Under proposed §411.354(d)(4), we are clarifying that the physician’s compensation must be set in advance. Any changes to the compensation (or the formula for determining the compensation) must also be set in advance (that is, made prospectively). We are also

clarifying that the physician's compensation must be consistent with the fair market value of the services performed. In addition, we are proposing to eliminate the parenthetical language in existing §411.354(d)(4) as it conflates the concept of fair market value and the volume or value standard. As noted previously, these are separate standards, and compliance with one is not contingent on compliance with the other. We are taking the opportunity to also propose nonsubstantive revisions for clarity. Although, as proposed, revised §411.354(d)(4) sets forth protections that apply to both the compensation arrangement that includes a directed referral requirement and also specifically to the compensation itself, for continuity in the application of the protections of the regulation, we are proposing to leave the regulation in §411.354(d) (special rules on compensation) rather than include it in §411.354(e), which includes special rules for compensation arrangements. We seek comment on this approach.

5. Fair Market Value (§411.351)

The term "fair market value," as it is defined at section 1877(h)(3) of the Act, consists of three basic components. Fair market value is defined generally as "the value in arms length [sic] transactions, consistent with the general market value." The statutory definition includes additional qualifications for leases generally, providing that fair market value with respect to rentals or leases also means "the value of rental property for general commercial purposes (not taking into account its intended use)." Finally, with respect to the lease of office space, in particular, the statutory definition further stipulates that fair market value also means that that value of the rental property is "not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient

referrals to the lessee.” Most of the statutory exceptions at section 1877(e) of the Act relating to compensation arrangements include requirements pertaining to fair market value compensation, including the exceptions for the rental of office space, the rental of equipment, *bona fide* employment relationships, personal service arrangements, isolated transactions, and payments by a physician. Many of the regulatory exceptions created using the Secretary’s authority under section 1877(b)(4) of the Act also include requirements pertaining to fair market value compensation, including the exceptions for academic medical centers, fair market value compensation, indirect compensation arrangements, EHR items and services, and assistance to compensate a nonphysician practitioner.

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

market at the time of acquisition.” We modified the definition drawn from §413.134(b)(2) to include analogous provisions for determining the fair market value of any items or services, including personal services, employment relationships, and rental arrangements. As proposed in the 1998 proposed rule, “general market value” would mean:

The price that an asset would bring, as the result of *bona fide* bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement, as the result of *bona fide* bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement. Usually the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement.

The proposed definition of “fair market value” in the 1998 proposed rule did not substantively modify the provisions of the fair market value definition pertaining to leases in general and office space leases in particular.

In Phase I, we finalized the definition of “fair market value” from the 1998 proposed rule with one modification (66 FR 944 through 945). The definition of “fair market” value finalized in Phase I clarified that a rental payment “does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.” In Phase I we

also responded to commenters who requested guidance on how to determine fair market value in a variety of circumstances. We stated that we would accept any commercially reasonable method for determining fair market value. However, we noted that, in most exceptions, the fair market value requirement is further modified by language that precludes taking into account the volume or value of referrals, and, in some cases, other business generated by the referring physician. We concluded that, in determining whether compensation is fair market value, requirements pertaining to the volume or value of referrals and other business generated may preclude reliance on comparables that involve entities and physicians in a position to refer or generate business (66 FR 944). Elsewhere in Phase I, we suggested a similar underlying connection between the fair market value requirement and requirements pertaining to the volume or value of a physician's referrals and other business generated (66 FR 877). In a discussion of the requirement that compensation not take into account other business generated, we stated that—

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

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

In Phase II, we made two significant modifications to the definition of "fair market value." First, we proposed certain "safe harbors" for determining fair market value for hourly payments made to physicians for physician services (69 FR 16092 and 16107). (These safe harbors were not finalized.) Second, and more importantly, we incorporated into the definition of "fair market value" a reference to the volume or value standard found in many exceptions to the physician self-referral law. The Phase II definition of "fair market value" provided, in relevant part, that fair market value is usually the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. We explained our view that the determination of fair market value under the physician self-referral law differs in significant respects from standard valuation techniques and methodologies. In particular, we noted that the methodology must exclude valuations where the parties to the transactions are at arm's length but in a position to refer to one another. We made no substantive changes to the definition of "fair market value" in Phase III or in any of our subsequent rulemaking.

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

As a preliminary matter and as described previously in section II.B.1. of this proposed rule, a careful reading of the statute shows that the fair market value requirement is separate and distinct from the volume or value standard and the other business generated standard. (See section II.B.3. of this proposed rule for a detailed discussion of the volume or value standard and the other business generated standard.) The volume or value and other business generated standards do not merely serve as “limiting phrases” to modify the fair market value requirement. In order to satisfy the requirements of the exceptions in which these concepts appear, compensation must both: (1) be fair market value for items or services provided; and (2) not take into account the volume or value of referrals (or the volume or value of other business generated by the physician, where such standard appears). We believe that the appropriate reading of the statute is that the requirement that compensation does not take into account the volume or value of referrals—which is plainly set out as an independent requirement of the relevant

exceptions—is not also part of the definition of “fair market value.” We note that the statutory definition of “fair market value” at section 1877(h)(3) of the Act includes no reference to the volume or value of referrals (or other business generated between the parties). For these reasons, we are proposing to revise the definition of “fair market value” to eliminate the connection to the volume or value standard.

In proposing revisions to the definition of “fair market value” at §411.351, we undertook to establish regulations that give meaning to the statutory language at section 1877(h)(3) of the Act. As described previously, the statute states a general definition of “fair market value” and then modifies that definition for application to leases of equipment and office space. One of the modifications applies to leases of both equipment and office space; the other applies only to the lease of office space. To illustrate this more clearly in our regulations, we are proposing to modify the definition of “fair market value” to provide for a definition of general application, a definition applicable to the rental of equipment, and a definition applicable to the rental of office space. (We are proposing to use the terms “rental” of equipment and “rental” of office space as those are the titles of the statutory exceptions at section 1877(e)(1)(A) and (B) of the Act and our regulatory exceptions at §411.357(a) and (b).) We believe that this approach provides parties with ready access to the definition of “fair market value,” with the attendant modifiers, that is applicable to the specific type of compensation arrangement at issue. Therefore, we are proposing that, generally, fair market value means the value in an arm's-length transaction with like parties and under like circumstances, of assets or services, consistent with the general market value of the subject transaction. We are also proposing that, with respect to the rental of equipment,

fair market value means the value, in an arm's-length transaction with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction. And, with respect to the rental of office space, we are proposing that fair market value means the value in an arm's length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction. We note that the proposed structure of the definition merely reorganizes for clarity, but does not significantly differ from, the statutory language at section 1877(h)(3) of the Act. We seek comment on our approach.

Second, we are proposing changes to the definition of "general market value," currently included within the definition of fair market value at §411.351. The current definition of "fair market value" states the following, some of which relates to fair market value and some of which relates to the included term, "general market value." Numerical references are added here for ease but do not appear in our current regulations:

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

(2) General market value means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona*

fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.

(3) Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

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

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

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

Items one, four, and five essentially restate the language at section 1877(h)(3) of the Act, albeit with the intervening language in items two and three, and item six was added in Phase I in response to a comment for the purpose of interpreting the modifier “(not taking into account its intended use)” in item four and at section 1877(h)(3) of the Act. We

stated in the 1998 proposed rule that items two and three were our attempt to give meaning to the statutory requirement that the fair market value of compensation must be “consistent with the general market value.” In doing so, we relied on a regulation that relates to the circumstances under which an appropriate allowance for depreciation on buildings and equipment used in furnishing patient care can be an allowable cost. We see no benefit at this time to connect the definition of “general market value” to principles of reasonable cost reimbursement for end stage renal disease services in order to explain what it means for a value to be consistent with general market value, as required by the statute. Moreover, the definition at §413.134(b)(2) upon which we relied states that fair market value (emphasis added) is defined as the price that the asset would bring by *bona fide* bargaining between well-informed buyers and sellers at the date of acquisition. The regulation goes on to state that, usually the fair market price is the price that *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition. This definition more closely ties to the widely accepted IRS definition of “fair market value,”² not general market value. Therefore, we considered whether current §411.351 includes an appropriate definition for “general market value.”

We see no indication in the legislative history or the statutory language itself that the Congress intended that the definition of “general market value” for purposes of the physician self-referral law should deviate from general concepts and principles in the valuation community. Yet, our current definition of “general market value” is

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

unconnected to the recognized valuation principle of “market value” and itself may be the driver of valuation industry policy and procedure. After revisiting the legislative history of section 1877 of the Act and our prior preamble language related to the term “general market value,” we believe that the Congress used the term “general market value” to ensure that the fair market value of the remuneration (that is, as described below, the hypothetical value) is generally consistent with the valuation that would result using accepted market valuation principles. Therefore, we equate “general market value” as that term appears in the statute and our regulations with “market value,” the term uniformly used in the valuation industry. Our own research indicates that, in the valuation industry, the term “market value” refers to the valuation of a planned transaction between two identified parties for identified assets or services, and intended to be consummated within a specified timeframe. Market value is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another. Thus, when parties to a potential personal service arrangement determine the (general) market value of the physician’s compensation, they must not consider that the physician could also refer patients to the entity when not acting as its medical director.

We are aware that our regulatory definition is likely at odds with general valuation principles, which do not use the term “general market value.” For this reason, we are proposing to establish a definition of “general market value” that is consistent with the recognized principle of “market” valuation to address this discrepancy and ease the burden on parties attempting to ensure compliance with the fair market value requirement in many of the compensation exceptions to the physician self-referral law.

We are proposing to define “general market value” at §411.351 to mean the price that assets or services would bring as the result of *bona fide* bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement; or, in the case of the rental of equipment or office space, the price that rental property would bring as the result of *bona fide* bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement. We note that many CMS RFI commenters requested that we simply return to the statutory language. We disagree that would be the best approach. Generally, *in the absence of agency guidance*, a reasonable interpretation of a statutory or regulatory requirement of the physician self-referral law is satisfactory when asserting compliance with the requirement. We believe it is important to provide guidance with respect to the requirement that compensation is fair market value in order not to stymie our enforcement efforts (or those of our law enforcement partners). This guidance is also crucial to support the compliance efforts of the regulated industry.

It is our view that the concept of fair market value relates to the value of an asset or service to hypothetical parties in a hypothetical transaction (that is, typical transactions for like assets or services, with like buyers and sellers, and under like circumstances), while general market value (or market value) relates to the value of an asset or service to the actual parties to a transaction that is set to occur within a specified timeframe. Some of the CMS RFI comments included similar information regarding the definition of general market value. Thus, under the statute, the hypothetical value of a transaction must be consistent with the value of the actual transaction transpiring between the particular buyer and seller. We are cognizant that the hypothetical value of a transaction

may not always be identical to the market value of the actual transaction being considered. Extenuating circumstances may dictate that parties to an arm's length transaction veer from values identified in salary surveys and other hypothetical valuation data that is not specific to the actual parties to the subject the transaction. By way of example, assume a hospital is engaged in negotiations to employ an orthopedic surgeon. Independent salary surveys indicate that compensation of \$450,000 per year would be appropriate for an orthopedic surgeon in the geographic location of the hospital. However, the orthopedic surgeon with whom the hospital is negotiating is one of the top orthopedic surgeons in the entire country and is highly sought after by professional athletes with knee injuries due to his specialized techniques and success rate. Thus, although the employee compensation of a hypothetical orthopedic surgeon may be \$450,000 per year, this particular physician commands a significantly higher salary and the general market value (or market value) of the transaction may, therefore, be well above \$450,000. The statute requires that the compensation is the value in an arm's length transaction, but that value must also be consistent with the general market value (or market value) of the subject transaction. In this example, compensation substantially above \$450,000 per year may be fair market value.

Some CMS RFI commenters pointed out that failure to consider the general market value (or market value) of a transaction, as we have proposed to define it here, results in hospitals and other entities paying more than they believe appropriate for physician services. By way of example, assume a hospital is engaged in negotiations to employ a family physician. Independent salary surveys indicate that compensation of \$250,000 per year would be appropriate for a family physician nationally; no local salary

surveys are available. However, the cost of living in the geographic location of the hospital is very low despite its proximity to good schools and desirable recreation opportunities. Yet, due to declining reimbursement rates and a somewhat poor payor mix, the hospital's economic position is tenuous. According to a CMS RFI commenter, the physician may request the \$250,000 that the hypothetical physician would earn, and the hospital may believe that it is compelled to pay the physician this amount, because our current definition of "fair market value" does not recognize the appropriate definition for the "general market value" (or market value) with which the physician's compensation must be consistent under the statute. In this example, the fair market value of the physician's compensation may be less than \$250,000 per year.

Finally, we are proposing to remove from the regulation text at §411.351 in the definition of "fair market value" the existing statement that, for purposes of the definition of "fair market value," a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements. This language was added to the regulation text as a result of our response in Phase I to a commenter to the 1998 proposed rule, where we stated that a rental payment does not violate the requirement that the fair market value of rental property is the value of the property for general commercial purposes, not taking into account its intended use, merely because it reflects any costs that were incurred by the lessor in developing or upgrading the property, or maintaining the property or its improvements, regardless of why the improvements were added (66 FR 945). That is, the rental payment may reflect the value of any similar commercial property with improvements or amenities of a similar value, regardless of why the

property was improved. We do not believe it is necessary to include this policy in regulation text. Moreover, based on some of the comments to the CMS RFI, this regulation text appears to have caused confusion among stakeholders. For this reason, we are proposing to remove the language from the definition of “fair market value” at §411.351.

C. Group Practices (§411.352)

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

from a volume-based to a value-based health care system. We may consider additional clarifications or revisions in a future rulemaking.

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

In section II.B. of this proposed rule, we are proposing new special rules for compensation that would codify in regulation our interpretation regarding when compensation will be considered to take into account the volume or value of referrals or other business generated (the “volume or value standard”). In connection with those proposals, we reviewed the physician self-referral regulations to ensure that the volume or value standard is expressed using standardized terminology and identified several occurrences of inconsistent expression of the volume or value standard. Although section 1877 of the Act uses more than one phrase to describe the volume or value standard, which may be one reason for variations in the regulation text, we believe that the references are all to the same underlying prohibition on compensation that fluctuates with the volume or value of referrals or other business generated. Therefore, as noted previously, we are proposing to make certain conforming changes throughout our regulations to delineate the volume or value standard as a prohibition on compensation that “takes into account the volume or value” of referrals or other business generated. Because the language in §411.352(g) and (i) mirrors the statutory language at section 1877(h)(4)(iv) of the Act, we are not proposing changes to the “volume or value” regulation text in either of those paragraphs. The terms “based on” and “related to” would remain in the regulation text at §411.352(g) and (i). However, we are taking the opportunity to remind readers that we interpret the requirements of §411.352(g) and (i) to incorporate the volume or value standard; that is, 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 provided in §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).

Our current regulation at §411.352(i) states that a physician in a group practice may be paid a share of overall profits of the group practice, provided that the share is not determined in any manner that is directly related to the volume or value of referrals by the physician. We have long interpreted "is directly related to" the volume or value of referrals to mean "takes into account" the volume or value of referrals. In Phase I, we discussed this provision and stated that the Congress expressly limited profit shares for group practice members to methodologies that do not directly take into account the member's [designated health services] referrals, and that, under the statutory scheme, revenues generated by designated health services may be distributed to group practice members and physicians in the group in accordance with methods that indirectly take into account referrals (emphasis added) (66 FR 862 and 908).

Our current regulation at §411.352(g) states that "[n]o physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals, except as provided in §411.352(i)" (emphasis added). We interpret this to mean that, in order to satisfy this requirement for qualification as a "group practice," no physician who is a member of the group practice receives

compensation that directly or indirectly takes into account the volume or value of his or her referrals (unless permitted under §411.352(i)). Our interpretation is consistent with the interpretation of “related to” set forth in Phase I. For the most part, we used the terms “based on,” “related to,” and “takes into account” interchangeably when describing the final Phase I group practice regulations (66 FR 908 through 910).

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

a. Distribution of Revenue Related to Participation in a Value-Based Enterprise

We are proposing new §411.352(i)(3) to address downstream compensation that derives from payments made to a group practice, rather than directly to a physician in the group, that relate to the physician’s participation in a value-based arrangement. Certain downstream distribution arrangements are currently protected under waivers in the Shared Savings Program and certain Innovation Center models. However, outside of the Shared Savings Program or an Innovation Center model, as the commenters correctly point out, profit shares or productivity bonuses paid to a physician in a group practice that directly take into account the volume or value of his or her referrals to the group practice are strictly prohibited by the physician self-referral statute and regulations.

Our current special rules for the profit shares and productivity bonuses paid to physicians in a group practice prohibit calculation methodologies that directly take into account the volume or value of the recipient physician’s referrals to the group practice. Thus, by way of example, in a 100-physician group practice where only two of the physicians participate with a hospital in a commercial payor-sponsored alternative payment model, the profits from the designated health services ordered by the physicians and furnished by the group practice to beneficiaries assigned to the model participants

may not be allocated directly to the two physicians. Commenters interpreted this to mean that the special rules at §411.352(i) would restrict the group practice to allocating alternative payment model-derived income that includes revenues from designated health services among all physicians in the group (or a component of at least five physicians in the group) in order to ensure that such income is allocated in a manner that only indirectly takes into account the volume or value of the two physicians' referrals. The commenters suggested that this restriction discourages physician participation in alternative payment or other value-based care models because physicians cannot be suitably rewarded for their accomplishments in advancing the goals of the model, which is at odds with the Secretary's vision for achieving value-based transformation by pioneering bold new payment models. Another commenter asserted that, because physician decisions drive the overwhelming majority of all health care spending and patient outcomes, it is not possible to transform health care without the participation of physicians in value-based health care delivery and payment models with other health care providers. We share the commenters' concerns regarding physician participation in value-based health care delivery and payment models and are also concerned that our current regulations could undermine the success of the Regulatory Sprint or the larger transition to a value-based health care system. Therefore, we are proposing changes to §411.352(i) with respect to the payment of profit shares.

For the reasons described elsewhere in this proposed rule, in the exceptions for value-based arrangements at proposed new §411.357(aa), we are not proposing to prohibit remuneration that takes into account the volume or value of a physician's referrals. The proposed changes to §411.352(i) are an extension of this policy.

Specifically, we are proposing to add regulation text at §411.352(i)(3) (see discussion in section II.A.2.b of this proposed rule) a deeming provision related to the distribution of profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise. Under our proposal, when such profits are distributed to the participating physician, they would be deemed not to directly take into account the volume or value of the physician's referrals. In other words, a group practice could distribute directly to a physician in the group the profits from designated health services furnished by the group that are derived from the physician's participation in a value-based enterprise, including profits from designated health services referred by the physician, and such remuneration would be deemed not to directly take into account the volume or value of the physician's referrals. Revised §411.352(i) would permit the 100-physician group practice in the previous example to distribute the profits from designated health services derived from the two physicians' participation in the alternative payment model directly to those physicians. Physician #1 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the model, and Physician #2 could receive a profit distribution that considers his or her referrals to the group that are directly attributable to his or her participation in the model. Neither distribution would jeopardize the group's ability to qualify as a "group practice" under §411.352. We seek comment regarding whether we should permit the distribution of "revenue" from designated health services or "profits" from designated health services (as proposed) in order to effectuate the goals described elsewhere in this proposed rule.

b. Clarifying Revisions

We are proposing to restructure and renumber §411.352(i) as well as clarify several provisions of the regulation. We believe that these revisions would enable groups to determine with more certainty whether compensation paid to a physician in the group as profit shares or productivity bonuses takes into account the volume or value of referrals and, if it does, whether there is a direct or indirect connection to the volume or value of the physician's referrals. Our purpose in restructuring the regulation is to more closely adhere to the structure of section 1877(h)(4)(B) of the Act and to express in affirmative language which profit shares and productivity bonuses are permissible; that is, permitting the payment of a profit share or productivity bonus that indirectly takes into account the volume or value of referrals is the affirmative and more simple way of saying, as our current regulations do, that the profit share or productivity bonus is permissible but only if it does not directly take into account the volume or value of referrals. In addition, as proposed, the special rules for profit shares and productivity bonuses would follow the format of our special rules on compensation at §411.354(d) and our special rules for compensation arrangements at §411.354(e). We do not intend that our proposed addition of introductory language at §411.352(i) and proposed revised language at §411.352(i)(1) and 411.352(i)(2) would be a substantive change to the noted provisions, but seek comment regarding the impact of these restructuring and rewording proposals.

We are also proposing revisions to clarify our interpretation of the overall profits of a group that can be distributed to physicians in the group. In current §411.352(i)(2), the term "overall profits" is defined to mean two different things: (1) the group's entire

profits derived from designated health services; and (2) the profits derived from designated health services of any component of the group practice that consists of at least five physicians. Although we believe our intent when establishing this definition was clear, stakeholders have informed us that they are confused about the definition. For example, stakeholders have informally inquired whether the profits of a group practice that has only two, three or four physicians may be distributed at all. In response to these types of inquiries, we are proposing to revise the definition of “overall profits” to state that this term 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. To further clarify this definition, we are proposing regulation text at revised §411.352(i)(1)(ii) stating that, 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. We believe that this more precisely states the policy articulated in Phase I (66 FR 909 through 910).

The proposed revision at §411.352(i)(1)(ii) includes the words “all the” before “designated health services” to codify in regulation our intent when finalizing the group practice rules in Phase I. Stakeholders’ informal inquiries regarding the permissible methods of distributing profits from designated health services have highlighted that the current regulation text may not precisely evidence our intent. Stakeholders have inquired whether it is permissible to distribute profit shares of only some types of designated health services provided by a group practice, without distributing the profits from the other types of designated health services provided by the group practice. Stakeholders also inquired whether a group practice may share the profits from each of the types of

designated health services independently; that is, whether it is permissible under our current regulations to share profits from one type of designated health service with a subset of physicians in a group practice and the profits from another type of designated health service with a different (possibly overlapping) subset of physicians in the group practice.

In response to these inquiries and to provide a clear expression of our policy, we are proposing that “the profits derived from all the designated health services” in proposed §411.352(i)(1)(ii) would mean that the profits from all the designated health services of the practice (or a component of at least five physicians in the practice) must be aggregated and distributed, with profit shares not determined in any manner that directly takes into account (that is, in any manner that is directly related to) the volume or value of a physician’s referrals. Under our proposal, a physician practice that wishes to qualify as a group practice could not distribute profits from designated health services on a service-by-service basis. To illustrate, suppose a physician practice provides both clinical laboratory services and diagnostic imaging services—both designated health services—to its patients in a location that qualifies as a “same building” under §411.351 and meets the requirements at §411.355(b)(2)(i). If the practice wishes to qualify as a group practice, it may not distribute the profits from clinical laboratory services to one subset of its physicians or using a particular methodology and distribute the profits from diagnostic imaging to a different subset of its physicians (or the same subset of its physicians but using a different methodology). We seek comment on our proposal to modify the renumbered regulation text at §411.352(i)(1)(ii) to clarify the guidelines for the distribution of “overall profits” from designated health services.

We are also proposing to remove the reference to Medicaid from the definition of overall profits. We believe the inclusion of this reference unnecessarily complicates the regulation. It is possible that the reference to designated health services payable by Medicaid is related to the proposed definition of “referral” in the 1998 proposed rule (63 FR 1692). There, with respect to the definition of group practice, we stated that, because of our interpretation of what constitutes a “referral,” an entity wishing to be considered a group practice in order to use the in-office ancillary services exception cannot compensate its members based on the volume or value of referrals for designated health services for Medicare or Medicaid patients but could do so in the case of other patients (63 FR 1690). However, when finalized, the definition of “referral” omitted all references to Medicaid. Nonetheless, the reference to Medicaid in final §411.352(i)(2), which was also proposed in the 1998 proposed rule (as a definition in §411.351), was not likewise omitted when finalized. Moreover, under our current definition of “designated health services” at §411.351, “designated health services payable by . . . Medicaid” would not include any services. This is because the definition of “designated health services” includes only those services payable in whole or in part by Medicare. Although the qualifying language in this definition potentially allows for a different definition “as otherwise noted in this subpart,” the regulations at §411.352(i)(2) do not expressly articulate an alternative definition for “designated health services.” Rather, they simply state that the overall profits of a group include designated health services payable by Medicaid. For consistency with the final definitions and regulations, we are updating the group practice rules at §411.352 by eliminating the references to Medicaid in the definition of overall profits.

Proposed §411.352(i)(1)(iii) articulates the general rule that overall profits should be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician's referrals of designated health services. The prefatory language of this subparagraph is simply moved from existing §411.352(i)(2) without substantive change. Proposed §411.352(i)(1)(iii) also makes revisions to the language introducing the methods for distributing profit shares that are deemed permissible under the physician self-referral law (the deeming provisions) by substituting "and would not be considered designated health services if they were payable by Medicare" for "are not [designated health services] payable by any Federal health care program or private [payor]." Current §411.352(i)(2)(ii) provides that a share of overall profits will be deemed not to directly take into account the volume or value of referrals if revenues derived from designated health services are distributed based on the distribution of the group practice's revenues attributed to services that are not designated health services payable by "any Federal health care program or private payer." As we noted, the definition of designated health services includes only those specified services that are payable by Medicare. Thus, we believe it better reflects our policy that overall profits may be distributed based on the distribution of the group practice's revenues from services other than those in the categories of services that are "designated health services" to deem the payment of a profit share not to directly take into account the volume or value of a physician's referrals if the revenues derived from designated health services are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare. We are proposing to revise the

regulation in this manner and renumber current §411.352(i)(2)(ii) to §411.352(i)(1)(iii)(B). We note that the regulation that deems a productivity bonus not to directly take into account the volume or value of a physician's referrals under certain circumstances includes a provision similar to §411.352(i)(1)(iii)(B) for overall profits. Therefore, we are proposing corresponding revisions at proposed §411.352(i)(2)(ii)(B) (renumbered from current §411.352(i)(3)(ii)) that would deem the payment of a productivity bonus not to directly take into account the volume or value of a physician's referrals if the services on which the productivity bonus is based are not revenues derived from designated health services and would not be considered designated health services if they were payable by Medicare. Finally, we are proposing to replace the term "allocated" with "distributed" at proposed (redesignated) §411.352(i)(1)(iii)(C) as the latter term reflects the actual payment of the profit share.

We are also proposing to renumber the regulation that lists the deeming provisions related to the payment of productivity bonuses from §411.352(i)(3) to §411.352(i)(2) and are proposing minor changes to the deeming provisions themselves. In addition to the proposal removing the language referencing Federal health care programs and private payers, we are proposing to update the language of existing §411.352(i)(1) (relocated to proposed §411.352(i)(2)(i)) to remove "or both" as unnecessary because the word "or" is interpreted to mean the conjunctive "and" as well as the disjunctive "or." Groups may continue to pay a productivity bonus based on services that the physician has personally performed, or services "incident to" such personally performed services, or both, provided that the bonus only indirectly takes into account the volume or value of the physician's referrals (except that the bonus may

directly take into account the volume or value of referrals by the physician if the referrals are for services “incident to” the physician's personally performed services).

For consistency with the regulations related to the payment of a share of overall profits, we are proposing to revise the introductory language in the deeming provisions for productivity bonuses at renumbered §411.352(i)(2)(ii) to state that a productivity bonus must be calculated in a reasonable and verifiable manner. To correct a misstatement about the nature of §414.22 of this chapter included in existing §411.352(i)(3)(i), we are proposing to revise the deeming provision related to the physician’s total patient encounters or relative value units to state that 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 relative value units (as described in §414.22 of this chapter) personally performed by the physician. We seek comment regarding whether this provision should limit the methodology to physician work relative value units as defined at §414.22(a) or whether any personally-performed relative value units should be an acceptable basis for calculating a productivity bonus that is deemed not to relate directly to (that is, directly take into account) the volume or value of referrals. Finally, we are proposing to replace the term “allocated” with “distributed” at proposed (redesignated) §411.352(i)(2)(ii)(C) as the latter term reflects the actual payment of the productivity bonus.

D. Recalibrating the Scope and Application of the Regulations

As we stated previously and in our Phase I rulemaking, our intent in implementing section 1877 of the Act was “to interpret the [referral and billing] prohibitions narrowly and the exceptions broadly, to the extent consistent with statutory

language and intent” (66 FR 860). One purpose of this proposed rule is to reexamine our current regulations to assess whether we have held true to that intention. In doing so, we have considered our own experience in administering the SRDP, stakeholder interactions and comments to the CMS RFI, and our experience working with our law enforcement partners. In this proposed rule, we are proposing revisions to, including deletions of, certain requirements in our regulatory exceptions that may be unnecessary at this time. We describe our specific proposals in this section of the proposed rule.

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

Section 1877 of the Act established numerous exceptions to the statute’s referral and billing prohibitions and granted the Secretary authority to create regulatory exceptions for other financial relationships that do not pose a risk of program or patient abuse. The vast majority of the exceptions issued using the Secretary’s authority at section 1877(b)(4) of the Act to establish exceptions for financial relationships that do not pose a risk of program or patient abuse (which we often call the regulatory exceptions) require that the arrangement does not violate the anti-kickback statute. Most of these exceptions also require that the arrangement does not violate any Federal or State law or regulation governing billing or claims submission.

In Phase I, we stated that the requirements pertaining to the anti-kickback statute and billing or claims submission are necessary in regulatory exceptions issued under the Secretary’s authority at section 1877(b)(4) of the Act to ensure that the excepted financial relationships do not pose a risk of program or patient abuse (66 FR 863). Even though we acknowledged that the physician self-referral law and the anti-kickback statute are

different statutes, we were concerned that, if the regulatory exceptions did not require compliance with the anti-kickback statute, unscrupulous physicians and entities could potentially protect intentional unlawful and abusive conduct by complying with the minimal requirements of a regulatory exception created under section 1877(b)(4) of the Act. In Phase II, we stated our interpretation that the statutory “no risk” standard is not limited to risks as determined under the physician self-referral law (69 FR 16108). We added that many arrangements that might otherwise warrant an exception under section 1877 of the Act—a strict liability statute—pose some degree of risk under the anti-kickback statute; these arrangements cannot, therefore, be said to pose *no* risk. Similarly, we stated that some arrangements that may be permissible under the physician self-referral law could pose a risk of violating certain laws pertaining to billing or claims submission. Therefore, we concluded that the regulatory exceptions created under the Secretary’s authority at section 1877(b)(4) of the Act must require that the excepted financial relationship not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

A substantial number of CMS RFI commenters expressed opposition to the continued coupling of the physician self-referral law with the anti-kickback statute and other billing and claims submission laws, explaining the significant burden associated with the inclusion of these requirements in regulatory exceptions to the physician self-referral law. Commenters noted that the physician self-referral law is a strict liability statute and compliance with each element of an exception is mandatory if the entity wishes to submit a claim for designated health services referred by a physician with which it has a financial relationship, while the anti-kickback statute is an intent-based

criminal statute and compliance with a safe harbor is not required. The commenters asserted that the inclusion of a requirement for compliance with the anti-kickback statute is misplaced in an exception to the physician self-referral law because it introduces an intent-based requirement into a strict liability statute. Commenters further noted that this requirement can make it unreasonably difficult for entities to meet their burden of proof under §411.353(c)(2) that a referral for designated health services does not violate the physician self-referral law. Commenters also noted that the requirement for compliance with the anti-kickback statute and the requirement pertaining to Federal or State laws or regulations governing billing or claims submission are not necessary, because parties remain subject to these laws or regulations, regardless of whether their financial relationships otherwise comply with the physician self-referral law.

Based on our experience working with our law enforcement partners in reviewing conduct that implicates the physician self-referral law and other Federal fraud and abuse laws, it is our belief that, when a compensation arrangement violates the intent-based criminal anti-kickback statute, it will likely also fail to meet one or more of the more key requirements of an exception to the physician self-referral law. That is, the compensation in such cases likely is not fair market value or is determined in a manner that takes into account the volume or value of the physician's referrals or other business generated for the entity. Since the Phase I regulation was issued, we are unaware of any instances of noncompliance with the physician self-referral law turned solely on an underlying violation of the anti-kickback statute (or any other Federal or State law governing billing or claims submission).

We have reconsidered our position and, based on our experience working with our law enforcement partners since our regulations were finalized, as well as comments received in response to the CMS RFI, we no longer believe that it is necessary or appropriate to include requirements pertaining to compliance with the anti-kickback statute and Federal and State laws or regulations governing billing or claims submission as requirements of the exceptions to the physician self-referral law. We note further that the Congress did not require compliance with the anti-kickback statute or any other law in existence at the time of enactment of the statute or its subsequent revision in order to avoid the law's referral and billing prohibitions. Therefore, we are proposing to remove from the exceptions in 42 CFR Part 411, subpart J the requirement that the arrangement does not violate the anti-kickback statute or any Federal or State law governing billing or claims submission wherever such requirements appear. Specifically, we are proposing to remove the following sections from our regulations: §411.353(f)(1)(iii); §411.355(b)(4)(v), (e)(1)(iv), (f)(3), (f)(4), (g)(2), (g)(3), (h)(2), (h)(3), (i)(2), (i)(3), (j)(1)(iv); §411.357(e)(4)(vii), (j)(3), (k)(1)(iii), (l)(5), (m)(7), (p)(3), (r)(2)(x), (s)(5), (t)(3)(iv), (u)(3), (w)(12), (x)(1)(viii), and (y)(8). We also propose to delete the following clause from §411.357(e)(6)(i) and (n): “, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.” Finally, we are proposing to remove the definition of “does not violate the anti-kickback statute” in §411.351. We note that the exceptions for referral services at §411.357(q) and obstetrical malpractice subsidies at §411.357(r)(1) provide that arrangements satisfy the requirements of the exception if the

arrangements comply with the requirements of certain specified anti-kickback statute safe harbors. Our proposal would not apply to or affect these provisions.

We emphasize that this proposal in no way affects parties' liability under the anti-kickback statute. Indeed, the Congress clarified when enacting section 1877 of the Act that "any prohibition, exemption, or exception authorized under this provision in no way alters (or reflects on) the scope and application of the anti-kickback provisions in section 1128B of the Social Security Act" (H. Report 101-386, 856 (1989).) Most importantly, the fact that a financial relationship complies with an exception to the physician self-referral law does *not* entail that the financial relationship does not violate the anti-kickback statute. (See 66 FR 879.) Similarly, compliance with the anti-kickback statute does not entail compliance with the physician self-referral law. To the extent that the financial relationship is governed by other laws or regulations, our proposed action does not affect the parties' compliance obligations under those other laws or regulations. Specifically, claims submitted to the Medicare program must comply with all laws, regulations, and other requirements governing billing and claims submission.

Although we no longer believe that the Secretary must include a requirement that the financial relationship does not violate the anti-kickback statute in exceptions to the physician self-referral law, we continue to believe that the Secretary has the authority under the statute to impose a requirement that the financial relationship not violate the anti-kickback or any other requirement if the Secretary determines it necessary and appropriate to ensure that an excepted financial relationship does not pose a risk of program or patient abuse. We intend to monitor excepted financial relationships, and we may propose in a future rulemaking to include the requirements proposed here for

deletion in some or all of the exceptions issued pursuant to the Secretary's statutory authority if we determine such requirements are necessary or appropriate to protect against program or patient abuse.

2. Definitions (§411.351)

a. Designated Health Services

Section 1877(1)(A) of the Act provides that, if a physician (or an immediate family member of a physician) has a financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of a designated health service for which payment may otherwise be made under Title XVIII of the Act, unless an exception applies. The referral prohibition is codified in our regulations at §411.353(a). In the 1998 proposed rule (63 FR 1694), we interpreted the phrase "designated health service for which payment otherwise may be made" broadly to mean "any designated health service that ordinarily 'may be' covered under Medicare (that is, that could be a covered service under Medicare in the community in which the service has been provided) for a Medicare-eligible individual, regardless of whether Medicare would actually pay for this particular service, at the time, for that particular individual" Our proposed definition of the term "designated health services" in the 1998 proposed rule was consistent with this broad interpretation of the referral prohibition. Section 1877(h)(6) of the Act defines "designated health services" by listing various categories of services that qualify as designated health services (for example, clinical laboratory services). In the 1998 proposed rule, we stated that a designated health service remains such "even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes" (63 FR 1673). By way of example, we stated that

clinical laboratory services that are provided by a skilled nursing facility (SNF) and reimbursed as part of the SNF composite rate would remain designated health services for purposes of section 1877 of the Act, even though SNF services are not listed as designated health services at section 1877(h)(6) of the Act and Medicare would not separately pay for the clinical laboratory service furnished by the SNF.

The now-deleted exception at §411.355(d), which was first finalized in the 1995 final rule (60 FR 41975), served as a counterbalance to the broad interpretation of designated health services that was proposed in the 1998 proposed rule. As finalized in the 1995 final rule (60 FR 41980), §411.355(d) provided that the referral prohibition in §411.353 did not apply to services furnished in an ambulatory surgical center (ASC) or end-stage renal disease (ESRD) facility, or by a hospice, if payment for those services was included in the ASC rate, the ESRD composite rate, or as part of the per diem hospice charge. We explained that the application of the composite rate “constitutes a barrier to either Medicare program or patient abuse because the Medicare program will pay only a set amount to the facilities irrespective of the number and frequency of laboratory tests that are ordered” (60 FR 41940). In the 1998 proposed rule, we proposed an amendment to §411.355(d) that would have allowed the Secretary to except services furnished under other payment rates that did not pose a risk of program or patient abuse (63 FR 1666). However, in Phase I, instead of expanding the exception at §411.354(d) to include services furnished under other payment rates, we narrowed the definition of designated health services (as explained in this section of the proposed rule) to exclude certain services that are paid as part of a composite rate, and we solicited comments on whether the exception at §411.355(d) was still necessary in light of the narrowed

definition of designated health services in Phase I (66 FR 923 through 924). We ultimately determined in Phase II that §411.355(d) was no longer necessary, given the change to the definition of designated health services finalized in Phase I, and we removed the exception from our regulations (69 FR 16111).

As finalized in Phase I, the definition of “designated health services” includes only designated health services payable, in whole or in part, by Medicare, and does not include services that would otherwise constitute designated health services, but that are reimbursed by Medicare as part of a composite rate, except to the extent that the services are specifically identified in §411.351 and are themselves payable through a composite rate. SNF services paid for under the Part A composite rate (that is, the Skilled Nursing Facility Prospective Payment System), for example, are not designated health services, even if the bundle of services includes services that would otherwise be designated health services, such as clinical laboratory services.³ On the other hand, although home health and inpatient and outpatient hospital services are reimbursed on a composite rate, they remain designated health services under the definition finalized in Phase I because section 1877(h)(6) of the Act explicitly lists these services as designated health services. We explained in Phase I that our ultimate definition of “designated health services” was based on issues of statutory construction (66 FR 923). In particular, commenters on the 1998 Proposed Rule asserted that the proposed definition of designated health services would have expanded the list of services that are considered to be designated health

³ ESRD services are also reimbursed on a composite rate, and thus are not considered to be designated health services. In this context, we would like to refer readers to the comment and response section of the CY 2018 ERSD PPS Final Rule, where we explained that, for purposes of the physician self-referral law, the “composite rate” for ESRD services is interpreted as the per-treatment payment amount (82 FR 50751). To the extent that outpatient prescription drugs are included in the ESRD per-treatment payment amount, they do not qualify as designated health services.

services beyond the services explicitly listed at section 1877(h)(1) of the Act. For example, clinical laboratory services furnished by a SNF and reimbursed under the Skilled Nursing Facility Prospective Payment System would have been considered designated health services under the proposed definition, even though SNF services are not included in the statutory list of designated health services. The commenters maintained that, where the Congress intended the physician self-referral law to cover specific services, including services that are paid on a composite rate such as home health services, it did so by explicitly listing the services at section 1877(h)(6) of the Act. We ultimately agreed with this statutory construction and finalized the definition of “designated health services” to include only those services paid under a composite rate that are explicitly listed at section 1877(h)(1) of the Act; that is, home health services and inpatient and outpatient hospital services.

In light of our experience with the SRDP and our review of the comments to our CMS RFI, we reviewed the regulatory history of our definition of “designated health services” at §411.351 to identify whether further clarification regarding what constitutes a designated health service is necessary. We are proposing here to revise the definition of “designated health services” to clarify that a service provided by a hospital to an inpatient does not constitute a designated health service payable, in whole or in part, by Medicare, if the furnishing of the service does not affect the amount of Medicare’s payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS). To illustrate, suppose that, after an inpatient has been admitted to a hospital under an established diagnosis-related group (DRG), the patient’s attending physician requests a consultation with a specialist who was not responsible for the patient’s admission, and the

specialist orders an X-ray. By the time the specialist orders the X-ray, the rate of Medicare reimbursement under the IPPS has already been established by the DRG (diagnostic imaging is bundled into the payment for the inpatient admission), and, unless the X-ray results in an outlier payment, the hospital will not receive any additional payment for the service over and above the payment rate established by the DRG. Moreover, insofar as the provision of the X-ray does not affect the rate of payment, the physician has no financial incentive to over-prescribe the service. As illustrated here, we do not believe that the X-ray is a designated health service that is payable, in whole or part, by Medicare, and our proposed definition of designated health services at §411.351 would exclude this service from the definition of designated health services, even though it falls within a category of services that, when billed separately, would be “designated health services.” Thus, assuming the specialist had a financial relationship with the hospital that failed to satisfy the requirements of an exception to the physician self-referral law at the time the X-ray was ordered, the inpatient hospital services would not be tainted by the unexcepted financial relationship, and the hospital would not be prohibited from billing Medicare for the admission. On the other hand, if the physician who ordered the inpatient hospital admission had a financial relationship with the hospital that failed to satisfy the requirements of an applicable exception, §411.353(b) would prohibit the hospital for billing for the inpatient hospital services.

We received several comments to our CMS RFI suggesting modifications similar to the change we are proposing. One commenter requested that we clarify that a service is not a designated health service “for which payment otherwise may be made” if the physician making a referral for the service “has not caused the beneficiary to be admitted,

the patient has already been admitted, and the service ordered by the physician is subsumed within the DRG already established for the beneficiary.” Numerous other commenters requested that we modify the definition of “referral” to clarify that a referral, for purposes of the physician self-referral law, must result in additional payments or an increase in payment. Although the change to the definition of “referral” suggested by the latter commenters would apply to referrals for any category of designated health services, the commenters provided examples drawn exclusively from the context of inpatient services. We do not believe it is necessary to modify the definition of “referral” to achieve the policy goals identified by the commenters. We believe that the situation identified by the commenters, where a service furnished pursuant to a physician’s referral does not increase the reimbursement received by the entity, occurs primarily or exclusively in the context of inpatient hospital services, where the DRG is established at the time of admission and physicians other than the attending or admitting physician may refer a patient for services that will not result in additional payment to the hospital. For this reason, our proposed clarification of the definition of “designated health services” would apply only to inpatient services that do not affect the Medicare reimbursement rate under the IPPS. Although outpatient services are also paid on a composite rate, we believe that there is typically only one ordering physician for outpatient services, and it rarely happens that physicians other than the ordering physician refer outpatients for additional outpatient services that would not be compensated separately under the OPPS. For this reason, our proposed modification of the definition of “designated health services” at §411.351 does not apply to outpatient hospital services.

Lastly, we are aware that not all hospitals are paid under the IPPS. We are

soliciting comments as to whether our proposal regarding certain hospital services that are not “designated health services payable, in whole or in part, by Medicare” should be extended to analogous services provided by hospitals that are not paid under the IPPS, and, if so, how we should effectuate this change in our regulation text. In addition, we are soliciting comment regarding whether we should extend our proposal to outpatient hospital services or other categories of designated health services and, if so, how we should effectuate this change in our regulation text.

b. Physician

In the 1992 proposed rule, we stated that, for purposes of the physician self-referral law, physicians are certain professionals who are “legally authorized to practice by the State in which they perform their professional functions or actions and when they are acting within the scope of their licenses.” (57 FR 8593). We included in the definition a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of optometry, and a chiropractor who meets certain qualifications. In Phase I, we finalized our definition of “physician” at §411.351, defining the term as “a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined at section 1861(r) of the Act.” (66 FR 955). Since Phase I, our definition of “physician” at §411.351 has consistently referred to the definition of “physician” at section 1861(r) of the Act. However, while the definition of “physician” found at §411.351 cross-references section 1861(r) of the Act, the two definitions are not entirely consistent. In particular, the definition of “physician” at §411.351 does not include all the limitations imposed by the definition of “physician” at section 1861(r) of the Act. In order to correct

this discrepancy and provide uniformity with regard to the definition of a “physician,” we are proposing to amend the definition of “physician” at §411.351. Under the proposed definition, the types of practitioners who qualify as “physicians” for purposes of the physician self-referral law will be defined by cross-reference to section 1861(r) of the Act. This amendment will incorporate into our definition of “physician” at §411.351 the statutory limitations imposed on the definition of “physician” by section 1861(r) of the Act. The definition at §411.351 would continue to provide that a physician is considered the same as his or her professional corporation for purposes of the physician self-referral law.

c. Referral

In Phase II, we stated that the exception for fair market value compensation is not available to protect recruitment arrangements (69 FR 16096). We noted that a hospital is not permitted to pay a physician for the benefit of receiving the physician’s referrals, and that such payments are antithetical to the premise of the statute. We are taking this opportunity to reiterate that a physician’s referrals are not items or services for which payment may be made under the physician self-referral law, and that neither the existing exceptions to the physician self-referral law nor the proposed exceptions in this proposed rule would protect such payments. We are proposing to revise the definition of “referral” at §411.351 to explicitly state our longstanding policy that a referral is not an item or service for purposes of section 1877 of the Act and the physician self-referral regulations.

d. Remuneration

A compensation arrangement between a physician (or an immediate family member of such physician) and an entity furnishing designated health services implicates

the referral and billing prohibitions of the physician self-referral law. Section 1877(h)(1)(A) of the Act defines the term “compensation arrangement” as any arrangement involving any “remuneration” between a physician (or an immediate family member of such physician) and an entity. However, section 1877(h)(1)(C) of the Act identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the referral and billing prohibitions of the physician self-referral law. Under section 1877(h)(1)(C)(ii) of the Act, the provision of the following does not create a compensation arrangement between the parties: items, devices, or supplies that are 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 such entity. Furthermore, under our definition of “remuneration” at § 411.351, the provision of such items, devices, or supplies is not considered to be remuneration.

In the 1998 proposed rule we explained our interpretation of the phrase “used solely” at section 1877(h)(1)(C)(ii) of the Act (66 FR 1693 through 1694). We observed that some pathology laboratories had been furnishing physicians with materials ranging from basic collection and storage items to more specialized or sophisticated items, devices, or equipment. We clarified that, in order for these items and devices to meet the statutory requirement, they must be used *solely* to collect, transport, process, or store specimens for the entity that provided the items and devices, or to order or communicate the results of tests or procedures for such entity. We provided examples of items that could meet the “used solely” test, including cups used for urine collection or vials used to hold and transport blood to the entity that supplied the items or devices. We emphasized

that an item or device would not meet the “used solely” requirement if it is used for any purpose besides the purposes listed in the statute. In particular, we noted that certain surgical tools which can be used to collect or store samples, but are also routinely used as part of a surgical or medical procedure, would not satisfy the “used solely” requirement.

As finalized in Phase I, the definition of “remuneration” included a parenthetical stipulating that the provision of surgical items, devices, and supplies would not qualify for the carve-out to the definition of “remuneration” for items, devices, or supplies that are used solely for the purposes listed at section 1877(h)(1)(C)(ii) of the Act (66 FR 947). We explained that we did not believe that the Congress intended section 1877(h)(1)(C)(ii) of the Act to allow entities to supply physicians with surgical items for free, noting that such items may have independent economic value to physicians apart from the six statutorily permitted uses. We stated our belief that the Congress intended to include at section 1877(h)(1)(C)(ii) of the Act single-use items, devices, and supplies of low value that are primarily provided by laboratories to ensure proper collection of specimens. In this context, we explained that reusable items may have value to physicians unrelated to the collection of specimens, and therefore could not meet the “used solely” requirement. Lastly, we stated that the provision of an excessive number of collection supplies creates an inference that the supplies are not provided “solely” to collect, transport, process, or store specimens for the entity that furnished them.

We made no changes to the definition of “remuneration” in Phase II and Phase III. In the CY 2016 PFS final rule, we clarified that the provision of an item, device, or supply that is used for *one or more* of the six purposes listed in the statute, and no other purpose, does not constitute remuneration (80 FR 41918). In two advisory opinions

issued in 2013 we applied the definition of “remuneration” at §411.351 to two proposed arrangements to provide certain devices to physicians free of charge. In CMS-AO-2013-01, we concluded that, based on the specific facts certified by the requestor of the opinion, the provision of liquid-based Pap smear specimen collection kits did not constitute remuneration, because the collection kits are not surgical devices, and because the devices are used solely in the collection of specimens. Among other things, our “used solely” analysis highlighted the following facts, as certified by the requestor: (1) the Pap smear collection kits contain only disposable items that cannot be reused after a specimen is collected; and (2) the entity furnishing the Pap smear collection kits has a system in place to ensure that physicians receive only the quantity of devices necessary for their practice needs, and to address potential instances of separation of the devices into their component parts for use other than to collect specimens. In contrast, in CMS-AO-2013-02, we concluded that, based on the specific facts certified by the requestor of the opinion, the furnishing of certain disposable biopsy brushes for use in obtaining a biopsy of visible exocervical lesions constituted remuneration under the definition at §411.351. We noted that, as certified by the requestor, the biopsy brush is a disposable, single-use, cervical biopsy device that is used to collect a specimen to be sent to a laboratory. After reviewing FDA rules and regulations and American Medical Association guidelines, and consulting with CMS medical officers, we concluded that the device is a “surgical item, device, or supply” for purposes of the physician self-referral law and, therefore, that the provision of the device constitutes remuneration under §411.351.

We have further considered our interpretation of section 1877(h)(1)((C)(ii) of the Act and the analysis set forth in the 2013 advisory opinions, and are proposing certain

modifications to the definition of “remuneration” at §411.351. Specifically, we are proposing to remove the parenthetical in the current definition of “remuneration,” which stipulates that the carve-out to the definition of “remuneration” does not apply to surgical items, devices, or supplies. We are no longer convinced that the mere fact that an item, device, or supply is routinely used as part of a surgical procedure means that the item, device, or supply is not used solely for one of the six purposes listed at section 1877(h)(1)(C)(ii) of the Act. Rather, we believe that the relevant inquiry for purposes of the physician self-referral law is whether the item, device, or supply is used solely for one or more of the statutory purposes, regardless of whether the device is also classified as a surgical device. To be clear, we continue to believe that the Congress intended the carve-out at section 1877(h)(1)(C)(ii) of the Act to cover single-use items, devices, or supplies of low value⁴ that are primarily provided by laboratories to ensure proper collection of specimens, but we are no longer convinced that the mere fact that an item, supply, or device is classified as a “surgical device” means that it does not fall within the carve-out.

We are also taking this opportunity to clarify the “used solely” requirement at §411.351. While the furnished item, device, or supply cannot be used for any purpose other than one or more of the six purposes listed in the statute, we recognize that in many instances the item, device, or supply could theoretically be used for numerous purposes. For example, a specimen lockbox could potentially be used for several purposes; it could be used to store unused specimen collection supplies or as a doorstop. However, if, during the course of the arrangement, the specimen box provided to the physician is not used for any of these purposes and is, in fact, used only for one or more of the six

⁴ See, for example, the OBRA 1993 Conference Report, H.R. 103-213 pp. 818 through 819, which characterized section 1877(h)(1)(C)(ii) of the Act as an “exception” for “certain minor remuneration.”

purposes outlined in the statute and our regulations, the furnishing of the specimen box would not be considered remuneration between parties. In other words, the mere fact that an item, device, or supply *could* be used for a purpose other than one or more of the permitted purposes does not automatically mean that the furnishing of the item, device, or supply at no cost constitutes remuneration. We are proposing to add the phrase “in fact” to the “used solely” requirement to clarify that an item, device, or supply can have several uses, including uses that are not among the six purposes listed in the statute; however, the furnishing of such items, supplies, or devices would not be considered remuneration if the item, device, or supply in question is, in fact, only used for one or more of the six purposes outlined in the statute. We refer readers to the guidance provided in the 1998 proposed rule and in Phase I on steps that a party can take to ensure that the furnished items, supplies, or devices are used appropriately (63 FR 1694 and 66 FR 947 through 948, respectively).

Although we are proposing certain modifications to the definition of “remuneration,” our proposal would not exclude from the definition those items, devices, or supplies whose main function is to prevent contamination or infection, even if the item, device, or supply could potentially be used for one or more of the six statutory purposes at section 1877(h)(1)(C)(ii) of the Act. In Phase I, we made clear that, although sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies that are used *solely* to collect, transport, process, or store specimens (66 FR 947). Sterile gloves are essential to the specimen collection process, but their primary purpose is to prevent infection or contamination. In addition, sterile gloves are fungible, general purpose items, and we continue to believe it would be

impractical for parties to monitor the use of the gloves to ensure that they are used solely for one or more of the purposes listed at section 1877(h)(1)(C)(ii) of the Act. Likewise, although there may be certain specialized equipment (including surgical tools) that may be used for one or more of the purposes described in the statute, in order not to be considered remuneration, the item, device, or supply must not have a primary function of preventing infection or contamination, or some other purpose besides one of the six purposes listed in the statute.

e. Transaction

Section 1877(e)(6) of the Act provides that an isolated financial transaction, such as a one-time sale of property or practice, is not a compensation arrangement for purposes of the physician self-referral law if: (1) the amount of remuneration under the transaction is consistent with fair market value of the transaction and is not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals by the referring physician; (2) the remuneration is pursuant to an arrangement that would be commercially reasonable even if no referrals were made to the entity; and (3) the transaction meets any other requirements that the Secretary imposes by regulation as needed to protect against program or patient abuse. As enacted by OBRA 1989, the statutory exception identified a one-time sale of property as an example of an isolated financial transaction. In OBRA 1993, the Congress further clarified the statutory exception by providing an additional example of an isolated transaction, namely, a one-time sale of a practice. (See House Conference Report at H.R. Rep. No. 213, 103d Cong., 1st Sess. 813-815 (1993).)

In our 1992 proposed rule, we proposed an exception at §411.357(f) to mirror the statutory exception at section 1877(e)(6) of the Act for certain isolated financial transactions (both titled and together referred to as the exception for isolated transactions) (57 FR 8588). In our proposal, we included a requirement—in addition to the statutory requirements—that there be no other transactions (that is, financial relationships) between the parties for 1 year before and 1 year after the financial transaction to ensure that financial transactions excepted under section 1877(e)(6) of the Act and §411.357(f) are truly *isolated* in nature (57 FR 8599). In the 1995 final rule, we finalized an exception for isolated financial transactions at §411.357(f), and we modified the proposed 1-year requirement in response to commenters who asserted that the requirement would create substantial and unnecessary problems (60 FR 41960). We stated that a transaction would be considered an isolated transaction for purposes of §411.357(f) if there were no other transactions between the parties for 6 months after the transaction, except those transactions that are specifically excepted by another provision in §§411.355 through 411.357. We further stated that individual payments between parties generally characterize a compensation arrangement; however, debt, as described in the definition of “ownership or investment interest” at section 1877(a)(2) of the Act, can constitute an ownership interest that continues to exist until the debt is paid off (60 FR 41960). The 1995 final rule also established definitions of “transaction” and “isolated transaction” at §411.351. We defined a “transaction” as an instance or process of two or more persons doing business and an “isolated transaction” as a transaction involving a single payment between two or more persons. The regulation at §411.351 specified that a

transaction involving long-term or installment payments is not considered an isolated transaction.

In the 1998 proposed rule, we proposed to revise the definition of “transaction” at §411.351 to clarify that a transaction can involve persons or entities, but we did not propose any substantive changes to the exception at §411.357(f) (63 FR 1669). This definition was finalized in Phase II, with modification to permit installment payments (and post-closing adjustments) under certain circumstances (69 FR 16098). In Phase II, we also responded to commenters who objected to the prohibition on other transactions within 6 months of the excepted transaction. We declined to modify the 6-month prohibition on other transactions, and we explained that the concept of an *isolated* transaction is incompatible with the parties routinely engaging in multiple transactions in a year or during a short period of time. In Phase III, we made no changes to the exception at §411.357(f), but updated the term “isolated transaction” at §411.351 to refer to an “isolated financial transaction,” as that specific term is used in the statutory and regulatory exceptions (72 FR 51084).

Through our administration of the SRDP, work with our law enforcement partners, and interactions with stakeholders, it has come to our attention that certain parties may believe that CMS’ policy is that the exceptions in section 1877(e)(6) of the Act and §411.357(f) for isolated transactions are available to protect service arrangements where a party makes a *single* payment for *multiple* services provided over an extended period of time. To illustrate, assume that a hospital makes a single payment to a physician for working multiple call coverage shifts over the course of a month (or several months) and seeks to utilize the exception at §411.357(f) to avoid qualification of

the payment as a financial relationship subject to the physician self-referral law's referral and billing prohibitions. That is, the parties wish to consider the single payment for multiple services an "isolated financial transaction." We have observed that parties turn to the exception for isolated transactions to protect single payments for multiple services when they discover, typically after the services have been provided, that they failed to set forth the service arrangement in writing, and thus cannot rely on the exceptions for personal service arrangements or fair market value compensation. In fact, it is our policy that the exception for isolated transactions is not available to except payments for multiple services provided over an extended period of time, even if there is only a single payment for all the services. Elsewhere in this proposed rule, we are proposing regulations that will facilitate compliance with the physician self-referral law in general and the writing and signature requirements in particular, including a 90-day period to reduce arrangements to a signed writing and an exception for limited remuneration to a physician. We believe that these provisions, if finalized, would afford parties with sufficient flexibility to ensure that personal service arrangements comply with the physician self-referral law, and see no reason to unduly stretch the meaning and applicability of the exception for isolated transactions beyond what was intended by the Congress.

To illustrate the kind of transactions that section 1877(e)(6) of the Act is meant to exempt, the Congress provided as examples a one-time sale of property and a one-time sale of a practice. In our view, a one-time sale of property or a practice is a unique, singular transaction. It is not possible for one party to repeatedly offer and sell the same property or medical practice to another party. In contrast, services can be provided and

purchased on a repeated basis. Moreover, in a one-time sale of property or a practice, the consideration for the transaction (that is, the transfer of ownership of the property or practice) is exchanged at the time payment is made in a single transaction (although §411.357(f) permits installment payments under certain circumstances). In contrast, if a physician provides multiple services to an entity over an extended period of time, remuneration in the form of an in-kind benefit has passed repeatedly from the physician to the entity receiving the service prior to the payment date. The provision of remuneration in the form of services commences a compensation arrangement at the time the services are provided, and the compensation arrangement must satisfy the requirements of an applicable exception *at that time* if the physician makes referrals for designated health services and the entity wishes to bill Medicare for such services. The exception for isolated transactions is not available to retroactively cure noncompliance with the physician self-referral law. Finally, we note that the Congress created an exception for personal service arrangements at section 1877(e)(3) of the Act and required, among other things, that the arrangement is set out in writing and signed by the parties, that the term of the arrangement is at least 1 year, and that the compensation is set in advance. We do not believe that the Congress would impose such requirements for service arrangements under this exception, and then permit parties to avoid these requirements as long as the parties made one retrospective payment for multiple services provided over an extended period of time relying on the exception for isolated transactions.

To provide a clear expression of our policy described in this section II.D.2.d. of this proposed rule, we are proposing to establish an independent definition of “isolated

financial transaction” at §411.351 and clarify that an “isolated financial transaction” does not include payment for multiple services provided over an extended period, even if there is only one payment for such services. We are not proposing further changes to the definition of “transaction” at §411.351. Under our proposals, the term “transaction” would mean an instance or process of two or more persons doing business. We are proposing corresponding revisions to the exception for isolated transactions at §411.357(f) to reference isolated financial transactions in order to align the regulation text with the statutory provisions at section 1877(e)(6). Even though the exception at §411.357(f) applies to isolated financial transactions, we are not proposing to change the title of the exception from “isolated transactions” to “isolated financial transactions,” as the title of the statutory exception is “isolated transactions.”

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

In the CY 2008 PFS proposed rule, we solicited comments on how to determine the period of time during which a physician may not make referrals for designated health services to an entity and the entity may not bill Medicare for the referred designated health services when a financial relationship between the parties failed to satisfy the requirements of any applicable exception (72 FR 38183). We referred to this time period as the “period of disallowance.” We stated that, as a general matter, the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy the requirements of any applicable exception and end on the date that the financial relationship ends or is brought back into compliance (that is, satisfies all requirements of an applicable exception). We noted, however, that it is not

always clear when a financial relationship has ended. By way of example, we stated that, if a physician paid less than fair market value for the rental of office space, the below market rental payments may have been in exchange for future or anticipated referrals, so it is not clear if the financial relationship ended on the date that the lease expires. We sought comments on whether we should employ a case-by-case method for determining when a financial relationship ends or if we should, to the extent practicable, create a provision that would deem certain kinds of financial relationships to last a prescribed period of time for purposes of determining the period of disallowance. Assuming we were to prescribe a determinate amount of time for the period of disallowance in certain circumstances, we sought comments on whether the period of disallowance could be terminated if parties returned or repaid the value of any problematic compensation under an arrangement.

In the FY 2009 IPPS proposed rule, we proposed provisions pertaining to the period of disallowance at §411.353(c)(1) (73 FR 23690 through 23692). Under that proposal, the period of disallowance would begin when the financial relationship failed to satisfy the requirements of any applicable exception. Where the noncompliance is unrelated to the payment of compensation, the period of disallowance would be deemed to end no later than the date that the financial relationship satisfies all requirements of an applicable exception. On the other hand, where the noncompliance is related to the payment of excess or insufficient compensation, the proposed rule provided that the period of disallowance would be deemed to end no later than the date on which the excess compensation was repaid or the additional required compensation was paid, and the arrangement satisfied all the elements of an applicable exception. We emphasized

that the proposal only prescribed an outside limit on the period of disallowance. We acknowledged that, in certain cases, a financial relationship may end before the excess compensation has been returned or the insufficient compensation paid in full, and that the period of disallowance in such cases would end when the financial relationship ended. However, we did not issue any rules or guidance on determining when a financial relationship has ended in such cases, and we stated that the period of disallowance would have to be determined in such instances on a case-by-case basis. Lastly, we recognized that noncompliance may also arise for other reasons related to compensation, such as payments that take into account the volume or value of a physician's referrals, but we did not propose any rules on how to determine the period of disallowance in such cases.

In the FY 2009 IPPS final rule, we finalized §411.353(c)(1) as proposed, without substantive modifications (73 FR 48700 through 48705). We emphasized once again that the rule only prescribed an outside date for the period of disallowance, and that the rule did not prevent parties from arguing that the period of disallowance ended earlier than the outside date prescribed by the rule, on the theory that the financial relationship ended prior to this date. We made it clear in response to commenters that the period of disallowance as prescribed by §411.353(c)(1) was not intended to extend the period of disallowance beyond the end of a financial relationship. Rather, the rule was merely intended to give parties clear guidance on steps that could be taken to ensure that the period of disallowance had ended. In addition, we explained the application of the rules regarding excess and insufficient compensation at §411.353(c)(1)(ii) and (iii).

In light of our experience administering the SRDP and stakeholder feedback we have received over the years, we are proposing to delete the rules on the period of

disallowance at §411.353(c)(1) in their entirety because we believe that, although the rules were initially intended merely to establish an outside, bright-line limit for the period of disallowance, the rules, in application, appear to be overly prescriptive and impractical. We emphasize that our current rulemaking is in no way meant to undermine parties who have relied on §411.353(c)(1)(ii) or (iii) in the past to establish that the period of disallowance has ended.

Throughout our rulemaking on the period of disallowance, we acknowledged that there are no definite rules for establishing in each and every case when a financial relationship has ended, and that the analysis typically must proceed on a case-by-case basis, taking into account the unique facts and circumstances of each financial relationship. The period of disallowance rules were meant to provide certainty in the face of this complexity, and to prescribe definite, practical steps that a party could take to establish that the period of disallowance had ended. However, we are concerned that parties may believe that the *only* way to establish that the period of disallowance has ended is to follow the steps outlined in §411.353(c)(1). Moreover, it has become clear that the steps outlined at §411.353(c)(1)(ii) and (iii) are not always as practical or clear cut as we originally envisioned. Often when there is an allegation of excess or insufficient compensation paid under an arrangement, there is a dispute between the parties as to what the proper amount of compensation should have been under the arrangement. To settle the dispute, the parties may need to litigate the matter. It is not clear under §411.353(c)(1)(ii) and (iii) at what point in the litigation, if any, the period of disallowance should end. In addition, in some cases, the cost of litigating the matter may far outweigh the amount in dispute, making litigation highly impractical. Thus, in

practice, the provisions at §411.353(c)(1)(ii) and (iii) often do not provide the clear, bright-line method for determining the end of the period of disallowance that we originally intended, and parties must continue to rely on a case-by-case analysis to determine when the period of disallowance has ended. For these reasons, we are deleting the period of disallowance rules at §411.353(c)(1) in their entirety.

We continue to agree with the general principle stated in the CY 2008 PFS proposed rule that the period of disallowance under the physician self-referral law should begin on the date when a financial relationship fails to satisfy all requirements of any applicable exception and end on the date that the financial relationship ends or satisfies all requirements of an applicable exception. We are aware that the payment of excess or insufficient compensation can complicate the question of when a financial relationship has ended or been brought back into compliance for purposes of the physician self-referral law. As a general matter, we agree with the FY 2009 IPPS final rule that *one* way to establish that the period of disallowance has ended in such circumstances is to follow the steps prescribed in §411.353(c)(1)(ii) or (iii); for example, recover any excess compensation and bring the financial relationship back into compliance with an applicable exception. However, we note that, since the publication of the FY 2009 IPPS final rule, stakeholders have questioned whether our preamble guidance was intended to state that administrative or other operational failures during the course of an arrangement, such as the erroneous payment of “excess” compensation or the erroneous failure to pay the full amount of compensation due during the timeframes established under the terms of an arrangement, would necessarily result in noncompliance with the physician self-referral law. Through submissions to the SRDP and other interactions with stakeholders,

we are aware of questions regarding whether administrative errors, such as invoicing for the wrong amount of rental charges (that is, an amount other than the amount specified in the written lease arrangement) or the payment of compensation above what is called for under a personal service arrangement due to a typographical error entered into an accounting system, create the type of “excess compensation” or “insufficient compensation” described in our preamble guidance and the period of disallowance rules. This was never our intent. However, the failure to remedy such operational inconsistencies could result in a distinct basis for noncompliance with the physician self-referral law.

The effect of deleting the period of disallowance rules would not be to permit parties to a financial relationship to make referrals for designated health services and to bill Medicare for the services when that financial relationship does not satisfy all requirements of an applicable exception. It is a fundamental principle of the physician self-referral law that a physician may not make a referral for designated health services to an entity with which he or she has a financial relationship, and the entity may not bill Medicare for the services, if the financial relationship between the parties does not satisfy all the requirements of an applicable exception. Nothing in this proposed rule affects the billing and referral prohibitions at §411.353(a) and (b). Our intent in deleting §411.353(c)(1) is merely to no longer prescribe the particular steps or manner for bringing the period of noncompliance to a close. At the same time, we are taking this opportunity to provide general guidance on how to remedy compensation problems that occur during the course of an arrangement and, when a remedy is not available, how to determine when the period of disallowance ends. Consistent with our intent in deleting

the period of disallowance rules at §411.353(c)(1), we emphasize that the analysis to determine when a financial relationship has ended is dependent in each case on the unique facts and circumstances of the financial relationship, including the operation of the financial relationship as negotiated between the parties, and it is not possible for us to provide definitive rules that would be valid in all cases.

For purposes of this analysis, assume there is a 1-year arrangement beginning January 1 for personal services between an entity and a physician; the arrangement is memorialized at the outset in a written agreement between the parties; the amount of compensation provided for in the writing does not exceed fair market value; and the arrangement otherwise fully complies with the requirements of an applicable exception. Assume further that the entity provides compensation to the physician in months 1 through 6 in an amount other than what is stipulated in the written agreement, and the parties discover the payment discrepancy in early July. For purposes of this illustration, assume that a hospital pays a physician \$150 per hour for medical director services when the written agreement between the parties identifies \$140 per hour as the physician's rate of pay. If the \$150 per hour payment is due to an administrative or other operational error—that is, the discrepancy was unintended—the parties may, while the arrangement is ongoing during the term initially anticipated (in this example, during the year of the arrangement), correct the error by collecting the overage (or making up the underpayment, if that is the case). We expect entities and the physicians who refer designated health services to them to operate effective compliance programs that identify these types of errors and rectify them promptly. However, if the parties fail to identify the error during the term of the arrangement as anticipated (that is, the “live” or ongoing

arrangement), they cannot simply “unring the bell” by correcting it at some date after the termination of the arrangement. Rather, the failure to timely identify and rectify the error through an effective compliance program would expose the parties to the referral and billing prohibitions of the physician self-referral law during the entirety of the arrangement.

In analyzing the compensation arrangement in this example—assuming that the operational error was not timely discovered and rectified—as we would with any financial relationship under the physician self-referral law, we consider the actual arrangement between the parties, which does not always coincide with the terms described in the written documentation. Thus, to properly characterize the potential noncompliance, it is important to determine whether the *actual* amount of compensation paid under the arrangement—that is, the amount the physician actually received, as opposed to the amount stipulated in the written agreement—exceeded fair market value for the services actually provided. Assuming that the *actual* amount paid did not exceed fair market value and was not determined in a manner that took into account the volume or value of the physician’s referrals or other business generated, then the potential noncompliance may relate primarily to the failure to properly document the *actual* arrangement in writing (assuming the arrangement otherwise satisfied the requirements of an applicable exception). Various provisions in this proposed rule and in our current regulations may offer parties a means of limiting the scope of potential noncompliance in such circumstances. For example, the parties could rely on the proposed special rule for writing and signature requirements at §411.354(e)(3), coupled with the clarification of the writing requirement at §411.354(e)(2), to establish that the actual amount of

compensation provided under the arrangement was set forth in writing within 90 days of the commencement of the arrangement via a collection of documents, including documents evidencing the course of conduct between the parties. In addition, the proposed exception for limited remuneration to a physician may also be available to protect some or all of the payments made during months 1 through 6. In this manner, depending on the facts and circumstances, the parties may be able to establish that the arrangement complied with the physician self-referral law for some or all of months 1 through 6 of the arrangement.

In certain instances, the failure to collect money that is legally owed under an arrangement may potentially give rise to a secondary financial relationship between the parties. In such circumstances, the parties may conclude that the only means to remedy the noncompliance with the physician self-referral law is to recoup the amount owed under the arrangement. This issue is especially acute if the *actual* amount of compensation paid under the arrangement for months 1 through 6 was not consistent with fair market value or took into account the volume or value of referrals. In such circumstances, parties cannot establish compliance by showing that the actual amount of compensation was documented in various writings, because the compensation itself is the reason for the potential noncompliance. Nevertheless, depending on the facts and circumstances, the parties may be able to remedy the noncompliance. Returning to the previous example, if the entity discovers the payment errors during the course of the arrangement, corrects the errors going forward, and collects any amount to which it is legally entitled as a result of the erroneous payments during months 1 through 6, then the arrangement may comply with the physician self-referral law for its duration, including

months 1 through 6. The relevant inquiry is whether the payment errors during months 1 through 6 gave rise to a secondary financial relationship (for example, an interest free loan) which must satisfy the requirements of an applicable exception, or, on the other hand, whether the payment errors arose from operational or administrative problems that were detected and corrected during the course of the arrangement as part of a normal business practice. In this context, we are taking this opportunity to clarify statements in the FY 2009 IPPS final rule regarding whether parties can “turn back the clock” or retroactively “cure” noncompliance. We believe that parties who detect and correct administrative or operational errors or discrepancies *during* the course of the arrangement are not necessarily “turning back the clock” to address past noncompliance. Rather, it is a normal business practice, and a key element of an effective compliance program, to actively monitor active ongoing, live financial relationships, and to correct problems that such monitoring uncovers. An entity that detects a problem in an active financial relationship and corrects the problem while the financial relationship is still active is addressing a current problem and is not “turning back the clock” to fix past noncompliance. On the other hand, once a financial relationship has ended, we believe that parties cannot retroactively “cure” previous noncompliance by recovering or repaying problematic compensation. Of course, to the extent that the financial relationship has ended, the period of disallowance has ended as well. We believe this policy encourages active, ongoing review of arrangements for compliance with the physician self-referral law.

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

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

In the FY 2009 IPPS final rule, we introduced the concept of titular ownership or investment interests in the context of our rulemaking pertaining the physician “stand in the shoes” provisions at §411.354(c) (73 FR 48693 through 48699). Under the rules finalized in the FY 2009 IPPS final rule, for purposes of determining whether a compensation arrangement between an entity and a physician organization is deemed to be a compensation arrangement between the entity and the physicians associated with the organization, a physician whose ownership or investment interest in the physician organization is merely titular in nature is not required to stand in the shoes of the physician organization (73 FR 48694). We explained that an ownership or investment interest is considered to be “titular” if the physician is not able or entitled to receive any of the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment (73 FR 48694). The concept of titular ownership or investment interests set forth in the FY 2009 IPPS final rule applied only to the stand in the shoes rules at §411.354(c) pertaining to compensation arrangements. Because we were responding to a comment to the 1998 proposed rule (and the Phase I comments thereafter) regarding the application of the exceptions for compensation arrangements, we did not propose to extend the concept of titular ownership or investment interests to the provisions at §411.354(b) pertaining to ownership or investment interests, although we had previously concluded in a 2005 Advisory Opinion (CMS-AO-2005-08-01) that, for purposes of section 1877(a) of the Act, physician-shareholders of a group practice who did not receive any of the purchase

and ownership rights or financial risks and benefits typically associated with stock ownership would not be considered to have an ownership or investment interest in the group practice.

We are now proposing to extend the concept of titular ownership or investment interests to our rules governing ownership or investment interests at §411.354(b). In particular, under proposed §411.354(b)(3)(vi), ownership and investment interests would not include titular ownership or investment interests. Consistent with the FY 2009 IPPS final rule, a “titular ownership or investment interest” would be an interest that excludes the ability or right to receive the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment. As noted in the FY 2009 IPPS final rule, whether an ownership or investment interest is titular is determined by whether the physician has any right to the financial benefits through ownership or investment (73 FR 48694). We believe that proposed §411.354(b)(3)(vi) would afford providers and suppliers with greater flexibility and certainty under our regulations, especially in states where the corporate practice of medicine is prohibited. For the reasons similar to those stated in CMS-AO-2005-08-01, namely that a physician with a titular ownership in an entity does not have a right to the distribution of profits or the proceeds of sale and, therefore, does not have a financial incentive to make referrals to the entity in which the titular ownership or investment interest exists, we believe that our proposed interpretation and revised definition of “ownership or investment interest” does not pose a risk of program or patient abuse.

b. Employee Stock Ownership Program

We stated in the preamble of the 1998 proposed rule that an interest in an entity

arising through a retirement fund constitutes an ownership or investment interest in the entity for purposes of section 1877 of the Act (63 FR 1708). Our interpretation was based on the premise that a retirement interest in an entity creates a financial incentive to make referrals to the entity. In Phase I, we reconsidered the issue and withdrew the statement regarding retirement interests made in the 1998 proposed rule (66 FR 870). As finalized in Phase I, §411.354(b)(3)(i) excluded an interest in a retirement plan from the definition of “ownership or investment interest.” We stated that retirement contributions, including contributions from an employer, would instead be considered to be part of an employee’s overall compensation.

We made no changes to §411.354(b)(3)(i) in Phase II. However, after publishing Phase II, we received a comment stating that, contrary to our intent, some physicians were using their retirement plans to purchase or invest in other entities (that is, entities other than the entity that sponsored the retirement plan) to which the physicians were making referrals for designated health services. We made no changes to §411.354(b)(3)(i) in Phase III, but proposed in the CY 2008 PFS proposed rule to address the potential abuse described by the commenter to Phase II (72 FR 38183). After reviewing the comments received in response to that proposal, in the FY 2009 IPPS final rule, we finalized changes to §411.354(b)(3)(i) that restricted the retirement interest carve-out to an interest in an entity that arises from a retirement plan offered by the entity to the physician (or an immediate family member) through the physician’s (or immediate family member’s) employment with that entity (73 FR 48737 through 48738). Under the current regulation at §411.354(b)(3)(i), if, through his or her employment by Entity A, a physician has an interest in a retirement plan offered by Entity A, any interest the

physician may have in Entity A by virtue of his or her interest in the retirement plan would not be considered to be an ownership or investment interest for purposes of section 1877 of the Act. On the other hand, if the retirement plan sponsored by Entity A purchased or invested in Entity B, the physician would have an interest in Entity B that would not be excluded from the definition of “ownership or investment interest” for purposes of the physician self-referral law. For the physician to make referrals for designated health services to Entity B, the ownership or investment interest in Entity B would have to satisfy the requirements of an applicable exception. We explained in the FY 2009 IPPS final rule that it would pose a risk of program or patient abuse to permit a physician to own another entity that furnishes designated health services (other than the entity which employs the physician) through his or her retirement plan, because the physician could then use the retirement interest carve-out to skirt the prohibitions of the physician self-referral law.

Since we published the 2009 IPPS final rule, stakeholders have informed us that, in certain cases, employers seeking to offer retirement plans to physician employees may find it necessary or practical, for reasons of Federal law, State law, or taxation, to structure a retirement plan using a holding company. By way of example, assume a home health agency desires to sponsor a retirement plan for its employees and elects to establish such plan using a holding company whose primary asset will be the home health agency. To effectuate the retirement plan, the home health agency’s assets are transferred to or purchased by the holding company, which then employs the physicians and other staff of the home health agency. The holding company sponsors the retirement plan for its employees, offering the employees (including physician employees) an

interest in the holding company. Under our current regulations, the physician's interest in the holding company would not be considered an ownership or investment interest under §411.354(b)(3)(i), because the physician is employed by the holding company, the holding company sponsors the retirement plan, and the physician's ownership interest in the holding company arises through the retirement plan sponsored by the holding company. However, because the retirement plan owns the holding company, and the holding company owns the home health agency, the physician has an indirect ownership or investment interest in the home health agency that would not be carved out under §411.354(b)(3)(i) and may not satisfy the requirements of an applicable exception at §411.356.

It is our understanding that a retirement plan structure involving ownership of a holding company and indirect ownership of a legally separate entity furnishing designated health services may be particularly advantageous or necessary in certain circumstances for the establishment of an employee stock ownership plan (ESOP). An ESOP is an individually designed stock bonus plan, which is qualified under Internal Revenue Code (IRC) section 401(a), or a stock bonus and a money purchase plan, both of which are qualified under IRC section 401(a), and which are designed to invest primarily in qualifying employer securities. It is our understanding that ESOPs must be structured to comply with certain safeguards under the Employee Retirement Income Security Act of 1974 (ERISA) (Pub. L. 93-406), including certain nondiscrimination rules and vesting rules that, among other things, do not allow an employee to receive the value of his or her employer stocks held through the retirement plan until at least 1 year after separation from the employer. Given the statutory and regulatory safeguards that exist for ESOPs,

we believe that an interest in an entity arising through participation in an ESOP merits the same protection from the physician self-referral law's prohibitions as an interest in an entity that arises from a retirement plan offered by that entity to the physician through the physician's employment with the entity. We do not believe that excluding from the definition of "ownership or investment interest" an interest in an entity that arises through participation in an ESOP qualified under IRC section 401(a) poses a risk of program or patient abuse, and we are proposing at §411.354(b)(3)(vii) to remove such interests from the definition of "ownership or investment interest" for purposes of section 1877 of the Act. To provide regulatory flexibility in structuring retirement plans, proposed §411.354(b)(3)(vii) is not restricted to an interest in an entity that both employs the physician and sponsors the retirement plan.

To illustrate our proposal, assume that a holding company is owned by its employees, including physician employees, through an ESOP, and that the holding company owns a separate legal entity that furnishes designated health services (an "entity" for purposes of section 1877 of the Act). Under proposed §411.354(b)(3)(vii), for purposes of the physician self-referral law, the physician's interest in the ESOP would not constitute an ownership or investment interest in the holding company or the legally separate entity the holding company owns. As with the current retirement interest carve-out at §411.354(b)(3)(i), employer contributions to the ESOP on behalf of an employed physician would be considered part of the physician's overall compensation and would have to meet the requirements of an applicable exception for compensation arrangements at §411.357.

We are seeking comments on whether the safeguards on ESOPs that are imposed

by ERISA are sufficient for purposes of the physician self-referral to ensure that they do not pose a risk of program or patient abuse and, if not, what additional safeguards we should include to ensure that such interests do not pose a risk of program or patient abuse. To prevent the kind of abuses of retirement plans identified by the commenter on Phase II, we seek comment as to whether it is necessary to restrict the number or scope of entities owned by an ESOP that would not be considered an ownership or investment interest of its physician employees. It is our understanding that an ESOP is designed to invest primarily in “qualifying employer securities,” but the ESOP may also invest in other securities. Further, we seek comment whether the exclusion from the definition of “ownership or investment interest” should apply only to an interest in an entity arising from an interest in “qualifying employer securities” that are offered to a physician as part of an ESOP. We are also seeking comment on whether the proposed revision to §411.354(b)(3)(vii) is necessary; that is, whether existing §411.354(b)(3)(i) affords entities furnishing designated health services sufficient regulatory flexibility to structure nonabusive retirement plans, including ESOPs or other plans that involve holding companies.

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

In the CY 2008 PFS proposed rule (72 FR 38184 through 38186), we proposed an alternative method for satisfying certain requirements of some of the exceptions in §§411.355 through 411.357. We explained that, although we do not have the authority to waive violations of the physician self-referral law, we do have the authority under section 1877(b)(4) of the Act to implement an alternative method for satisfying the requirements of an exception. The proposed method would have required, among other things, that an

entity self-disclose the facts and circumstances of the arrangement at issue and that CMS make a determination that the arrangement satisfied all but the “procedural or ‘form’ requirements” of an exception (72 FR 38185). We cited the signature requirement of the exception for personal service arrangements at §411.357(d)(1) as an example of a procedural or “form” requirement, and explained that the alternative method would not be available for violations of requirements such as compensation that is fair market value, set in advance, and not determined in a manner that takes into account the volume or value of referrals.

In the FY 2009 IPPS final rule, we did not finalize the alternative method proposed in the CY 2008 PFS proposed rule. Instead, relying on our authority under section 1877(b)(4) of the Act, we finalized a rule for temporary noncompliance with signature requirements at §411.353(g) (73 FR 48705 through 48709). As finalized in the FY 2009 IPPS final rule, §411.353(g) applied only to the signature requirement of an applicable exception at §411.357. We declined to extend the special rule for temporary noncompliance to any other procedural or “form” requirement of an exception (73 FR 48706) or to noncompliance arising from “minor payment errors” (73 FR 48703). The special rule at §411.353(g) permitted an entity to submit a bill and receive payment for a designated health service if the compensation arrangement between the referring physician and the entity fully complied with the requirements of an applicable exception at §411.357, except with respect to the signature requirement, and the parties obtained the required signatures within 90 days if the failure to obtain the signatures was inadvertent, or within 30 days if the failure to obtain the signatures was not inadvertent (73 FR 48706). Entities were allowed to use the special rule at §411.353(g) only once every 3

years with respect to the same physician. We stated that we would evaluate our experience with the special rule at §411.353(g) and that we may propose modifications, either more or less restrictive, at a later date (73 FR 48707). Subsequently, in the CY 2016 PFS final rule, we removed the distinction between failures to obtain missing signatures that were inadvertent and not inadvertent, thereby allowing all parties up to 90 days to obtain the missing signatures (80 FR 71333). As discussed in further detail in this section of the proposed rule, in the FY 2019 PFS final rule, we removed the provision limiting the use of the special rule at §411.353(g) to once every 3 years with respect to the same physician (83 FR 59715 through 59717).

In the CY 2016 PFS final rule, we clarified that the writing requirement of various exceptions in §411.357 can be satisfied with a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties (80 FR 71314 through 71317).⁵ A commenter requested that CMS permit a 60- or 90-day grace period for satisfying the writing requirement of an applicable exception, stating that such a grace period is needed for last minute arrangements between physicians and entities to which they refer patient for designated health services (80 FR 71316 through 71317). In response, we noted that the special rule at §411.353(g) applied only to temporary noncompliance with the signature requirement of an applicable exception, and we declined to extend the special rule to the writing requirement of various exceptions at §411.357. We stated our belief that a “grace period” for satisfying the writing requirement poses a risk of program or patient abuse; for example, if the rate of

⁵ Our guidance on the writing requirement was subsequently codified in statute at section 1877(h)(1)(D) of the Act and incorporated into our regulations at §411.354(e). See CY 2019 PFS final rule (83 FR 59715 through 59717).

compensation is not documented before a physician provides services to an entity, the entity could adjust the rate of compensation during the proposed grace period in a manner that takes into account the volume or value of the physician's referrals (80 FR 71317). We added that an entity could not satisfy the "set in advance" requirement at the outset of an arrangement if the only documents stating the compensation term of an arrangement were generated after the arrangement began. Finally, we reminded parties that, even if an arrangement is not sufficiently documented at the outset, depending on the facts and circumstances, contemporaneous documents created during the course of an arrangement may allow parties to satisfy the writing requirement and the "set in advance" requirement for referrals made *after* the contemporaneous documents were created.

Section 50404 of the Bipartisan Budget Act of 2018 (Pub. L. 115-123, enacted February 9, 2018) added provisions to section 1877(h)(1) of the Act pertaining to the writing and signature requirements in certain compensation arrangement exceptions. As amended, section 1877(h)(1)(D) of the Act provides that the writing requirement in various compensation arrangement exceptions "shall be satisfied by such means as determined by the Secretary," including by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. Section 1877(h)(1)(E) of the Act created a statutory special rule for temporary noncompliance with signature requirements, providing that the signature requirement of an applicable compensation arrangement exception shall be satisfied if the arrangement otherwise complies with all the requirements of the exception and the parties obtain the required signatures no later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant. In the CY 2019

PFS final rule, we finalized at §411.354(e) a special rule on compensation arrangements, which codified in our regulations the clarification of the writing requirement found at section 1877(h)(1)(D) of the Act (83 FR 59715 through 59717). In addition, we removed the 3-year limitation on the special rule on temporary noncompliance with signature requirements at §411.353(g)(2) in order to align the regulatory provision at §411.353(g) with section 1877(h)(1)(E) of the Act. We proposed, in the alternative, to delete §411.353(g) in its entirety and to codify section 1877(h)(1)(E) of the Act in the newly created special rules on compensation arrangements at §411.354(e). However, we declined to finalize the alternative proposal in the CY 2019 PFS final rule, because we believed it would be less disruptive to stakeholder compliance efforts to amend the already-existing §411.353(g).

We have reconsidered our policy on temporary noncompliance with the signature and writing requirements of various compensation arrangement exceptions. In our administration of the SRDP, we have reviewed numerous compensation arrangements that fully satisfied all the requirements of an applicable exception, including requirements pertaining to fair market value compensation and the volume or value of referrals, except for the writing or signature requirements. In many cases, there are short periods of noncompliance with the physician self-referral law at the outset of a compensation arrangement, because the parties begin performance under the arrangement before reducing the key terms and conditions of the arrangement to writing. As long as the arrangement otherwise meets all the requirements of an applicable exception, and the parties memorialize the arrangement in writing and sign the written documentation within 90 days, we do not believe that the arrangement poses a risk of program or patient abuse.

Therefore, we believe that entities and physicians should be provided flexibility under our rules to satisfy the writing or signature requirement of an applicable exception within 90 calendar days of the inception of a compensation arrangement.

Relying on our authority at section 1877(h)(1)(D) of the Act, which grants the Secretary the authority to determine the means by which the writing requirement of a compensation arrangement exception may be satisfied, and section 1877(h)(1)(E) of the Act, which establishes a statutory rule for temporary noncompliance with signature requirements, we are proposing to create a special rule for noncompliance with the writing or signature requirement of an applicable compensation arrangement exception. Specifically, we are proposing to delete §411.353(g) in its entirety, codify the statutory rule for noncompliance with signature requirements at section 1877(h)(1)(E) of the Act in a special rule on compensation arrangements at §411.354(e)(3), and incorporate a special rule for noncompliance with the writing requirement into the new special rule at §411.354(e)(3). Under this proposal, the writing requirement or the signature requirement would be deemed to be satisfied if: (1) the compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirement(s); and (2) the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the requirement(s) of the applicable exception. We note that the writing and signature requirements would not be mutually exclusive under the proposal; that is, a party could rely on proposed §411.354(e)(3) if an arrangement was neither in writing nor signed at the outset, provided both the required writing and signature(s) were obtained within 90 days and the arrangement otherwise satisfied all the requirements of an

applicable exception. For arrangements that are 90 days or less, such as short term arrangements as permitted under the exception for fair market value compensation at §411.357(l), if the parties never obtain the required writing or signature(s), the arrangement could never have complied with an exception in §411.357 that includes a writing or signature requirement; therefore, the special rule at §411.354(e)(3) is not available to protect such arrangements. However, depending on the facts and circumstances, the proposed exception for limited remuneration at §411.357(z), which does not include a writing or signature requirement, if finalized, might be available to protect the short term arrangement.

We remind readers that, as we explained in the CY 2016 PFS final rule and subsequently codified at §411.354(e)(2), a single formal written contract is not necessary to satisfy the writing requirement (80 FR 71314 through 71317). Depending on the facts and circumstances, the writing requirement can be satisfied by a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties. In this context, parties may rely on the special rule at §411.354(e)(3) like a safe harbor to be sure that they have met the writing or signature requirements of an applicable exception. The special rule would not be the only way to show compliance with the writing or signature requirements.

The proposal to permit parties up to 90 days to satisfy the writing requirement of an applicable exception does not amend, nor does it affect, the requirement under various exceptions in §411.357 that compensation be set in advance, including the special rule on compensation that is considered to be set in advance at §411.354(d)(1). For an arrangement to be protected by proposed §411.354(e)(3), the amount of or formula for

calculating the compensation must be set in advance and the arrangement must satisfy all other requirements of an applicable exception, other than the writing or signature requirements. Section 1877(h)(1)(D) of the Act provides the Secretary with the authority to determine the means by which the writing requirement of various compensation arrangement exceptions may be satisfied, but it does not provide the Secretary similar authority with respect to the set in advance requirement. Moreover, we believe the “set in advance” requirement is necessary to prevent the amount of compensation paid under an arrangement from fluctuating in a manner that takes into account the volume or value of a physician’s referrals over the course of the arrangement, including the first 90 days.

While we are not proposing to amend the special rule on compensation that is considered to be set in advance at §411.354(d)(1), we are taking this opportunity to reiterate that the special rule is merely a deeming provision (*see* Phase II, 69 FR 16070). That is, while compensation is considered to be set in advance under §411.354(d)(1) if the compensation is “set out in writing before the furnishing of items or services” and the other requirements of §411.354(d)(1) are met, in order to satisfy the “set in advance” requirement included in various exceptions in §411.357, it is not necessary that the parties reduce the compensation to writing before the furnishing of items or services. For example, assume that the parties to an arrangement agree on the rate of compensation before the furnishing of items or services, but do not reduce the compensation rate to writing at that point in time. Assume further that the first payment under the arrangement is documented and that, under proposed §411.354(e)(3), during the 90-day period after the items or services are initially furnished, the parties compile sufficient documentation of the arrangement to satisfy the writing requirement of an applicable exception. Finally,

assume that the written documentation compiled during the 90-day period provides for a rate of compensation that is consistent with the documented amount of the first payment, that is, the rate of compensation did not change during the 90-day period. Under these specific circumstances, we would consider the compensation to be set in advance. More broadly speaking, records of a consistent rate of payment over the course of an arrangement, from the first payment to the last, typically support the inference that the rate of compensation was set in advance. To the extent that our preamble discussion in the CY 2016 PFS final rule suggested that the rate of compensation must be set out in writing before the furnishing of items or services in order to meet the “set in advance” requirement of an applicable exception, we are retracting that statement (80 FR 71317).

We also note that there are many ways in which the amount of or a formula for calculating the compensation under an arrangement can be documented before the furnishing of items or services. It is not necessary that the document stating the amount of or a formula for calculating the compensation, taken by itself, satisfies the writing requirement at §411.354(e)(2); the document stating the amount of or a formula for calculating the compensation may be one document among many which, taken together, constitute a collection of documents sufficient to satisfy the writing requirement at §411.354(e)(2). For example, depending on the facts and circumstances, informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules, or other documents recording similar payments to or from other similarly situated physicians for similar items or services, may be sufficient to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of items or

services. Even if the amount of or a formula for calculating the compensation is not set in advance, depending on the facts and circumstances, the parties may be able to rely on the newly proposed exception for limited remuneration to a physician at §411.357(z), if finalized. If proposed §411.357(z) is finalized, and an entity initially pays a physician for services relying on the exception for limited remuneration to a physician, if the parties subsequently decide to continue the arrangement relying on an exception that requires the compensation to be set in advance, such as the exception for personal services arrangements at §411.357(d)(1), depending on the facts and circumstances, the parties may be able to use documentation of the initial payments made while relying on §411.357(z) to establish that the amount of or a formula for calculating the compensation was set in advance before the furnishing of services under the personal service arrangement.

Finally, we are taking this opportunity to clarify our longstanding policy that an electronic signature that is legally valid under Federal or State law is sufficient to satisfy the signature requirement of various exceptions in our regulations. We also note that the collection of writings that parties may rely on under §411.354(e)(2) to satisfy the writing requirement of our exceptions can include documents and records that are stored electronically. We are soliciting comments on whether we should include specific regulation text at §411.354(e) to reflect our policy on electronic signatures and documents.

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

Section 1877(e)(1) of the Act establishes an exception to the physician self-referral law's referral and billing prohibitions for certain arrangements involving the

rental of office space or equipment. Among other things, sections 1877(e)(1)(A)(ii) and (e)(1)(B)(ii) of the Act require the office space or equipment to be used exclusively by the lessee when being used by the lessee. The exclusive use requirements are incorporated into our regulations at §411.357(a)(3) and (b)(2).

In the 1998 proposed rule, we stated our belief that the exclusive use requirement in the statute was meant to prevent “paper leases,” where payment passes from a lessee to a lessor, even though the lessee is not actually using the office space or equipment (63 FR 1714). In Phase II, we further explained our interpretation of the exclusive use requirement (69 FR 16086). We stated that, after reviewing the statutory scheme, we believe that the purpose of the exclusive use requirement was to ensure that the rented office space or equipment cannot be shared with the lessor when it is being used or rented by the lessee (or any subsequent sublessee). In other words, a lessee (or sublessee) cannot “rent” office space or equipment that the lessor will be using concurrently with, or in lieu of, the lessee (or sublessee). We added that we were concerned that unscrupulous physicians or physicians groups might attempt to skirt the exclusive use requirement by establishing holding companies to act as lessors. To foreclose this possibility, we modified the exclusive use requirements at §411.357(a)(3) and (b)(2), to stipulate that the rented office space or equipment may not be “shared with or used by the lessor or any person or entity related to the lessor” when the lessee is using the office space or equipment.

Disclosures to the SRDP have included several arrangements where multiple lessees use the same rented office space or equipment either contemporaneously or in close succession to one another, while the lessor is excluded from using the premises or

equipment. At least one entity disclosed that it had invited a physician who was not the lessor into its office space to treat a mutual patient for the patient's convenience. The disclosing parties assumed that the arrangements violated the physician self-referral law, because, based on their understanding of the exceptions at §411.357(a) and (b), the arrangements did not satisfy the exclusive use requirement of the applicable exception. As noted in the 1998 proposed rule and in Phase II, the purpose of the exclusive use rule is to prevent sham leases where a lessor "rents" space or equipment to a lessee, but continues to use the space or equipment during the time period ostensibly reserved for the lessee. We do not interpret sections 1877(e)(1)(A)(ii) and (B)(ii) of the Act to prevent multiple lessees from using the rented space or equipment at the same time, so long as the lessor is excluded, nor do we interpret sections 1877(e)(1)(A)(ii) and (B)(ii) of the Act to prohibit a lessee from inviting a party other than the lessor (or any person or entity related to the lessor) to use the office space or equipment rented by the lessee. Moreover, we do not believe it would pose a risk of program or patient abuse for multiple lessees (and their invitees) to use the space or equipment to the exclusion of the lessor, provided that the arrangements satisfy all requirements of the applicable exception for the rental of office space or equipment, and any financial relationships between the lessees (or their invitees) that implicate the physician self-referral law likewise satisfy the requirements of an applicable exception. Therefore, relying on the Secretary's authority under section 1877(b)(4) of the Act, we are proposing to clarify our longstanding policy that the lessor (or any person or entity related to the lessor) is the only party that must be excluded from using the space or equipment under §411.357(a)(3) and 411.357(b)(2). Specifically, we are proposing to add the following clarification to the regulation text: For purposes of

this exception, exclusive use means that the lessee (and any other lessees of the same office space or equipment) uses the office space or equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the office space or the equipment.

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

Section 1877(e)(5) of the Act established an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff. The exception at section 1877(e)(5) of the Act authorizes the Secretary to impose additional requirements on recruitment arrangements as needed to protect against program or patient abuse. The 1995 final rule incorporated the provisions of section 1877(e)(5) of the Act into our regulations at §411.357(e). As finalized in the 1995 final rule, §411.357(e) requires the recruitment arrangement to be in writing and signed by both parties, that is, the recruited physician and the hospital.

In Phase II, we substantially modified §411.357(e). Relying on our authority under section 1877(b)(4) of the Act, we expanded the exception at §411.357(e)(4) to address remuneration from a hospital (or a federally qualified health center (FQHC), which was added as a permissible recruiting entity under Phase II) to a physician who joins a physician practice. There, we established requirements for recruitment arrangements under which remuneration is provided by a hospital or FQHC indirectly to a physician through payments made to his or her physician practice as well as directly to the physician who joins a physician practice (69 FR 16094 through 16095). When

payment is made to a physician indirectly through a physician practice that the recruited physician joins, the practice is permitted to retain actual costs incurred by the practice in recruiting the physician under §411.357(e)(4)(ii), and, in the case of an income guarantee made by the hospital or FQHC to the recruited physician, the practice may also retain the actual additional incremental costs attributable to the recruited physician under §411.357(e)(4)(iii). Under the Phase II regulation, if a recruited physician joined a physician practice, §411.357(e)(4)(i) required the party to whom the payments are directly made (that is, the physician practice that the recruited physician joins) to sign the written recruitment agreement (69 FR 16139).

In Phase III, we responded to a commenter who requested clarification with respect to who must sign the writing documenting the physician recruitment arrangement (72 FR 51012). The commenter's concern was that §411.357(e)(4)(i) could be interpreted to require that the recruiting entity (in the commenter's example, a hospital), the physician practice, and the recruited physician all had to sign one document. The commenter asserted that this would be unnecessary and would add to the transaction costs of the recruitment. The commenter suggested that we require a written agreement between the hospital and either the recruited physician or the physician practice to which the payments would be made or, in the alternative, that we should permit the hospital and the physician practice receiving the payments to sign a written recruitment agreement and require the recruited physician to sign a one-page acknowledgment agreeing to be bound by the terms and conditions set forth in that agreement. We responded that the exception for physician recruitment requires a writing that is signed by all parties, including the recruiting hospital (or FQHC or rural health clinic, which was added as a permissible

recruiting entity under Phase III), the recruited physician, and the physician practice that the physician will be joining, if any, and explained that nothing in the regulations precluded execution of the agreement in counterparts.

We have reconsidered our position regarding the signature requirement at §411.357(e)(4)(i). In the SRDP, we have seen arrangements in which a physician practice that hired a physician who was recruited by a hospital (or FQHC or rural health clinic) did not receive any financial benefit as a result of the hospital and physician's recruitment arrangement. Examples of such arrangements include arrangements under which: (1) the recruited physician joined a physician practice but the hospital paid the recruitment remuneration to the recruited physician directly; (2) remuneration was transferred from the hospital to the physician practice, but the practice passed all of the remuneration from the hospital to the recruited physician (that is, the practice served merely as an intermediary for the hospital's payments to the recruited physician and did not retain any actual costs for recruitment, actual additional incremental costs attributable to the recruited physician, or any other remuneration); and (3) the recruited physician joined the physician practice after the period of the income guarantee but before the physician's "community service" repayment obligation was completed. In each of the arrangements disclosed to the SRDP, the arrangement was determined by the disclosing party not to satisfy the requirements of the exception at §411.357(e) solely because the physician practice that the recruited physician joined had not signed the writing evidencing the arrangement. We do not believe, however, that, under the circumstances described by parties disclosing to the SRDP, there exists a compensation arrangement between the physician practice and the hospital (or FQHC or rural health clinic) of the

type against which the statute is intended to protect; that is, the type of financial self-interest that impacts a physician's medical decision making. Because the physician practice is not receiving a financial benefit from the recruitment arrangement, we do not believe it is necessary for the physician practice to also sign the writing documenting the recruitment arrangement between the recruited physician and the hospital (or FQHC or rural health clinic) in order to protect against program or patient abuse. We also believe that eliminating the signature requirement for a physician practice that receives no financial benefit under the recruitment arrangement would reduce undue burden without posing a risk of program and patient abuse. For these reasons, we are proposing to modify the signature requirement at §411.357(e)(4)(i). We are proposing to require the physician practice to sign the writing documenting the recruitment arrangement, if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

8. Exception for Remuneration Unrelated to the Provision of Designated Health Services (§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 designated health services. The statutory exception is codified in our regulations at §411.357(g). Our prior rulemaking regarding §411.357(g) has been based in part on an interpretation of the legislative history of section 1877(e)(4) of the Act. In order to explain the changes we are currently proposing to §411.357(g), it is necessary to examine the legislative history

of section 1877(e)(4) of the Act and certain provisions that preceded it.

As originally enacted by OBRA 1989, the referral and billing prohibitions of the physician self-referral law applied only to clinical laboratory services. OBRA 1989 created three general exceptions for both ownership and compensation arrangements at sections 1877(b)(1) through (3) of the Act, and granted the Secretary the authority at section 1877(b)(4) of the Act to create additional exceptions. Section 42017(e) of OBRA 1990 (Pub. L. 101-508) redesignated section 1877(b)(4) as 1877(b)(5) of the Act, and added an exception at section 1877(b)(4) of the Act for financial relationships with hospitals that are unrelated to the provision of clinical laboratory services. (To avoid confusion between the exception added by OBRA 1990 at section 1877(b)(4) of the Act and section 1877(b)(4) of the Act as it currently exists, the exception for financial relationships unrelated to the provision of clinical laboratory services enacted by OBRA 1990 is referred to herein as the “OBRA 1990 exception.”) The OBRA 1990 exception applied to both ownership or investment interests and compensation arrangements, and excepted financial relationships between physicians (or immediate family members of physicians) and hospitals that did not relate to the provision of clinical laboratory services. OBRA 1993 eliminated the OBRA 1990 exception, but the Social Security Act Amendments of 1994 (Pub. L. 103-432) (SSA 1994) reinstated the exception through January 1, 1995.

In place of the OBRA 1990 exception, OBRA 1993 added a new exception at section 1877(e)(4) of the Act. Under section 1877(e)(4) of the Act, remuneration provided by a hospital to a physician that does not relate to the provision of designated health services is not considered a compensation arrangement for purposes of the referral

and billing prohibitions. Although there are certain similarities between section 1877(e)(4) of the Act and the OBRA 1990 exception, the exception at section 1877(e)(4) of the Act is narrower than the OBRA 1990 exception in several important respects: (1) the OBRA 1990 exception excepts both ownership interests and compensation arrangements between hospitals and physicians, whereas section 1877(e)(4) of the Act applies only to compensation arrangements under which remuneration passes from the hospital to the physician; (2) the OBRA 1990 exception protects a broad range of financial relationships that are unrelated to the provision of clinical laboratory services, whereas section 1877(e)(4) of the Act has a narrower application, applying only to remuneration unrelated to the provision of designated health services; and (3) the OBRA 1990 exception applies to financial relationships between entities and physicians or their immediate family members, whereas section 1877(e)(4) of the Act applies only to compensation arrangements with physicians.

In the 1998 proposed rule, we proposed to revise our regulation at §411.357(g) to reflect our interpretation of section 1877(e)(4) of the Act (63 FR 1702). (The prior regulation at §411.357(g) was based on former sections 1877(b)(4) and (e)(4) of the Act as they were effective on January 1, 1992 (63 FR 1669).) We stated that, for remuneration from a hospital to a physician to be excepted under §411.357(g), the remuneration must be “completely unrelated” to the furnishing of designated health services. We clarified that the remuneration could not in any direct or indirect way involve designated health services, and further that the exception would not apply in any situation involving remuneration that might have a nexus with the provision of, or referrals for, a designated health service (63 FR 1702). We further stated that the

remuneration could in no way reflect the volume or value of a physician's referrals, and that payments to physicians that were "inordinately high" or above fair market value would be presumed to be related to the furnishing of designated health services. We provided the following examples of remuneration that might be completely unrelated to the furnishing of designated health services and excepted under §411.357(g): (1) fair market value 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; and (2) compensation for teaching, general utilization review, or administrative services.

In Phase II, we finalized the exception at §411.357(g) with modifications (69 FR 16093 through 16094). As finalized, in addition to requiring that the remuneration does not in any way take into account the volume or value of the physician's referrals, §411.357(g) requires that the remuneration is wholly unrelated (that is, neither directly nor indirectly related) to the furnishing of designated health services. The regulation stipulates that remuneration relates to the furnishing of designated health services if it: (1) is an item, service, or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles; (2) is furnished, directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals; or (3) otherwise takes into account the volume or value of referrals or other business generated by the referring physician. We stated that we incorporated cost reporting principles in the regulation in order to provide the industry with bright-line rules to determine whether remuneration is related to the furnishing of designated health services (69 FR 16093). At the same time, we retracted the statement from the 1998 proposed rule that general utilization review or

administrative services might not be related to the furnishing of designated health services. We justified our narrow interpretation of section 1877(e)(4) of the Act on the legislative history of the exception, noting that, initially, under the original statute, the exception was necessary to insulate a hospital's relationships with physicians that were unrelated to the provision of clinical laboratory services, a very small element of a hospital's practice. We continued that, since 1995, however, all hospital services are designated health services and a narrower interpretation of the exception is required to prevent abuse (69 FR 16093). We have made no changes to §411.357(g) since Phase II. Commenters on Phase II stated that the Congress intended hospitals to be able to provide any amount of remuneration to physicians, provided that the remuneration did not *directly* relate to designated health services. In Phase III, based on our interpretation of the legislative history at that time, we reaffirmed our narrow interpretation of section 1877(e)(4) of the Act (72 FR 51056).

Based on our review of the statutory history of the OBRA 1990 exception and section 1877(e)(4) of the Act, and comments we received on our CMS RFI, we are proposing certain modifications to the exception at §411.357(g) to broaden the application of the exception. As a preliminary matter, we agree with the statement in Phase II that the exception at section 1877(e)(4) of the Act is significantly narrower than the OBRA 1990 exception. There are many financial relationships between hospitals and physicians that would be permissible under the OBRA 1990 exception because they do not relate, directly or indirectly, to the provision of clinical laboratory services. On the other hand, insofar as the exception at section 1877(e)(4) of the Act requires the remuneration to be unrelated to the provision of designated health services, and OBRA

1993 defines this term to include inpatient and outpatient services, the scope of protected compensation arrangements under section 1877(e)(4) of the Act is much narrower than that of the OBRA 1990 exception. Generally speaking, most financial relationships between hospitals and physicians relate to the furnishing of designated health services, in particular, inpatient or outpatient hospital services. That being said, we must also consider that OBRA 1993 did not merely strike the term “clinical laboratory services” in the OBRA 1990 exception and substitute the term “designated health services.” Rather, OBRA 1993 eliminated the OBRA 1990 exception and created a new (albeit somewhat similar) exception at section 1877(e)(4) of the Act. In light of this statutory history, we believe that the most accurate interpretation of section 1877(e)(4) of the Act is not as a carryover of the 1990 OBRA exception into the significantly revised statutory regime established by OBRA 1993. Rather, we believe that section 1877(e)(4) of the Act should be interpreted as a new exception that was intentionally created by the Congress in OBRA 1993, the very same legislation in which the Congress expanded the referral and billing prohibition of the physician self-referral law to inpatient and outpatient hospital services. In creating a new exception for remuneration unrelated to the provision of designated health services *and* expanding the definition of “designated health services” to include inpatient and outpatient hospital services, we believe that the Congress intended the exception to apply to a narrow—but not empty—subset of compensation arrangements between hospitals and physicians.

According to commenters that responded to the CMS RFI, current §411.357(g) has an extremely limited application. Several commenters stated that it is not clear what remuneration, if any, is permissible under the exception, if the exception does not apply

to any item, cost, or service that could be allocated to Medicare or Medicaid under cost reporting principles, or to remuneration that is offered in any preferential or selective manner whatsoever. After reconsidering the matter, we agree with the commenters that the current exception is too restrictive.

To give appropriate meaning to the statutory exception at section 1877(e)(4) of the Act, we are proposing to delete the current provisions at §411.357(g)(1) and (2) in their entirety and to remove the phrase “directly or indirectly” from the regulation text. In place of existing §411.357(g)(1) and (2), we are proposing language that incorporates the concept of patient care services as the touchstone for determining when remuneration for an item or service is related to the provision of designated health services. In particular, we are proposing regulation text to clarify that remuneration from a hospital to a physician does not relate to the provision of designated health services if the remuneration is for items or services that are not related to patient care services. Section 1877(e)(4) of the Act specifically excepts remuneration unrelated to the *provision* of designated health services. For purposes of applying the exception at section §411.357(g), we are interpreting section 1877(e)(4) of the Act to except remuneration unrelated to the act or process of providing designated health services, a concept which is not as all-encompassing as remuneration that is unrelated in any manner whatsoever to designated health services. We believe that patient care services provided by a physician, when the physician is acting in his or her capacity as a medical professional, are integrally related to the act or process of providing designated health services, regardless of whether such services are provided to patients of the hospital; thus, payment for such services relates to the provision of designated health services. Likewise, we believe that

items that are used in the act or process of furnishing patient care services are integrally related to the provision of designated health services, and payments for such items relate to the provision of designated health services. On the other hand, we believe that remuneration from a hospital to a physician for services that are not patient care services or items that are not used in the act or process of providing designated health services does not relate to the *provision* of designated health services and would, therefore, not be prohibited under section 1877(e)(4) of the Act or our regulations at proposed §411.357(g) (provided that the remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals).

We believe that the concept of patient care services, as further specified in the proposed regulation text and as explained in this section of the proposed rule, provides a determinant and practicable principle for applying §411.357(g) to compensation arrangements between hospitals and physicians. We note that the proposed regulation at §411.357(g) retains the requirement that the remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals. Remuneration that is determined in a manner that takes into account the volume or value of a physician's referrals clearly relates to the provision of designated health services, regardless of the nature of the item or service for which the physician receives remuneration. Thus, the proposed provisions at §411.357(g)(2) and (g)(3), which are intended to clarify when remuneration does not relate to the provision of designated health services, do not apply to any remuneration that is determined in a manner that takes into account the volume or value of a physician's referrals.

We believe that remuneration from a hospital to a physician that pertains to the

physician's patient care services is the paradigm of remuneration that relates to the provision of designated health services. Most obviously, when a physician provides patient care services to hospital patients, the physician's patient care services are directly correlated with the provision of designated health services. Thus, remuneration from the hospital to the physician for such services is clearly related to designated health services. However, there does not have to be a direct one-to-one correlation between a physician's services and the provision of designated health services in order for payments for the service to be related to the provision designated health services. For example, payment for emergency department call coverage relates to the furnishing of designated health services, even if the physician is not as a matter of fact called to the hospital to provide patient care services, because the hospital is paying the physician to be available to provide patient care services at the hospital. Similarly, medical director services typically include, among other things, establishing clinical pathways and overseeing the provision of designated health services in a hospital. It is our policy that payments for such services are related to the furnishing of designated health services for purposes of applying the exception at proposed §411.357(g). We also believe that utilization review services are closely related to patient care services, and for this reason, we consider remuneration for such services to be related to the furnishing of designated health services.

In contrast to the services described above, we do not believe that the administrative services of a physician pertaining solely to the business operations of a hospital relate to patient care services. Thus, if a physician is a member of a governing board along with persons who are not licensed medical professionals, and the physician

receives stipends or meals that are available to the other board members, it is our policy that this remuneration would not relate to the provision of designated health services under proposed §411.357(g), provided the physician's compensation for the administrative services is not determined in a manner that takes into account the volume or value of his or her referrals. In this instance, we believe that the dispositive factor in determining that a physician's services are not related to the provision of designated health services is that the services are also provided by persons who are not licensed medical professionals, and the physician is compensated on the same terms and conditions as the non-medical professionals. Insofar as services may be provided by persons who are not licensed medical professionals, we do not believe that they are patient care services. To provide clarity for stakeholders, we are proposing a general principle at §411.357(g)(3) for determining when remuneration for a particular service, when provided by a physician, is related to the provision of designated health services. We believe that, if a service can be provided legally by a person who is not a licensed medical professional and the service is of the type that is typically provided by such persons, then payment for such a service is unrelated to the provision of designated health services and may be protected under proposed §411.357(g), provided that it is not determined in a manner that takes into account the volume or value of the physician's referrals. We note in this context that "licensed medical professional" includes, but is not limited to, a licensed physician. That is, if a service can be provided legally by both a physician and a medical professional who is not a physician, such as a registered nurse, but the service cannot be provided by a person who is not a licensed medical professional, it is still considered to be a patient care service for purposes of

§411.357(g)(3). Thus, remuneration provided by a hospital to a physician for the service would not be excepted under proposed §411.357(g), notwithstanding the fact that the service does not have to be performed by a *physician*.

With respect to remuneration from a hospital for items provided by a physician, typical examples of remuneration that is related to the provision of designated health services include rental of medical equipment and purchasing of medical devices from physicians. Because these items are used in the provision of patient care services, and the patient care services may be designated health services or be directly correlated with the provision of designated health services, remuneration for such items clearly relates to the provision of designated health services. We also believe that rental of office space where patient care services are provided, including patient services that are not necessarily designated health services, is remuneration related to the provision of designated health services. However, if a physician who joins another practice sells the furniture from his or her medical office to a hospital, and the hospital places the furniture in the hospital's facilities, as long as the payment is not determined in a manner that takes into account the physician's referrals, we do not believe that the remuneration is related to the provision of designated health services. Also, we continue to believe that, as first stated in the 1998 proposed rule, §411.357(g) (including proposed §411.357(g)) 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. To provide stakeholders with greater clarity, we are proposing to stipulate in regulation that remuneration provided in exchange for any item, supply, device, equipment, or office space that is used in the diagnosis or treatment of patients, or any technology that is used to communicate with

patients regarding patient care services, is presumed to be related to the provision of designated health services for purposes of §411.357(g).

We believe that proposed §411.357(g)(2) and (3) provide clarity regarding when payments for items and services relate to the provision of designated health services, and also give the meaning to the statutory exception. We believe that the requirement pertaining to the volume or value of a physician's referrals at §411.357(g)(1) will ensure that payments to a physician for items or services that are ostensibly not related to patient care services are not in fact disguised payments for the physician's referrals. We seek comments on our proposals, as well as other possible ways for distinguishing between remuneration that is related to the provision of designated health services and remuneration that is unrelated to the provision of designated health services. Specifically, we seek comment as to whether we should limit what we consider to be "remuneration related to the provision of designated health services" to remuneration paid explicitly for a physician's provision of designated health services to a 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 the provision of clinical laboratory services, or to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value. The 1995 final rule (60 FR 41929) incorporated the provisions of section 1877(e)(8) of the Act into our regulations at §411.357(i). In the 1998 proposed rule, we proposed to interpret "other items and services" to mean any kind of item or service that a physician might purchase (that is, not limited to "services" for

purposes of the Medicare program in §400.202 of this Chapter), but not including clinical laboratory services or those items or services that are specifically excepted by another provision in §§411.355 through 411.357 (63 FR 1703). We stated that we did not believe that the Congress meant the exception for payments by a physician to protect financial relationships that were covered by more specific exceptions with specific requirements, such as the exceptions for rental arrangements at section 1877(e)(1) of the Act.

In Phase II, we responded to commenters who disagreed with our position that the exception for payments by a physician is not available for arrangements involving any items or services excepted by another exception (69 FR 16099). We reiterated the statutory interpretation from the 1998 proposed rule, explaining that the determination that items and services addressed by another exception should not be covered in this exception is consistent with the overall statutory scheme and purpose and is necessary to prevent the exception for payments by a physician from negating the statute (69 FR 16099; *see also* 72 FR 51057). As a result, we made no changes to the regulation at §411.357(i) in Phase II. Thus, as finalized in Phase II, the exception for payments by a physician at §411.357(i) stated that the exception could not be used for items or services that are specifically *excepted* by another exception in §§411.355 through 411.357, with a parenthetical clarifying that this included the exception for fair market value compensation at §411.357(l). However, at that time, the exception for fair market value compensation applied only to the provision of items or services *by* physicians *to* entities; the exception did not apply to items or services provided by entities to physicians.

Following the publication of Phase II, commenters complained that neither §411.357(i) nor §411.357(l) were available to protect many legitimate arrangements

wherein physicians purchased items and services from entities, because: (1) the exception for payments by a physician was limited to the purchase of items and services not specifically excepted by another exception in §§411.355 through 411.357 (including §411.357(l)); and (2) the exception for fair market value compensation did not apply to items or services provided by an entity to a physician (72 FR 51057). In response to the commenters, we expanded §411.357(l) in Phase III to include both items and services furnished by physicians to entities *and* items and services furnished by entities to physicians (72 FR 51094 through 51095). However, Phase III did not modify the exception for payments by a physician,⁶ including the parenthetical indicating that §411.357(i) could not be used for items or services specifically excepted under §411.357(l). We acknowledged that the expansion of the exception for fair market value compensation to items or services furnished by entities to physicians would require parties in some instances to rely on §411.357(l) instead of §411.357(i). We concluded, however, that upon further consideration, we believe that the required application of the fair market value compensation exception, which contains conditions not found in the less transparent exception for payments by a physician to a hospital, further reduces the risk of program abuse (72 FR 51057). We also emphasized in Phase III that the exception for payments by a physician could not be used to protect office space leases (72 FR 51044 through 51045). We explained that we did not believe that the lease of office space is an “item or service” and that parties seeking to protect arrangements for

⁶ In the September 5, 2007 **Federal Register**, the regulation text of the exception for payments by a physician was modified in error. Phase II stated that §411.357(i) is limited to payments for items or services that are “not specifically excepted by another provision in §§411.355 through 411.357” (69 FR 16140). The September 5, 2007 **Federal Register** replaced “excepted” with “addressed” (72 FR 51094). The original language of the exception was restored in a correction notice to Phase III and published in the December 4, 2007 **Federal Register** (72 FR 68076).

the rental of office space must rely on §411.357(a) (72 FR 51059). In 2015, when we finalized the exception at §411.357(y) for timeshare arrangements, we reaffirmed our position that the exception for payments by a physician is not available for arrangements involving the rental of office space (80 FR 71325 through 71327).

Commenters on the CMS RFI stated that our interpretation of the exception for payments by a physician, especially our determination that the exception is not available if any other exception would apply to an arrangement, unreasonably narrowed the scope of the statutory exception. Commenters also noted that compliance with other exceptions is generally more burdensome than compliance with the statutory exception for payments by a physician, and urged us to conform the language of the exception at §411.357(i) to the statutory language at section 1877(e)(8) of the Act. We find the CMS RFI comments regarding the narrowing of the statutory exception persuasive and, as a result, have reconsidered our position regarding the availability of the exception for payments by a physician for certain compensation arrangements.

To explain the policies we set forth in this proposed rule regarding the availability of the exception at §411.357(i), it is important to distinguish between the statutory exceptions found at section 1877(e) of the Act (codified at §411.357(a) through §411.357(i) of our regulations) and the regulatory exceptions (codified at §411.357(j) *et seq.*) issued using the Secretary's authority under section 1877(b)(4) of the Act.⁷ We

⁷ Section 1877(b)(5) of the Act directs the Secretary to establish a regulatory exception for electronic prescribing, but does not provide any statutory text or specific requirements for the exception. Pursuant to this authority, we established an exception for electronic prescribing items and services at §411.357(v). Although §411.357(v), unlike all the other exceptions at §411.357(j) *et seq.*, was not issued using the Secretary's authority under section 1877(b)(4) of the Act, for purposes of our interpretation of the exception for payments by a physician, we treat §411.357(v) as a regulatory exception. In particular, we interpret section 1877(b)(5) of the Act as a grant of authority for the Secretary to issue a regulatory

continue to believe that the exception for payments by a physician at section 1877(e)(8) of the Act was not meant to apply to compensation arrangements that are specifically excepted by other *statutory* exceptions in section 1877 of the Act. Given the placement of the exception for payments by a physician as the final statutory exception at section 1877(e) of the Act, we believe that this exception functions as a catch-all to protect certain legitimate arrangements that are not covered by the exceptions at sections 1877(e)(1) through (7) of the Act. As a matter of statutory construction, the catch-all exception at section 1877(e)(8) of the Act does not supersede the previous exceptions. With respect to arrangements for the rental of office space or the rental of equipment, in particular, we note that the statutory exceptions for such arrangements at section 1877(e)(1) of the Act include requirements that are specific to rental arrangements, as well as general requirements that the arrangements are commercially reasonable, that rental charges are fair market value, and that compensation is not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. We do not believe that the Congress would have imposed these particularized requirements at section 1877(e)(1) of the Act, but also allowed parties to sidestep them by relying on the exception for payments by a physician to protect rental arrangements.

Although we maintain our policy with respect to the statutory exceptions, we no longer believe that the regulatory exceptions should limit the scope of the exception for payments by a physician. Thus, we are proposing to remove from §411.357(i)(2) the

exception; it is not itself a statutory exception, just as section 1877(b)(4) of the Act grants the Secretary authority to create exceptions, but is not an exception in its own right.

reference to the regulatory exceptions, including the parenthetical referencing the exception for fair market value compensation. We are also proposing that the exception at §411.357(i) would not be available to protect compensation arrangements specifically addressed by one of the statutory exceptions, codified in our regulations at §411.357(a) through (h). Under the proposal, parties would generally be able to rely on the exception at §411.357(i) to protect fair market value payments by a physician to an entity for items or services furnished by the entity, even if a regulatory exception at §411.357(j) *et seq.* may be applicable. However, for the reasons noted previously, §411.357(i) would not be applicable to arrangements for the rental of office space or equipment.⁸ That is, we believe that, as a matter of statutory construction, the exception for payments by a physician is not available to protect any type of arrangement that is specifically addressed by another statutory exception at section 1877(e) of the Act, including arrangements for the rental of office space or the rental of equipment.

We are retracting our prior statements that office space is neither an “item” nor a “service.” We made these statements, in significant part, to emphasize that we do not believe that the exception for payments by a physician should be available to protect the type of arrangement for which the Congress established a specific exception in statute. In this proposed rule, we have more clearly explained this position and no longer believe it is necessary to preclude office space from the categories of “items” and “services.” (We note that we have not made prior similar statements regarding equipment.) As such, and because the exception at §411.357(i) is unavailable to protect an arrangement for the

⁸ Elsewhere in this proposed rule, we are proposing to extend §411.357(l) to arrangements for the rental of office space, including rentals of less than 1 year, provided all the requirements of the proposed exception are satisfied.

rental of office space or equipment, parties seeking to protect an arrangement for the rental of office space or equipment must structure the arrangement to satisfy the requirements of §411.357(a), §411.357(b), §411.357(l) (for direct compensation arrangements), or §411.357(p) (for indirect compensation arrangements). We note that, under our proposal, §411.357(i) may be available to protect payments by a physician for the lease or use of space that is *not* office space, such as storage space or residential real estate.

We are also proposing to remove from §411.357(i)(2) the reference to exceptions in §§411.355 and 411.356. As noted previously, we believe that the exception at section 1877(e)(8) of the Act for payments by a physician functions in the statutory scheme as a catch-all, to apply to compensation arrangements for the furnishing of other items or services by entities that are not specifically addressed at sections 1877(e)(1) through (7) of the Act. Therefore, we no longer believe that the exception should be limited by the exceptions at sections 1877(b) and (c) of the Act or the regulatory exceptions codified in §§411.355 and 411.356.

Lastly, we would like to stress that the “items or services” furnished by the entity under the exception for payments by a physician may not include cash or cash equivalents. That is, the physician may not make in-kind “payments” to the entity in exchange for cash from the entity. We believe that cash provided by an entity to a physician poses a risk of program or patient abuse, and that the Congress would have included additional safeguards at section 1877(e)(8) of the Act if the exception were designed to cover such arrangements. At the same time, we note that, if a physician pays an entity \$10 in cash for a gift card worth \$10, we do not believe that this would

constitute a financial relationship for purposes of the physician self-referral law.

Likewise, in cases where a physician or an entity acts as a pure pass-through, taking money from one party and passing the *exact* same amount of money to another party, we do not believe that the pass-through arrangement is a financial relationship for purposes of the physician self-referral law.

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

In the 1998 proposed rule, we proposed an exception at §411.357(l) for fair market value compensation (63 FR 1699). We noted that the statutory exceptions at section 1877(e) of the Act apply to specific categories of financial relationships and do not address many common and legitimate compensation arrangements between physicians and the entities to which they refer designated health services. The exception for fair market value compensation was proposed as an open-ended exception to protect certain compensation arrangements that may not be specifically addressed in the statutory exceptions. Among other things, we stated that the exception might be used to protect arrangements for the sublease of office space (63 FR 1714). We suggested that parties could use the exception for fair market value compensation if they had any doubts about whether they met the requirements of another exception in §411.357.

In Phase I, we finalized §411.357(l), stating that parties could use the exception, even if another exception potentially applied to an arrangement (66 FR 919). We explained our belief that the safeguards incorporated into the exception for fair market value compensation were sufficient to cover various compensation arrangements, including arrangements covered by other exceptions. In Phase II, we responded to commenters who requested that the exception at §411.357(l) be made available to protect

arrangements for the rental of office space, including arrangements where space is rented *by* entities *to* physicians (69 FR 16111). We declined to extend §411.357(l) to arrangements for the rental of office space, and emphasized that §411.357(l) applied only to payments *from* an entity *to* a physician for items and services furnished by the physician. We modified our policy in Phase III and extended the application of the exception at §411.357(l) to payments *from* a physician *to* an entity for items or services provided by the entity, but continued to decline to make §411.357(l) applicable to an arrangement for the rental of office space (72 FR 51059 through 51060). As noted previously, we explained that the rental of office space is not an “item or service.” We added that, because arrangements for the rental of office space had been subject to abuse, we believed that it could pose a risk of program or patient abuse to permit parties to protect such arrangements relying on §411.357(l). In the CY 2016 PFS final rule, we reaffirmed our position that the exception for fair market value compensation does not apply to arrangements for the rental of office space (80 FR 71327).

We have reconsidered our policy regarding the application of §411.357(l). Through our administration of the SRDP, we have seen legitimate, nonabusive arrangements for the rental of office space that could not satisfy the requirements of §411.357(a) because the term of the arrangement was less than 1 year, and could not satisfy the requirements of §411.357(y) because the arrangement conveyed a possessory leasehold interest in the office space. To provide flexibility to stakeholders to protect such nonabusive arrangements, we are proposing to make §411.357(l) available to protect arrangements for the rental or lease of office space.

As discussed in many of our previous rulemakings and most recently in the CY

2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534), we are concerned about potential abuse that may arise when rental charges for the lease of office space or equipment are determined using a formula based on: (1) a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space (a “percentage-based compensation formula”); or (2) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee (a “per-click compensation formula”). We stated that arrangements based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize overutilization and patient steering. To address this risk, in the FY 2009 IPPS final rule, we included in the exceptions for the rental of office space, the rental of equipment, fair market value compensation, and indirect compensation arrangements restrictions on percentage-based compensation and per-click compensation formulas when determining the rental charges for the lease of equipment. Because the exception at §411.357(l), to date, has not been applicable to arrangements for the rental of office space, it does not include a prohibition on percentage-based compensation and per-click compensation formulas when determining the rental charges for the lease of office space. (The exceptions for the rental of office space and indirect compensation arrangements currently include the prohibitions as they relate to the determination of rental charges for the lease of office space.) We remain concerned about the potential abuse related to percentage-based compensation and per-click compensation formulas for determining the rental charges of both office space and equipment. Therefore, we are proposing to incorporate into the exception at

§411.357(l) prohibitions on percentage-based compensation and per-unit of service compensation formulas with respect to the determination of rental charges for the lease of office space, similar to the restrictions found in §411.357(a)(5)(ii) and §411.357(p)(1)(ii).

Unlike the exception for the rental of office space at §411.357(a), the exception for fair market value compensation does not require a 1-year term. Therefore, short-term arrangements for the rental of office space of less than 1 year would be permissible under the proposed exception. However, as with other compensation arrangements permitted under §411.357(l), the parties would be permitted to enter into only one arrangement for the rental of the same office space during the course of a year. The parties would be able to renew the arrangement on the same terms and conditions any number of times, provided that the terms of the arrangement and the compensation for the same office space do not change. Although we believe that, in most cases, parties seeking to lease office space prefer leases with longer terms—for instance, to justify expenses spent on property improvements—as described by commenters, some parties, especially parties in rural areas, would prefer or find necessary the flexibility of a short-term rental of office space. Given the requirements of the exception for fair market value compensation, including the requirement that parties enter into only one arrangement for the leased office space over the course of a year, we do not believe that short-term arrangements for the rental of office space that satisfy all the requirements of §411.357(l) pose a risk of program or patient abuse. We remind readers that, as explained in section II.D.9 of this proposed rule, the exception for payments by a physician at §411.357(i) is not available to protect any leases of office space, including short-term leases.

Lastly, §411.357(l)(6) requires that any services to be performed under the

arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law. As explained in section II.D.1. of this rule, we are proposing to remove from our exceptions the requirements pertaining to the anti-kickback statute and Federal or State billing and claims submission rules. Although similar, at this time, we are not proposing to remove §411.357(l)(6). However, we are soliciting comments on whether this requirement is necessary to protect against program or patient abuse or should be removed from the exception, and whether substitute safeguards such as those included in many of the statutory or regulatory exceptions to the physician self-referral law would be appropriate.

11. Electronic Health Records Items and Services (§411.357(w))

Relying on our authority at section 1877(b)(4) of the Act, on August 8, 2006, we published a final rule (the 2006 EHR final rule) that, among other things, finalized an exception at §411.357(w) for certain arrangements involving the donation of interoperable EHR software or information technology and training services (the EHR exception) (71 FR 45140). The EHR exception was initially scheduled to expire on December 31, 2013. On December 27, 2013, we published a final rule (the 2013 EHR final rule) modifying the EHR exception by, among other things, extending the expiration date of the exception to December 31, 2021, excluding laboratory companies from the types of entities that may donate EHR items and services under the exception, and updating the provision under which EHR software is deemed interoperable (78 FR 78751).

Although we did not specifically request comments on the EHR exception in the CMS RFI, we received several comments on the exception. In addition, in its request for

information, OIG requested comments on the anti-kickback statute EHR safe harbor at 42 CFR 1001.952(y), which is substantively similar to the EHR exception at §411.357(w). After reviewing comments submitted on the EHR exception and safe harbor, as well as recent statutory and regulatory developments arising from the 21st Century Cures Act (Pub. L. 114-255 (December 13, 2016)) (Cures Act), we are proposing to update provisions in the EHR exception pertaining to interoperability (§411.357(w)(2)) and data lock-in (§411.357(w)(3)), clarify that donations of certain cybersecurity software and services are permitted under the EHR exception, remove the sunset provision, and modify the definitions of “electronic health record” and “interoperable” to ensure consistency with the Cures Act. We are also proposing to modify the 15 percent physician contribution requirement and to permit certain donations of replacement technology.

This proposed rule sets forth certain proposed changes to the EHR exception. The OIG is considering changes to the EHR safe harbor elsewhere in this issue of the **Federal Register**. We seek comment on our proposals and, as noted above, given the close nexus between our proposals and OIG’s proposals, we encourage stakeholders to review and submit comments on both proposed rules. Despite the differences in the respective underlying statutes, we attempted to ensure as much consistency as possible between our proposed changes to the EHR exception and the policies that OIG is considering with respect to its safe harbor. Because of the close nexus between this proposed rule and OIG’s proposed rule, we may consider comments submitted in response to OIG’s proposed rule, even if we do not receive such comments on our proposals, and take additional actions when crafting our final rule.

a. Interoperability

The requirements at §411.357(w)(2) and (3) require donated items and services to be interoperable and prohibit the donor (or someone on the donor’s behalf) from taking action to limit the interoperability of the donated item or service. We are proposing changes that impact §411.357(w)(2) and (3) based on the Cures Act and the Office of the National Coordinator for Health Information Technology (ONC), HHS Notice of Proposed Rulemaking, “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” (ONC NPRM), which proposes to implement key provisions in Title IV of the Cures Act.⁹ Among other things, the ONC NPRM proposes conditions and maintenance of certification requirements for health IT developers under the ONC Health IT Certification Program (certification program) and reasonable and necessary activities that do not constitute information blocking for purposes of section 3022(a)(1) of the Public Health Service Act (PHSA). These proposed changes, if finalized, would affect the deeming provision pertaining to interoperability at §411.357(w)(2) and provisions related to interoperability and data lock-in at §411.357(w)(3).

(1) The “Deeming Provision” (§411.357(w)(2))

Section 411.357(w)(2) requires software donated under the EHR exception to be interoperable. The deeming provision at §411.357(w)(2) provides certainty to parties seeking protection of the EHR exception by providing an optional method of ensuring that donated items or services meet the interoperability requirement at §411.357(w)(2). Specifically, §411.357(w)(2) provides that software is deemed to be interoperable if it is

⁹ 84 FR 7424 (March 4, 2019).

certified under ONC’s certification program. In the 2013 EHR final rule, we modified the deeming provision to reflect developments in the ONC certification program and to track ONC’s anticipated regulatory cycle. By relying on ONC’s certification program and related updates of criteria and standards, we stated that the deeming provision would meet our objective of ensuring that software is certified to the current required standard of interoperability when it is donated (78 FR 78753). We are proposing to retain this general construct for the proposed updated EHR exception. However, we are proposing two textual clarifications to this provision. Our current regulation text specifies that the software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170. We are proposing to modify this language to clarify that, on the date the software is provided, it “is” certified. In other words, the certification must be current as of the date of the donation, as opposed to the software having been certified at some point in the past but no longer maintaining certification on the date of the donation. We also propose to remove the reference to “an edition” of certification criteria to align with proposed changes to ONC’s certification program. We solicit comments on these clarifications.

As we describe in more detail below, however, we are proposing to update the definition of “interoperable.” Although the revised definition would not require a change to the text of paragraph (w)(2), the revision would impact the deeming provision, and we solicit comments regarding this update. We emphasize that any final revisions to the deeming provisions or the definition of “interoperable” would be prospective only. That is, donated software that met the definition of interoperable and satisfied the requirements

of §411.357(w) at the time the donation was made would not cease to be protected by the exception if these proposed changes are finalized.

(2) Information Blocking and Data Lock-in (§411.357(w)(3))

The current requirement at §411.357(w)(3) prohibits the donor (or any person on the donor's behalf) from taking any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or EHR systems (including, but not limited to, health IT applications, products, or services). Beginning with the 2006 EHR final rule and reaffirmed in the 2013 EHR final rule, §411.357(w)(3) has been designed to: (1) prevent the misuse of the exception that results in data and referral lock-in; and (2) encourage the free exchange of data (in accordance with protections for privacy) (78 FR 78762). Since the publication of the final rules, significant legislative, regulatory, policy, and other Federal government action defined this problem further (now commonly referred to as "information blocking") and established penalties for certain types of individuals and entities that engage in information blocking. Most notably, the Cures Act added section 3022 of the PHSA, known as "the information blocking provision," which defines conduct by health care providers, health IT developers of certified health IT, exchanges, and networks that constitutes information blocking. Section 3022(a)(1) of the PHSA defines "information blocking" in broad terms, while section 3022(a)(3) of the PHSA authorizes and charges the Secretary to identify reasonable and necessary activities that do not constitute information blocking. The ONC NPRM, which includes proposals to implement the statutory definition of information blocking at 45 CFR part 171, proposes to define certain terms related to the statutory definition of information blocking, and proposes

seven exceptions to the information blocking definition.¹⁰

In this proposed rule, we are proposing modifications to §411.357(w)(3) to recognize these significant updates since the 2013 EHR final rule. Specifically, we are proposing at §411.357(w)(3) to prohibit the donor (or any person on the donor's behalf) from engaging in a practice constituting information blocking, as defined in section 3022 of the PHSA, in connection with the donated items or services. Should ONC finalize its proposals to implement section 3022 of the PHSA at 45 CFR part 171, we would incorporate such regulations into the requirement at §411.357(w)(3) for purposes of the physician self-referral law if we finalize the proposals described in this proposed rule. In addition, proposed §411.357(w)(3) provides that the donor (or any person on the donor's behalf) cannot engage in information blocking "in connection with the donated items or services," in order to clarify that §411.357(w)(3) prohibits *both* engaging in conduct constituting information blocking that affects the functions of the donated items or services *and* using the donated items or services as an instrument of information blocking.

We note that the current EHR exception requirements, while not using the term "information blocking," already include concepts similar to those found in the Cures Act's prohibition on information blocking. For example, in our prior rulemaking, we were concerned about donors (or those on the donor's behalf) taking steps to limit the interoperability of donated software to lock in or steer referrals.¹¹ The modifications proposed here are not intended to change the underlying purpose of this requirement, but

¹⁰ 84 FR at 7602 through 7605.

¹¹ See, for example, *Implementation of the 21st Century Cures Act: Achieving the Promise of Health Information Technology Before the S. Comm. On Health, Education, Labor, & Pensions*, 115th Cong. 1 (2017) (statement of James Cannatti, Senior Counselor for Health Information Technology HHS OIG).

instead further our longstanding goal of preventing abusive arrangements that lead to information blocking and referral lock-in through modern understandings of those concepts established in the Cures Act.¹² We solicit comments on aligning the condition at §411.357(w)(3) with the PHSA and the information blocking definition in proposed 45 CFR part 171, if finalized.

b. Cybersecurity

We are proposing to amend the EHR exception to clarify that the exception is available (and always has been available) to protect certain cybersecurity software and services,¹³ and to more broadly protect the donation of software and services related to cybersecurity. Currently, the exception protects EHR software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records. We are proposing to modify this language to include software that “protects” electronic health records, and to expressly include services related to cybersecurity.

In the 2006 EHR final rule, we emphasized the requirement that software, information technology and training services donated must be closely related to EHR and that the EHR functions must predominate (71 FR 54151). We stated that the core functionality of the technology must be the creation, maintenance, transmission, or receipt of individual patients' EHR, but, recognizing that EHR software is commonly integrated with other features, we also stated that arrangements in which the software

¹² We recognize that the ONC NPRM is not a final rule and is subject to change. However, we base our proposals on both the statutory language and the language in ONC’s NPRM for purposes of soliciting public input on our proposals.

¹³ For instance, a secure log-in or encrypted access mechanism included with an EHR system or EHR software suite would be cybersecurity features of the EHR that may be protected under the existing EHR exception.

package included other functionality related to the care and treatment of individual patients would be protected. Under our proposal, the same criteria would apply to cybersecurity software and services: the predominant purpose of the software or services must be cybersecurity associated with the EHR.

In section II.E.2. of this proposed rule, we also are proposing a new exception at proposed §411.357(bb) specifically to protect arrangements involving the donation of cybersecurity technology and related services (the cybersecurity exception). As proposed, the cybersecurity exception is broader and includes fewer requirements than the EHR exception. Nonetheless, we are proposing to expand the EHR exception to expressly include certain cybersecurity software and services so that it is clear that an entity donating EHR software, and providing training and other related services, may also donate related cybersecurity software and services to protect the EHR. As detailed in section II.E.2.a. of this proposed rule, we are proposing a definition of “cybersecurity” at §411.351 that would apply to both the EHR exception and the proposed cybersecurity exception at §411.357(bb). A party seeking to protect an arrangement involving the donation of cybersecurity software and services only needs to comply with the requirements of one applicable exception. We solicit comments on this approach. In particular, with the addition of a stand-alone cybersecurity exception, we solicit comments on whether it is necessary to modify the EHR exception to expressly include cybersecurity.

c. The Sunset Provision

The EHR exception originally was scheduled to expire on December 31, 2013. In adopting this sunset provision, we acknowledged in the 2006 EHR final rule that the

need for an exception for donations of EHR technology should diminish substantially over time as the use of such technology becomes a standard and expected part of medical practice. In the 2013 notice of proposed rulemaking for an amendment to the EHR exception, we acknowledged that, although EHR technology adoption had risen dramatically, use of such technology had not yet been universally adopted nationwide. Because continued EHR technology adoption remained an important goal of the Department, we solicited comments regarding an extension of the EHR exception. In response to those comments, in the 2013 EHR final rule, we extended the sunset date of the exception to December 31, 2021, a date that corresponds to the end of the EHR Medicaid incentives. We stated our continued belief that, as progress on this goal is achieved, the need for an exception for donations should continue to diminish over time. However, commenters on the CMS RFI and on OIG's request for information requested that we make the EHR exception and safe harbor permanent.

Although we acknowledge that widespread adoption of EHR technology, though not universal, largely has been achieved, we no longer believe that once this goal is achieved the need for an exception for arrangements involving the donation of such technology will diminish over time or completely disappear. Rather, our experience indicates that the continued availability of the EHR exception plays a part in achieving the Department's goal of promoting EHR technology adoption by providing certainty with respect to the cost of EHR items and services for recipients, by encouraging adoption by physicians who are new entrants into medical practice or have postponed adoption based on financial concerns regarding the ongoing costs of maintaining and supporting an EHR system, and by preserving the gains already made in the adoption of

interoperable EHR technology. Therefore, we are proposing to eliminate the sunset provision at §411.357(w)(13). In the alternative, we are considering an extension of the sunset date. We seek comment on whether we should select a later sunset date instead of making the exception permanent, and if so, what that date should be.

d. Definitions

We are proposing to modify the definitions of “interoperable” and “electronic health record.” In the 2006 EHR final rule, we finalized these definitions based on contemporaneous terminology, the emerging standards for EHR, and other resources cited by commenters at that time. The following proposed modifications to these definitions are largely based on terms and provisions in the Cures Act that update or supersede terminology we used in the 2006 EHR final rule.

The term “electronic health record” is currently defined at §411.351 as a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions. We are proposing the following modifications: replace the term “consumer health status information” with “electronic health information;” replace the term “computer processable form” with “is transmitted by or maintained in electronic media;” and replace the phrase “used for clinical diagnosis and treatment for a broad array of clinical conditions” with “relates to the past, present, or future health or condition of an individual or the provision of health care to an individual.” We are proposing these modifications to this definition to reflect the term “electronic health information” that is used throughout the Cures Act and that is central to the definition of interoperability at section 3000(9) of the PHSA and the information blocking provisions at section 3022 of

the PHSA. Additionally, the ONC NPRM proposes a definition of “electronic health information.”¹⁴ We have based our proposed modifications, in part, on ONC’s proposed definition of “electronic health information” to reflect more modern terminology used to describe the type of information that is part of an electronic health record. We solicit comments on this updated definition.

The term “interoperable” is defined at existing §411.351 and means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purposes and meaning of the data are preserved and unaltered. This definition of “interoperable” was based on 44 U.S.C. 3601(6) (pertaining to the management and promotion of electronic Government services) and several comments we received in response to the proposed rule that referenced emerging industry definitions and standards related to interoperability.¹⁵

We are proposing to update the definition of “interoperable” to align with the statutory definition of “interoperability” added by the Cures Act to section 3000(9) of the PHSA. Consistent with section 3000(9) of the PHSA, we are proposing to define “interoperable” to mean: (i) able to securely exchange data with and use data from other health information technology without special effort on the part of the user; (ii) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (iii) does not constitute information blocking as defined in section 3022 of the PHSA. Should ONC finalize its proposals to implement section 3022 of the PHSA at 45 CFR part 171, and if we finalize

¹⁴ 84 FR 7424, 7513 (Mar. 4, 2019).

¹⁵ See 70 FR 59186 and 71 FR 45155 through 45156.

our proposed definition of “interoperable,” we would incorporate the final ONC regulations into the definition of “interoperable” at §411.351 by referencing 45 CFR part 171 instead of section 3022 of the PHSA.

We believe the statutory definition of “interoperability” includes concepts similar to the existing definition of “interoperable” at §411.351 (for example, the ability to securely exchange data across different systems or technology). Two new concepts in the statutory definition are included in the proposed modification: (1) interoperable means the ability to exchange electronic health information without special effort on the part of the user and (2) interoperable expressly does not mean information blocking.¹⁶ As a practical matter, we believe these two concepts are not substantively different from the existing definition and only reflect an updated understanding of interoperability and related terminology. We solicit comments on the proposed definition that would align the definition of “interoperable” with the statutory definition of “interoperability.”

In the alternative, we are considering revising our regulations to eliminate the term “interoperable” and instead incorporate the term “interoperability” and define this term by reference to section 3000(9) of the PHSA and 45 CFR part 170 (if finalized). Under this alternative proposal, we would revise §411.357(w)(2) to require that the software meets interoperability standards established under Title XXX of the PHSA and its implementing regulations. Software would be deemed to meet interoperability standards if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to electronic health record certification criteria identified in the then-applicable version of 45 CFR part

¹⁶ Section 3000(9) of the PHSA; (42 U.S.C. 300jj(9)).

170. We seek comment regarding whether using terminology identical to the PHSA and ONC regulations would facilitate compliance with the requirements of the EHR exception and reduce any regulatory burden resulting from the differences in the agencies' different terminology related to the singular concept of interoperability.

We emphasize that our proposed modifications of the definitions of “electronic health record” and “interoperable” are prospective only. Donations made prior to the effective date of any finalized revisions to these definitions are governed by the definitions that are in effect when the donations are made. We solicit comments on this proposal.

e. Additional Proposals and Considerations

(1) 15 Percent Recipient Contribution

In the 2006 EHR final rule, we agreed with a number of commenters who suggested that cost sharing is an appropriate method to address some of the fraud and abuse risks inherent in unlimited donations of technology. Accordingly, we incorporated a requirement into §411.357(w) that the physician pays 15 percent of the donor's cost of the technology. We noted in the 2006 EHR final rule that the 15 percent cost sharing requirement is high enough to encourage prudent and robust EHR arrangements, without imposing a prohibitive financial burden on recipients. Moreover, we stated that this approach requires recipients to contribute toward the benefits they may experience from the adoption of interoperable EHR (for example, a decrease in practice expenses or access to incentive payments related to the adoption of health IT).

We received a number of comments in response to our RFI, and OIG received similar comments in response to its RFI, indicating that the 15 percent contribution has

proven burdensome to some recipients and acts as a barrier to adoption of EHR technology. We understand that this burden may be particularly acute for small and rural practices that cannot afford the contribution. Other commenters suggested that applying the 15 percent requirement to upgrades and updates to EHR technology is restrictive and cumbersome and similarly acts as a barrier. We are considering and solicit comments on two alternatives to the existing requirement as outlined below; however, we are not proposing specific regulation text regarding the 15 percent contribution requirement at this time.

First, we are considering eliminating or reducing the percentage contribution required for small or rural physician organizations. In particular, we solicit comments on how we should define “small or rural physician organization.” We solicit comments on 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). We also solicit comments on other subsets of potential physician recipients for which the 15 percent contribution is a particular burden.

As an alternative, we are considering reducing or eliminating the 15 percent contribution requirement in the EHR exception for all physician recipients. We solicit comments regarding the impact this might have on the use and adoption of EHR technology, and any attendant risks of fraud and abuse. We are interested in specific examples of any prohibitive costs associated with the 15 percent contribution requirement, both for the initial donation of EHR technology, and subsequent upgrades and updates to the technology.

Regardless of whether we retain the 15 percent contribution requirement or reduce that contribution requirement for some or all physician recipients, we are considering modifying or eliminating the contribution requirement for updates to previously donated EHR software or technology. We solicit comments on this approach as well as what such a modification should entail. For example, we are considering requiring a contribution for the initial investment only, as well as any new modules, but not requiring a contribution for any update of the software already purchased. We solicit comments on these alternatives, or another similar alternative that would still involve some contribution but could reduce the uncertainty and administrative burden associated with assessing a contribution for each update.

(2) Replacement Technology

In the 2013 EHR final rule, we highlighted a commenter's assertion that the prohibition on donating equivalent technology currently included in the exception locks physician practices into a vendor, even if they are dissatisfied with the technology, because the recipient must choose between paying the full amount for a new system and continuing to pay 15 percent of the cost of the substandard system (78 FR 78766). The same commenter asserted that the cost differential between these two options is too high and effectively locks physician practices into EHR technology vendors. In the 2013 EHR final rule, we responded that we continue to believe that items and services are not necessary if the recipient already possesses the equivalent items or services. We noted that providing equivalent items and services confers independent value on the physician recipient and noted our expectation that physicians would not select or continue to use a substandard system if it posed a threat to patient safety.

We appreciate that advancements in EHR technology are continuous and rapid. According to commenters, in some situations replacement technology is appropriate but prohibitively expensive. We are proposing to allow donations of replacement EHR technology. We specifically seek comment as to the types of situations in which the donation of replacement technology would be appropriate. We further solicit comment as to how we might safeguard against situations where donors inappropriately offer, or physician recipients inappropriately solicit, unnecessary technology instead of upgrading their existing technology for appropriate reasons.

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

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital to be a member of the hospital's medical staff, subject to certain requirements. This exception is codified in our regulations at §411.357(e). In Phase III, we declined a commenter's request to expand §411.357(e) to cover the recruitment of nonphysician practitioners (NPPs) into a hospital's service area, including into an existing physician practice, stating that the exception for physician recruitment at §411.357(e) applies only to payments made directly (or, in some circumstances, passed through) to a recruited physician (72 FR 51049). Recruitment payments made by a hospital directly to an NPP would not implicate the physician self-referral law, unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician. We further stated that payments made by a hospital to subsidize a physician practice's costs of recruiting and employing NPPs would create a compensation arrangement between the hospital and the physician practice for which no

exception would apply, and that these kinds of subsidy arrangements pose a substantial risk of fraud and abuse. Following the publication of Phase III, we reconsidered our position. There have been significant changes in our health care delivery and payment systems, as well as projected shortages in the primary care workforce. To address this changed landscape, in the CY 2016 PFS final rule, we finalized a limited exception at §411.357(x) for hospitals, FQHCs, and rural health clinics (RHCs) to provide remuneration to a physician to assist with the employment of an NPP (80 FR 71301 through 71311).

The exception at §411.357(x) applies to remuneration provided by a hospital to a physician to compensate an NPP to provide patient care services. We have received several inquiries regarding the meaning of the term “patient care services” as it relates to an NPP. The inquiries generally concentrate on the requirement at §411.357(x)(1)(v)(B) that the NPP has not, within 1 year of the commencement of his or her compensation arrangement with the physician, been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital. Often, prior to becoming an NPP, an individual may have been a registered nurse (or some other health care professional) and may have provided services to patients that are similar to the services provided by an NPP. For purposes of the exception at §411.357(x), the question presented by stakeholders is whether the services provided by the individual before the individual became an NPP constitute “patient care services.”

We realize that the definition of “patient care services” found at §411.351 relates to tasks performed by a physician only. To clarify the meaning of “patient care services”

for purposes of the exception for assistance to compensate an NPP, we are proposing to revise §411.357(x) to change the references to “patient care services” to “NPP patient care services” and include a definition of the term “NPP patient care services” in the exception at §411.357(x)(4)(i). We are proposing to define “NPP patient care services” to mean direct patient care services furnished by an NPP that address the medical needs of specific patients or any task performed by an NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement. Under the proposed definition of “NPP patient care services,” services provided by an individual who is not an NPP (as the term is defined at §411.357(x)(3)) at the time the services are provided, are not NPP patient care services for purposes of §411.357(x). Thus, if an individual worked in the geographic area served by the hospital providing the assistance (for example, as a registered nurse) for some period immediately prior to the commencement of his or her compensation arrangement with the physician or physician organization in whose shoes the physician stands, but had not worked as an NPP in that area during that time period, the exception at §411.357(x) would be available to protect remuneration from the hospital to the physician to compensate the NPP to provide NPP patient care services, provided that all of the requirements of the exception are satisfied. In this example, the registered nursing services would not be considered NPP patient care services when determining whether the arrangement satisfies the 1-year restriction at §411.357(x)(1)(v).

In addition, we are proposing conforming changes to the term “referral” as defined at §411.357(x)(4) for purposes of the exception. Specifically, we are proposing to revise §411.357(x) to change references to “referral” when describing the actions of an

NPP to “NPP referral” and revise §411.357(x)(4) accordingly. We believe that it is unnecessary to have a general definition of “referral” at §411.351 that is applicable throughout our regulations and a different definition of the same term that applies only for purposes of the exception at §411.357(x). We are not proposing substantive changes to the definition itself; however, we are proposing to move the definition to §411.357(x)(4)(ii) in order to accommodate the inclusion of the related definition of “NPP patient care services” within section §411.357(x)(4).

We are also proposing a related change to §411.357(x)(1)(v)(A). As currently drafted, §411.357(x)(1)(v)(A) requires the NPP to not have practiced in the geographical area served by the hospital within 1 year of the commencement of the compensation arrangement with the physician. According to stakeholders that requested guidance on the scope of the exception, the word “practiced” may be interpreted to include the provision of NPP patient care services (as we are proposing to define the term here) and other services, for example, services provided by a health care professional who is not an NPP at the time the services are furnished. To resolve any potential stakeholder confusion, we are proposing to replace the term “practiced” with “furnished NPP patient care services.” Under the proposal, a hospital would not run afoul of §411.357(x)(1)(v)(A) if the hospital provided remuneration to a physician to compensate an NPP, and the individual receiving compensation from the physician furnished services in the hospital’s geographic service area within 1 year of the commencement of his or her compensation arrangement with the physician, provided that the services furnished by the individual during the 1-year period were not NPP patient care services, as we are proposing to define the term at §411.357(x)(4)(i).

In addition to the inquiries related to the meaning of the terms “patient care services” and “practice,” we are aware of stakeholder uncertainty regarding the timing of arrangements that may be permissible under §411.357(x). Specifically, stakeholders have inquired whether an NPP must begin his or her compensation arrangement with the physician (or physician organization in whose shoes the physician stands) on or after the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician. Stakeholders noted that the exception includes no explicit prohibition on an entity providing assistance to a physician to reimburse the physician for the compensation, signing bonus, or benefits paid to an NPP already employed or contracted by the physician prior to the date of the commencement of the physician’s compensation arrangement with the hospital, FQHC, or RHC. As we stated when finalizing the exception at §411.357(x), our underlying goal is to increase access to needed care (80 FR 71309). Permitting a hospital, FQHC, or RHC to simply reimburse a physician for overhead costs of current employees or contractors already serving patients in the geographic area served by the hospital, FQHC, or RHC does not support this goal. Nonetheless, as stakeholders pointed out, there is no express requirement regarding the timing of the compensation arrangement between the NPP and the physician (or physician organization in whose shoes the physician stands) in §411.357(x). To ensure that compensation arrangements protected under the exception do not pose a risk of program or patient abuse, we are proposing to amend §411.357(x)(1)(i) to expressly require that the compensation arrangement between the hospital, FQHC, or RHC and the physician commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation with the NPP. Put

another way, the compensation arrangement between the NPP and the physician (or physician organization in whose shoes the physician stands) must commence on or after the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician.

13. Updating and Eliminating an Out-of-Date References

a. Medicare+Choice (§411.355(c)(5))

Section 1877(b)(3) of the Act and §411.355(c) of the physician self-referral regulations set forth exceptions for designated health services furnished by various organizations to enrollees of certain prepaid health plans. When the Medicare+Choice program was established in the Balanced Budget Act of 1997 (Pub. L.105–33) (BBA), the Congress failed to update section 1877(b)(3) of the Act to except the designated health services furnished under Medicare+Choice coordinated care plans. Based on our belief that this was an oversight, in the June 26, 1998 interim final rule with comment period (Medicare Program; Establishment of the Medicare+Choice Program (63 FR 34968)), we revised §411.355(c) to accommodate the creation of the Medicare+Choice program and, relying on the Secretary’s authority to create new exceptions under section 1877(b)(4) of the Act, we included Medicare+Choice coordinated care plans in §411.355(c)(5) of our regulations (63 FR 35033 through 35034). (We declined to include Medicare+Choice medical savings account plans and Medicare+Choice private fee-for-service plans due to the risk of patient abuse related to financial liability for premiums and cost sharing, which were not limited by the BBA.) We included Medicare+Choice coordinated care plans at §411.355(c)(5), in part, to avoid contradiction with the BBA’s establishment of provider-sponsored organization (PSO) plans as coordinated care plans.

PSOs are defined in the BBA as entities that must be organized and operated by a provider (which may be a physician) or a group of affiliated health care providers (which may include physicians). The BBA requires that the providers have at least a majority financial interest in the entity and share a substantial financial risk for the provision of items and services. If such ownership was not excepted, the physician owners of PSOs would not be permitted to refer enrollees for designated health services furnished by the coordinated care plan (or its contractors and subcontractors). Subsequently, in 1999, the Congress amended section 1877(b)(3) of the Act to create a similar statutory exception for Medicare+Choice at section 1877(b)(3)(E) of the Act (Pub. L. 106-113).

Section 201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173, enacted on December 8, 2003) (MMA) renamed the Medicare+Choice program as the Medicare Advantage program and provided that any statutory reference to “Medicare+Choice” was deemed to be a reference to the Medicare Advantage program. In reviewing our regulations for out-of-date references, including references to Medicare+Choice, as part of this proposed rulemaking, it came to our attention that the language of §411.355(c)(5) may be inconsistent with other program regulations. Current §411.355(c)(5) excepts designated health services furnished by an organization (or its subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by an organization in accordance with a contract with CMS under section 1857 of the Act and Part 422 of Title 42, Chapter IV of the Code of Federal Regulations. For consistency with the MMA directive and to ensure the accuracy of our regulations, we are proposing to revise §411.355(c)(5) to more accurately reference Medicare Advantage plans. Under this proposal, §411.355(c)(5)

would reference designated health services furnished by an organization (or its contractors or subcontractors) to enrollees of a coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter. This proposal does not represent a change in our policy.

The Medicare Advantage program varies from the Medicare+Choice program in ways other than its name and has matured in the years since passage of the MMA. More than 20 years have passed since we determined to protect designated health services furnished to enrollees of coordinated care plans and exclude medical savings account plans and private fee-for-service plans from the scope of §411.355(c)(5). In light of this, we are seeking comments regarding whether §411.355(c)(5) is broad enough to protect designated health services furnished to enrollees in the full range of Medicare Advantage plans that exist today and that do not pose a risk of program or patient abuse. Specifically, we are interested in commenters' views on which, if any, other Medicare Advantage plans we should include within the scope of §411.355(c)(5).

b. Web site

We are proposing to modernize the regulatory text by changing “Web site” to “website” throughout the physician self-referral regulations to conform to the spelling of the term in the Government Publishing Office’s Style Manual and other current style guides.

E. Providing Flexibility for Nonabusive Business Practices

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

In the 1998 proposed rule, we proposed an exception for *de minimis*

compensation in the form of noncash items or services (63 FR 1699). In Phase I, using the Secretary's authority at section 1877(b)(4) of the Act, we finalized the proposal at §411.357(k) and changed the name of the exception to nonmonetary compensation, noting that, although free or discounted items and services such as free samples of certain drugs, chemicals from a laboratory, or free coffee mugs or note pads from a hospital fall within the definition of "compensation arrangement," we believe that such compensation is unlikely to cause overutilization, if held within reasonable limits (66 FR 920). The exception for nonmonetary compensation at §411.357(k) permits an entity to provide compensation to a physician in the form of items or services (other than cash or cash equivalents) up to an aggregate amount of \$300 per calendar year, adjusted annually for inflation and currently \$416 per calendar year, provided that the compensation is not solicited by the physician and is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. The exception does not require that the physician provide anything to the entity in return for the nonmonetary compensation, nor does it require that the arrangement be set forth in writing and signed by the parties.

We also recognized in Phase I that many of the incidental benefits that hospitals provide to medical staff members do not qualify for the exception at §411.357(c) for *bona fide* employment relationships because most members of a hospital's medical staff are not hospital employees, nor would they qualify for the exception at §411.357(l) for fair market value compensation because, to the extent that the medical staff membership is the only relationship between the hospital and the physician, there is no written arrangement between the parties to which these incidental benefits could be added. We

acknowledged that many medical staff incidental benefits are customary industry practices that are intended to benefit the hospital and its patients; for example, free computer and Internet access benefits the hospital and its patients by facilitating the maintenance of up-to-date, accurate medical records and the availability of cutting edge medical information (66 FR 921). To address this, using the Secretary's authority under section 1877(b)(4) of the Act, we finalized a second exception for noncash items or services provided to a physician. The exception at §411.357(m) for medical staff incidental benefits permits a hospital to provide noncash items or services to members of its medical staff when the item or service is used on the hospital's campus and certain conditions are met, including that the compensation is reasonably related to the provision of (or designed to facilitate) the delivery of medical services at the hospital and the item or service is provided only during periods when the physician is making rounds or engaged in other services or activities that benefit the hospital or its patients (66 FR 921). In addition the compensation may not be offered in a manner that takes into account the volume or value of referrals or other business generated between the parties. Under the exception, permissible noncash compensation is limited on a per-instance basis, and the current limit is \$35 per instance. Like the exception at §411.357(k) for nonmonetary compensation, the exception at §411.357(m) for medical staff incidental benefits does not impose any documentation or signature requirements.

Through our administration of the SRDP, we have been made aware of numerous nonabusive arrangements under which a limited amount of remuneration was paid by an entity to a physician in exchange for the physician's provision of items and services to the entity. In some instances, the arrangements were ongoing service arrangements under

which services were furnished sporadically or for a low rate of compensation; in others, services were furnished during a short period of time and the arrangement did not continue past the service period. For example, one submission to the SRDP disclosed an arrangement with a physician for short-term medical director services while the hospital was finalizing the engagement of its new medical director following the unexpected resignation of its previous medical director. Despite the hospital's legitimate need for the services and compensation that was fair market value and not determined in any manner that took into account the volume or value of the referrals or other business generated by the physician, the arrangement could not satisfy all requirements of any applicable exception because the compensation was not set in advance of the provision of the services and was not reduced to writing and signed by the parties. Under arrangements such as this, insofar as the hospital paid the physician in cash, the exception at §411.357(k) for nonmonetary compensation would not apply to the arrangement. Similarly, the exception at §411.357(l) for fair market value compensation would not protect the payment if the arrangement was not documented in contemporaneous signed writings and the amount of or formula for calculating the compensation was not set in advance of provision of the items or services, even if the payment did not exceed fair market value for actual items or services provided and was not determined in a manner that takes into account the volume or value of referrals or other business generated by the physician.

After reviewing numerous arrangements in the SRDP, we believe that the provision of limited remuneration to a physician would not pose a risk of program or patient abuse, even in the absence of documentation regarding the arrangement and

where the amount of or a formula for calculating the remuneration is not set in advance of the provision of items or services, if: (1) the arrangement is for items or services actually provided by the physician; (2) the amount of the remuneration to the physician is limited; (3) the arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements, regardless of whether it results in profit for either or both of the parties; (4) the remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and (5) the remuneration does not exceed the fair market value for the items or services. Under these circumstances, we believe that, if held within reasonable limits, remuneration is unlikely to cause overutilization or similar harms to the Medicare program. Therefore, using the Secretary's authority under section 1877(b)(4) of the Act, we are proposing an exception for limited remuneration from an entity to a physician for items or services actually provided by the physician. We are proposing that the exception would apply only where the remuneration does not exceed an aggregate of \$3,500 per calendar year, which would be adjusted for inflation in the same manner as the annual limit on nonmonetary compensation and the per-instance limit on medical staff incidental benefits; that is, adjusted to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items for the 12-month period ending the preceding September 30. Under the proposal, the remuneration may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician or exceed fair market value for the items or services provided by the physician, and the compensation arrangement must be commercially reasonable. We believe that an annual aggregate limit of \$3,500 is sufficient to cover the typical range of commercially

reasonable arrangements for the provision of items and services that a physician might provide to an entity on an infrequent or short-term basis. The proposed exception would not be applicable to payments from an entity to a physician's immediate family member or to payments for items or services provided by the physician's immediate family member.

Given the low annual limit of the proposed exception and the other proposed safeguards of the exception, we believe that the exception for limited remuneration to a physician would not pose a risk of program or patient abuse. In contrast, when the remuneration a physician receives from an entity for items or services exceeds the aggregate annual limit of \$3,500, as adjusted annually for inflation, we believe that the additional safeguards of other applicable exceptions are necessary to prevent program or patient abuse. For example, for long-term arrangements for items or services provided on a more routine or frequent basis, where the aggregate annual compensation exceeds \$3,500, we believe that the requirement that compensation is set in advance before the provision of the items or services is necessary to ensure that various payments made over the term of the arrangement are not determined retrospectively to reward past referrals or encourage increased referrals from the physician. We note that the annual limit of \$3,500 for the proposed exception is higher than the annual limit for the exception for nonmonetary compensation at §411.357(k) because the exception for limited remuneration to a physician would protect a fair market value exchange of remuneration for items or services actually furnished by a physician, while the exception for nonmonetary compensation does not require a physician to provide actual items or services in exchange for the nonmonetary compensation. We seek public comment on

whether the \$3,500 limit is appropriate, too high, or too low to accommodate nonabusive compensation arrangements for the provision of items or services by a physician. We are also interested in comments regarding whether it is necessary to limit the applicability of the exception to services that are personally performed by the physician and items provided by the physician in order to further safeguard against program or patient abuse.

The proposed exception at §411.357(z) for limited remuneration to a physician would apply to the furnishing of both items and services by a physician. Previously, we stated that we are retracting prior statements that office space is neither an “item” nor a “service.” Thus, for the reasons articulated in section II.D.10. of this proposed rule and the CY 2017 PFS proposed rule (81 FR 46448 through 46453) and final rule (81 FR 80524 through 80534), we are proposing to incorporate in proposed §411.357(z) prohibitions on percentage-based and per-unit of service compensation to the extent the remuneration is for the use or lease of office space or equipment, similar to the provisions at existing §411.357(p)(1)(ii) for indirect compensation arrangements and §411.357(y)(6)(ii) for timeshare arrangements. Lastly, in keeping with our policy decision in this rule to decouple exceptions issued under our authority at section 1877(b)(4) of the Act from the anti-kickback statute, the proposed exception for limited remuneration to a physician does not include a requirement that the arrangement must not violate the anti-kickback statute or other Federal or State law or regulation governing billing or claims submission. However, we are soliciting comment regarding whether such a safeguard is necessary here in light of the absence of requirements for set in advance compensation and written documentation of the arrangement. We note that, if we do not finalize our proposal to remove the requirements related to the compliance

with the anti-kickback statute and Federal and State laws and regulations governing billing or claims submission, we would include a requirement at proposed §411.357(z) that the arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. Moreover, to the extent that remuneration implicates the anti-kickback statute, nothing in our proposals would affect the parties' obligation to comply with the anti-kickback statute, and compliance with the exception for limited remuneration to a physician, if finalized, would not consequentially result in compliance with the anti-kickback statute. As we stated in Phase I, section 1877 of the Act is limited in its application and does not address every abuse in the health care industry. The fact that particular referrals and claims are not prohibited by section 1877 of the Act does not mean that the arrangement is not abusive (66 FR 879).

In determining whether payments to a physician under the proposed exception for limited remuneration to a physician exceed the annual limit, we would not count compensation to a physician for items or services provided outside of the arrangement, if the items or services provided are protected under an exception in §411.355 or the arrangement for the other items or services fully complies with the requirements of another exception in §411.357. To illustrate, assume an entity has an established call coverage arrangement with a physician that fully satisfies the requirements of §411.357(d)(1) or §411.357(l). Assume further that the entity later engages the physician to provide supervision services on a sporadic basis during the same year but failed to document the arrangement in a writing signed by the parties. In determining whether the supervision arrangement satisfies the requirements of the proposed exception for limited remuneration to a physician, we would not count the compensation provided under the

call coverage arrangement towards the aggregate \$3,500 annual limit. However, if an entity has multiple undocumented, unsigned arrangements under which it provides compensation to a physician for items or services provided by the physician, we would consider the parties to have a single compensation arrangement for various items and services, and the aggregate of all the compensation provided under the arrangement could not exceed \$3,500 during the calendar year in order for the proposed exception to protect the remuneration to the physician. To illustrate, assume the entity in the previous example also engaged the physician to provide occasional EKG interpretations during the course of the year, and that the aggregate annual compensation for the supervision services and the EKG interpretation services *taken together* exceeded \$3,500.¹⁷ Assuming neither arrangement satisfied the requirements of any other applicable exception, the exception for limited remuneration to a physician would not protect either arrangement (which, as noted, we would treat as a single arrangement for multiple services) after the \$3,500 limit was exceeded during the calendar year.

We note that the proposed exception for limited remuneration to a physician could be used in conjunction with other exceptions to protect an arrangement during the course of a calendar year in certain circumstances. To illustrate, assume that an entity engages a physician to provide call coverage services, and that the arrangement is not documented or the rate of compensation has not been set in advance at the time the services are first provided. Further, assume that, after the services are provided and payment is made, the parties agree to continue the arrangement on a going forward basis and agree to a rate of

¹⁷ As noted previously, compensation paid under the call coverage arrangement would not be included when determining whether the limit was exceeded, because the call coverage arrangement in this example fully complies with an applicable exception.

compensation. Assume also that the parties have no other arrangements between them. Depending on the facts and circumstances, the parties could rely on the proposed exception to protect the first payments up to the \$3,500 annual limit, provided that the requirements of the proposed exception are satisfied. For the ongoing compensation arrangement, the parties could rely on another applicable exception, such as §411.357(d)(1), to protect the arrangement once the compensation is set in advance and the other requirements of the exception are satisfied. (We remind readers that, under proposed §411.354(e)(3), the parties would have up to 90 consecutive calendar days to document and sign the arrangement.)

We note that §411.357(d)(1)(ii) requires that the personal service arrangement covers all the services provided by the physician (or an immediate family member of the physician) to the entity (or incorporate other arrangements by reference or cross-reference a master list of contracts) and §411.357(l)(2) requires that parties enter into only one arrangement for the same services in a year. For purposes of §411.357(d)(1)(ii), we would not require an arrangement for items or services that satisfies all of the requirements of the proposed exception 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. Likewise, with respect to the restriction in the exception for fair market value compensation at §411.357(l)(2), we would not consider an arrangement for items or services that is protected under the proposed exception at §411.357(z) to violate the prohibition on entering into an arrangement for the same items and services during a calendar year. We are seeking comments on whether the regulation text at §411.357(d)(1)(ii) or §411.357(l)(2) should be modified to explicitly state this policy.

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

Relying on our authority under section 1877(b)(4) of the Act, we are proposing an exception at §411.357(bb) to protect arrangements involving the donation of certain cybersecurity technology and related services. We believe that the proposed exception will help improve the cybersecurity posture of the health care industry by removing a perceived barrier to donations to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the delivery of health care. The OIG is considering a similar safe harbor to the anti-kickback statute elsewhere in this issue of the **Federal Register**. Despite the differences in the respective underlying statutes, we attempted to ensure as much consistency as possible between our proposed exception and OIG's proposed safe harbor. Because of the close nexus between our proposed exception and the policies under consideration by OIG, we may consider comments submitted in response to OIG's proposals, even if we do not receive such comments on our proposals, and take additional actions when crafting our final rule.

In recent years, both CMS and OIG have received numerous comments and suggestions urging the creation of an exception and a safe harbor to protect donations of cybersecurity technology and related services.¹⁸ The digitization of health care delivery and rules designed to increase interoperability and data sharing in the delivery of health care create numerous targets for cyberattacks. The health care industry and the technology used to deliver health care have been described as an interconnected

¹⁸ See, for example, U.S. Department of Health and Human Services, Office of Inspector General, *Semiannual Report to Congress*, Apr. 1, 2018-Sept. 30, 2018, at 84.

ecosystem where the weakest link in the system can compromise the entire system.¹⁹

Given the prevalence of electronic health record storage, as well as the processing and transit of health records and other critical protected health information (PHI) between and within the components of the health care ecosystem, the risks associated with cyberattacks originating with “weak links” are borne by every component of the system.

Although we did not specifically request comments on cybersecurity, numerous commenters on the CMS RFI requested that we create an exception to protect the donation of cybersecurity technology and related services. Likewise, in response to its request for information specifically related to cybersecurity, OIG received overwhelming support for a safe harbor to protect the donation of cybersecurity technology and related services. Many commenters on both requests for information outlined the increasing prevalence of cyberattacks and other threats. Commenters noted that cyberattacks pose a fundamental risk to the health care ecosystem and that data breaches result in high costs to the health care industry and may endanger patients. Moreover, disclosures of PHI through a data breach can result in identity fraud, among other things.

The Health Care Industry Cybersecurity (HCIC) Task Force, created by the Cybersecurity Information Sharing Act of 2015 (CISA),²⁰ was established in March 2016 and is comprised of government and private sector experts. The HCIC Task Force produced its HCIC Task Force Report in June 2017.²¹ The HCIC Task Force recommended, among other things, that the Congress “evaluate an amendment to [the

¹⁹ See, for example, Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry*, June 2017 (HCIC Task Force Report), available at <https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf>.

²⁰ Pub. L. 114-113, 129 Stat. 2242.

²¹ HCIC Task Force Report, available at <https://www.phe.gov/preparedness/planning/cybertf/documents/report2017.pdf>.

physician self-referral law and the anti-kickback statute] specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy,” and noted that the regulatory exception to the physician self-referral law for EHR items and services and the safe harbor for EHR items and services could serve as a template for a new statutory exception.²²

Based on responses to OIG’s request for information, we understand that the cost of cybersecurity technology and related services has increased dramatically, to the point where some providers and suppliers are unable to invest in and, therefore, have not invested in, adequate cybersecurity measures. Therefore, we believe that allowing entities that are willing to donate certain cybersecurity technology and related services, with appropriate safeguards, would greatly strengthen the entire health care ecosystem. Although donated technology and services may have value for the recipients of a donation inasmuch as the recipient would be able to use its resources for needs other than cybersecurity expenses, we believe that a primary reason donors would provide cybersecurity technology and related services is to protect themselves from cyberattacks. As previously noted, the risks associated with a cyberattack on a single provider or supplier in an interconnected system are ultimately borne by every player in the system. Thus, an entity wishing to protect itself from cyberattacks has a vested interest in ensuring that the physicians with whom the entity shares data are also protected from cyberattacks, particularly where the connections allow the physicians to establish bidirectional interfaces with the entity, which inherently present higher risk than

²² *Id.* at 27.

connections that permit physicians “read-only” access to the entity’s data systems. We believe that certain cybersecurity donations would not pose a risk of program or patient abuse, provided that they satisfy all the requirements of the proposed exception, and that the exception we are proposing in this proposed rule, if finalized, would promote increased security for interconnected and interoperable health care IT systems without protecting potentially abusive arrangements.

We are proposing to protect nonmonetary remuneration in the form of certain types of cybersecurity technology and related services. We are proposing to include within the scope of covered technology any software or other type of IT, other than hardware. In section II.E.2.e. of this proposed rule, we are alternatively proposing to permit the donation of certain cybersecurity hardware under certain circumstances. In an effort to foster beneficial cybersecurity donation arrangements without permitting arrangements that pose a risk of program or patient abuse, the proposed exception at §411.357(bb) would impose a number of requirements for cybersecurity donations, as set forth below. Notably, the proposed exception would require the donation to be necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

a. Definitions

We are proposing to define the terms “cybersecurity” and “technology.” Because the definition of “cybersecurity” would also apply to our proposal to explicitly permit the donation of cybersecurity software and services under §411.357(w), we are proposing to include the definition of “cybersecurity” in our regulations at §411.351. The proposed definition of “technology,” on the other hand, would be applicable only to the proposed exception for the donation of cybersecurity technology and related services and,

therefore, would be included in the regulation text at proposed §411.357(bb)(2). We are proposing to define the term “cybersecurity” to mean the process of protecting information by preventing, detecting, and responding to cyberattacks and define the term “technology” to mean any software or other type of information technology other than hardware.

We intend to interpret “cybersecurity” broadly and our proposed definition is derived from the National Institute for Standards and Technology (NIST) Framework for Improving Critical Infrastructure,²³ a framework that does not apply specifically to the health care industry, but applies generally to any United States critical infrastructure. Our goal is to broadly define cybersecurity and avoid unintentionally limiting donations by relying on a narrow definition or a definition that might become obsolete over time. We solicit comment on this approach and whether a definition tailored to the health care industry would be more appropriate.

Our proposed definition of “technology” is similarly broad. We intend to be neutral with respect to the types of non-hardware cybersecurity technology to which the exception would be applicable. We intend for this exception to be broad enough to include cybersecurity software and other IT, such as an Application Programming Interface (API), which is neither software nor a service as those terms are generally used, that is available now and technology that may become available as the industry continues to develop. The definition of “technology” for purposes of the proposed exception excludes hardware. Although we recognize that effective cybersecurity may require hardware that meets certain standards (for example, encrypted endpoints or updated

²³ Appendix B, Version 1.1 (April 16, 2018) available at <https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf>.

servers), we are concerned that donations of valuable, multifunctional hardware may pose a risk of program or patient abuse. We believe that donations of technology that may be used for purposes other than cybersecurity present a risk that the donation is being made to influence referrals. Hardware is usually multifunctional and, as a result, likely would not be necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity. To illustrate this policy, the proposed exception would not protect a laptop computer or tablet used in the general course by a physician to enter patient visit information into an EHR and respond to emails. However, it would protect encryption software for the laptop computer or tablet. Our proposal is consistent with a similar exclusion of hardware in the EHR exception at §411.357(w). (See 71 FR 45149 for a discussion of our rationale for excluding hardware from protection under the EHR exception.) We solicit comments on this approach.

We are considering two alternative proposals that would allow for the donation of certain cybersecurity hardware. Under the first alternative proposal, the exception at §411.357(bb) would cover specific hardware that is necessary for cybersecurity, provided that the hardware is stand-alone (that is, is not integrated within multifunctional equipment) and serves only cybersecurity purposes (for example, a two-factor authentication dongle). We solicit comments on what types of hardware might qualify and whether we should protect them under the proposed exception. Under our second alternative proposal, we would permit entities to donate a broader range of cybersecurity technology, including hardware, provided that specified requirements are satisfied. We discuss the second alternative proposal in section II.E.2.e. of this proposed rule.

Finally, we note that the proposed exception only protects items and services that meet the definition of cybersecurity technology and related services. It does not extend to other types of cybersecurity measures outside of technology or services. For example, the proposed exception would not protect donations of installation, improvement, or repair of infrastructure related to physical safeguards, even if they could improve cybersecurity (for example, upgraded wiring or installing high security doors). Donations of infrastructure upgrades are extremely valuable and have multiple benefits in addition to cybersecurity, and, thus, pose an increased risk that one purpose of the donation is to pay for or influence a physician's referrals to the donor entity.

b. Conditions on Donation and Protected Donors

At §411.357(bb)(1)(i), we are proposing to limit the applicability of the exception for cybersecurity technology and related services to donated technology or services that are necessary and predominantly used to implement, maintain, or reestablish cybersecurity. The goal of this condition is to ensure that donations are being made for the purposes of addressing legitimate cybersecurity needs of donors and recipients; that is, the core function of the donated technology or service must be to protect information by preventing, detecting, and responding to cyberattacks. Our intent is to protect a wide range of technology and services that are specifically donated for the purpose of, and are necessary for, ensuring that donors and recipients have cybersecurity.

As stated previously, we are taking a neutral position with respect to protected technology, including as to the types and versions of software that can receive protection. We do not distinguish between cloud-based software and software that must be installed locally. The types of technology potentially protected under the proposed exception

include, but are not limited to, software that provides malware prevention, software security measures to protect endpoints that allow for network access control, business continuity software, data protection and encryption, and email traffic filtering. We believe these examples are indicative of the types of technology that are necessary and used predominantly for cybersecurity. We solicit comments on the proposed breadth of protected technology as well as whether we should expressly include (or exclude) other technology or categories of technology in the proposed exception.

Similarly, we are proposing to protect a broad range of services. Such services could include—

- Services associated with developing, installing, and updating cybersecurity software;
- Cybersecurity training services, such as training recipients on how to use the cybersecurity technology, how to prevent, detect, and respond to cyber threats, and how to troubleshoot problems with the cybersecurity technology (for example, “help desk” services specific to cybersecurity);
- Cybersecurity services for business continuity and data recovery services to ensure the recipient’s operations can continue during and after a cybersecurity attack;
- “Cybersecurity as a service” models that rely on a third-party service provider to manage, monitor, or operate cybersecurity of a recipient;
- Services associated with performing a cybersecurity risk assessment or analysis, vulnerability analysis, or penetration test; or
- Services associated with sharing information about known cyber threats, and assisting recipients responding to threats or attacks on their systems.

We believe these types of services are indicative of the types of services that are necessary and used predominantly for cybersecurity. We solicit comments on the proposed breadth of protected services as well as whether we should expressly include (or exclude) other services or categories of services in the proposed exception. In all cases, the donation of services must be nonmonetary. For example, donating the time of a consultant to implement a cybersecurity program could be protected, but if an entity were to experience a cyberattack that involved ransomware, payment of the ransom amount for a recipient would not be protected.

We reiterate that, although technology or services may have multiple uses, the proposed exception would only protect donations of technology and services that are used predominantly to implement, maintain, and reestablish cybersecurity. As explained in the discussion of the definition of technology, we remain concerned that donations of valuable multi-use technology or services pose a risk of program or patient abuse. The proposed exception would not protect donations of technology or services that are otherwise used in the normal course of the recipient's business (for example, general help desk services related to use of a practice's IT). We solicit comment on this approach and whether this proposed limitation would prohibit the donation of cybersecurity technology and related services that are vital to improving the cybersecurity posture of the health care industry.

For the purposes of meeting the proposed requirement at §411.357(bb)(1)(i) that the technology or services are necessary to implement, maintain, or reestablish cybersecurity, we are considering, and seek comment on, whether to deem certain arrangements to satisfy this requirement. (The deeming provision would not affect the

requirement that the technology or services are used predominantly to implement, maintain, or reestablish cybersecurity. Parties would have to show on a case-by-case basis that this requirement is met.) Specifically, if we determine that a deeming provision is appropriate, we would deem donors and recipients to satisfy the requirement that the technology or services are necessary to implement, maintain, or reestablish cybersecurity if the parties demonstrate that the donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework or set of standards. Examples of such frameworks and sets of standards include those developed or endorsed by NIST, another American National Standards Institute-accredited standards body, or an international voluntary standards body such as the International Organization for Standardization. If finalized, the deeming provision would not require compliance with a specific framework or specific set of standards; rather, a deeming provision would merely provide an option for donors to demonstrate that the donation is necessary to implement, maintain, or reestablish cybersecurity. We believe that a deeming provision would provide some assurance to donors and recipients about how to demonstrate that donations are necessary to secure IT systems, devices, and patient data. We solicit comments on incorporating a deeming provision in §411.357(bb)(1)(i), including comments on ways that parties could reliably demonstrate that a donation furthers a recipient's compliance with a written cybersecurity program that reasonably conforms to a widely-recognized cybersecurity framework or set of standards. For example, we seek comments on whether parties could demonstrate that a donation meets the cybersecurity deeming provision through documentation,

certifications, or other methods not proscribed by regulation, as well as what qualifies as a widely recognized cybersecurity framework or set of standards.

At proposed §411.357(bb)(1)(ii), we would require that donors not condition the amount or nature of, or eligibility for, cybersecurity donations on referrals. In other words, we are proposing that a donor could not require, explicitly or implicitly, that a recipient either refer to the donor or recommend the donor's business as a condition of receiving a cybersecurity donation. We understand that the purpose of donating cybersecurity technology and related services is to guard against threats that come from interconnected systems, and we understand and expect that a donor would provide the cybersecurity technology and related services only to physicians that connect to its systems, which includes physicians that refer to the donor. However, this condition would restrict a donor from conditioning the donation on referrals or other business generated.²⁴

Nothing in the proposed requirements of the exception is intended to require a donor to donate cybersecurity technology and related services to every physician that connects to its system. Donors would be able to select recipients in a variety of ways, provided that neither a recipient's eligibility, nor the amount or nature of the cybersecurity technology or related services donated, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For example, a donor could perform a risk assessment of a potential recipient (or require a potential recipient to provide the donor with a risk assessment) before determining whether to make a donation or the scope of a donation. If a donor is a

²⁴ We note that, if a system is only as strong as its weakest link, then even a very low-referring physician's practice poses a cybersecurity risk.

hospital, the hospital might choose to limit donations to physicians who are on the hospital's medical staff. Or, the donor might select recipients based on the type of actual or proposed interface between them. For example, an entity may elect to provide a higher level of cybersecurity technology and services to a physician with whom it has a higher-risk, bi-directional read-write connection than the entity would provide to a physician with whom it has a read-only connection to a properly implemented, standards-based API that enables only the secure transmission of a copy of the patient's record to the physician. We solicit comments on this requirement.

In contrast to the similar requirement in the EHR exception at §411.357(w)(6), the proposed exception for cybersecurity technology and related services does not include a list of selection criteria which, if met, would be deemed not to directly take into account the volume or value of referrals or other business generated by the physician. Our intent in proposing this exception is to remove obstacles to the adoption of cybersecurity in the health care industry in order to address the growing threat of cyberattacks. We are concerned that deeming provisions pertaining to the volume or value of referrals or other business generated may be interpreted as prescriptive requirements. It is our experience that deeming provisions may act as limits on the type or range of items or services that are deemed acceptable. Because we do not want to inhibit legitimate cybersecurity donations that may not fit squarely within an enumerated deeming provision, we are not proposing any deeming provisions pertaining to the requirement at proposed §411.357(bb)(1)(ii). At the same time, we recognize that some parties may prefer the guidance and assurance offered by deeming provisions, even if the deeming provisions are only "safe harbors" and are not requirements of the exception. Therefore, we are

soliciting comments on whether we should include deeming provisions in the exception for cybersecurity donations that are similar to the provisions at §411.357(w)(6). We solicit comments on this approach and any other conditions or permitted conduct we should enumerate in this exception.

We do not propose to restrict the types of entities that may make cybersecurity donations under this exception. Although donating cybersecurity technology and related services would relieve a recipient of a cost that it otherwise would incur, the fraud and abuse risks associated with cybersecurity are different than donations of other valuable technology, such as EHR items and services.

Several commenters to OIG's request for information suggest that technology donations risk making referral sources beholden to the donors. Therefore, we are considering narrowing the scope of entities that may provide remuneration under the exception as we have done in other exceptions, such as the EHR exception. We solicit comments on whether particular types of entities should be excluded from donating cybersecurity technology and related services, and if so, why. Specifically, in past rulemakings we have 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, such as laboratories, and manufacturers or vendors that indirectly furnish items and services used in the care of patients. (For a discussion of our rationale in past rulemakings, see 78 FR 78757 through 78762.) We seek comments as to whether our historical concerns and other considerations regarding direct and indirect patient care apply in the context of cybersecurity donations.

c. Conditions for Recipients

In proposed §411.357(bb)(1)(iii), we are proposing a requirement that neither a potential recipient, nor a potential recipient's practice (including employees or staff members), may make the receipt of cybersecurity technology and related services, or the amount or nature of the technology or services, a condition of continuing to do business with the donor. This requirement mirrors a requirement in the EHR exception at §411.357(w)(5). We solicit comments on this proposed requirement.

We are not proposing to require a recipient contribution under the exception for cybersecurity technology and related services. As we explained previously, with this proposed exception, we seek to remove a barrier to donations that improve cybersecurity throughout the health care industry in response to the critical cybersecurity issues identified in the HCIC Task Force Report, by commenters to the CMS RFI and OIG request for information, and elsewhere. We are proposing to include only those requirements under the proposed exception that we believe are necessary to ensure that the arrangements do not pose a risk of program or patient abuse. In the case of cybersecurity technology and related services, we do not believe that requiring a minimum contribution to the cost by the recipient is necessary or, in some cases, practical. We recognize that the level of services for each recipient might vary, and might be higher or lower each year, each month, or even each week, resulting in the inability of certain physician practices, especially those in rural areas, to make the required contribution, which, in turn, risks the overall cybersecurity of the health ecosystem of which the practices are a part. Similarly, donors may aggregate the cost of certain services across all recipients, such as cybersecurity patches and updates, on a

regular basis, which may result in a contribution requirement becoming a barrier to widespread, low-cost improvements in cybersecurity because of the amount allocated to each recipient. Moreover, if physicians are not required to utilize resources to contribute to the cost of cybersecurity that benefits both the donor and the physician, they will instead have the flexibility to contribute to the overall cybersecurity of the health care system by using available resources for otherwise unprotected cybersecurity-related hardware that is core to their business, including updates or replacements for outdated legacy hardware that may pose a cybersecurity risk.

Importantly, although the proposed exception would not require a recipient to contribute to the cost of donated cybersecurity technology or related services, the exception would not prohibit donors from requiring such a contribution. Donors are free to require recipients to contribute to the cost, and such contributions would be excepted under proposed §411.357(bb), provided that the arrangement satisfies all other requirements of the proposed exception, including the requirement at proposed §411.357(bb)(ii) regarding determinations of the eligibility for or the amount or nature of the donated cybersecurity technology and related services. For example, if a donor gave a full suite of cybersecurity technology and related services at no cost to a high-referring practice but required a low-referring practice to contribute 20 percent of the cost, then the donor could violate the conditions at proposed §411.357(bb)(1)(ii).

d. Written Documentation

At §411.357(bb)(iv), we are proposing to require that the arrangement is documented in writing. Although we would not interpret this requirement to mean that every item of cybersecurity technology and every potential related cybersecurity service

must be specified in the documentation evidencing the arrangement, we expect that written documentation of the arrangement would identify the recipient of the donation and include the following: a general description of the cybersecurity technology and related services provided to the recipient over the course of the arrangement, the timeframe of donations made under the arrangement, a reasonable estimate of the value of the donation(s), and, if applicable, any financial responsibility for the cost of the cybersecurity technology and related services that is shared by the recipient. We are not requiring the parties to document the arrangement in a signed contract, because we believe that this requirement may lead to inadvertent violation of the physician self-referral law, especially in situations where donors need to act quickly and decisively—prior to obtaining the signature of each physician who is considered a party to the arrangement—to provide needed cybersecurity technology or related services to recipients. However, we note that a written agreement between the parties that includes the identified elements would satisfy the proposed writing requirement at §411.357(bb)(1)(iv). We solicit comments on whether we should specify in regulation which terms should be required to be in writing and, if so, whether they should be the terms discussed in this section II.E.2.d. or whether additional or different terms should be required. We also seek comment regarding whether we should require a signed writing between the parties to the arrangement.

e. Alternative Proposal for Inclusion of Cybersecurity Hardware Donations

We are also proposing and solicit comments on an alternative approach that would allow the donation of cybersecurity hardware, provided that an additional requirement is satisfied. Under this alternative proposal, a protected donation could also

include cybersecurity hardware that a donor has determined is reasonably necessary based on cybersecurity risk assessments of its own organization and the potential recipient. We believe that this alternative proposal would provide donors and recipients the ability to provide most types of technology necessary to bolster cybersecurity without creating a risk of program or patient abuse because the hardware would be necessary to implement and maintain effective cybersecurity if it was identified in the cybersecurity risk assessments.

This alternative proposal builds on existing legal requirements and best practices related to information security generally and the health care industry more specifically. NIST Special Publication 800-30, which does not directly apply to the health care industry, but represents industry standards for information security practices, explains that the purpose of a risk assessment is to inform decision makers and support risk responses.²⁵ According to NIST, a risk assessment does so by identifying: (i) relevant threats to organizations or threats directed through organizations against other organizations; (ii) vulnerabilities both internal and external to organizations; (iii) impact ([that is], harm) to organizations that may occur given the potential for threats exploiting vulnerabilities; and (iv) likelihood that harm will occur. The end result is a determination of risk ([that is], typically a function of the degree of harm and likelihood of harm occurring). With respect to health care organizations, the HHS Office for Civil Rights has explained that conducting a risk analysis is the first step in identifying and implementing safeguards that comply with and carry out the standards and implementation specifications in the Health Information Technology for Economic and

²⁵ 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>.

Clinical Health (HITECH) Act (Title XIII of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5). (For more information, see HHS Guidance on Risk Analysis at <https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html?language=es>.) We believe that risk assessments are a key component to developing effective organization-wide risk management for information security and that, when conducted consistent with industry standards, would provide a reasonable basis for donors to identify risks and threats to their organizational information security that could be mitigated by donating cybersecurity hardware to physicians who connect with their IT systems. We expect that donations made in response to a risk or threat identified through a cybersecurity risk assessment would satisfy the core requirement of the proposed exception; that is, that the donated cybersecurity technology and related services are necessary to implement and maintain effective cybersecurity.

Under this alternative proposal, a donor must have a cybersecurity risk assessment that identifies the recipient as a risk to its cybersecurity. In addition, the recipient must have a cybersecurity risk assessment (which may be provided by the donor if all the requirements of proposed §411.357(bb) are satisfied) that would provide a reasonable basis to determine that the donated cybersecurity hardware is needed to address a risk or threat identified by a risk assessment. Both risk assessments must be conducted in a manner consistent with industry standards. We are proposing to base our definition of “risk assessment” on NIST Special Publication 800-30 and we are soliciting comment on whether such a definition would be sufficient for purposes of our proposed exception and the alternative proposal to allow donations of hardware. We are also soliciting comment on whether we should include specific standards for cybersecurity risk assessments as

independent requirements of the exception at §411.357(bb) if we finalize this alternative proposal, and whether the requirement that any donated cybersecurity hardware must be necessary and used predominantly for cybersecurity obviates the need for requiring that the recipient has a cybersecurity risk assessment. Finally, we are interested in commenters' perspectives as to whether the requirement that both the donor and recipient have cybersecurity risk assessments: (1) is necessary in light of other laws and regulations that require similar risk assessments; and (2) would inhibit donations of critical cybersecurity technology and related services by diverting resources to the procurement of such risk assessments that could otherwise be used to improve the cybersecurity of the parties to the arrangement or the health care ecosystem as a whole.

As described previously in this section II.E.2., the proposed exception for cybersecurity technology and related services would allow an entity to donate a cybersecurity risk assessment, provided that all of the requirements of the exception are satisfied. One goal of our proposed exception is to eliminate certain barriers to the donation of cybersecurity and related services, in order to increase the cybersecurity of all health care organizations and improve their cybersecurity practices. We believe that protecting the donation of cybersecurity hardware that is reasonably based on the risks or threats identified in a risk assessment (whether or not the risk assessment is donated by the donor) would lead to improved cybersecurity for all health care organizations, especially those organizations that cannot afford to retain dedicated in-house information security personnel or designate an IT staff member with cybersecurity as a collateral duty. We expect that risk assessment practices vary across the health care industry and may be dependent on the size and sophistication of the organization. We are interested in

comments that describe the existing practices of potential donors and recipients with respect to the conducting of risk assessments that would provide a reasonable basis to determine that a donation of cybersecurity hardware is reasonable and necessary.

We are considering additional safeguards in the event we finalize this alternate proposal. For instance, we might limit the types of cybersecurity hardware permitted under the alternative proposal by defining “hardware” for purposes of §411.357(bb). We are interested in comments that explain what types of hardware are necessary for effective cybersecurity. Even if we finalize this alternative proposal, multifunctional hardware still would be prohibited because it would not be necessary and predominantly used to implement and maintain effective cybersecurity, as required under proposed §411.357(bb)(1)(i). We are also considering requiring a 15 percent financial contribution from the recipient, similar to the EHR exception at §411.357(w)(4). We are interested in comments on this approach, whether a 15 percent financial contribution would be sufficient to ensure that the recipient would use the donated hardware to improve its cybersecurity posture as well as that of the donor, and whether a different financial contribution percentage would be more appropriate and why. We are proposing to exempt small and rural providers from the financial contribution requirement if we finalize this alternative proposal, and we are interested in comments on this approach. Finally, we are soliciting comments regarding whether we should limit the amount or type of donated hardware by establishing a cap on the value of the donated hardware, either in lieu of or in conjunction with the 15 percent financial contribution.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Exceptions to the Physician Self-Referral Law Related to Compensation (§411.357)

We are proposing new exceptions for compensation arrangements that facilitate value-based health care delivery and payment in a value-based enterprise (§411.357(aa)). A value-based enterprise would be required to have a governing document that describes the enterprise and how its VBE participants intend to achieve the value-based purposes of that enterprise (see the proposed definition of “value-based enterprise” at §411.351). The proposed exception for value-based arrangements with meaningful downside

financial risk to the physician at §411.357(aa)(2) would require a description of the nature and extent of the physician's downside financial risk to be set forth in writing. The proposed exception for value-based arrangements at §411.357(aa)(3) would require the arrangement to be set forth in writing and signed by the parties. All proposed exceptions at §411.357(aa) would require records of the methodology for determining and the actual amount of remuneration paid under the arrangement to be maintained for a period of at least 6 years. We have also proposed a new exception for cybersecurity technology and related services (§411.357(bb)), and arrangements under this new exception would have to be documented in writing. Finally, we have proposed streamlining the parties who must sign the writing in the exception for physician recruitment (§411.357(e)). The burden associated with writing and signature requirements would be the time and effort necessary to prepare written documents and obtain signatures of the parties. The burden associated with record retention requirements would be the time and effort necessary to compile and store the records.

While the writing, signature, and record retention requirements are subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons without federal regulation during the normal course of their activities. Specifically, we believe that, for normal business operations purposes, health care providers and suppliers document their financial arrangements with physicians and others and retain these documents in order to identify and be able to enforce the legal obligations of the parties. Therefore, we believe that the writing, signature and record retention requirements should be considered usual and customary business practices.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS-1720-P

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement (or Analysis) (RIA)

A. Statement of Need

This proposed rule aims to remove potential regulatory barriers to care coordination and value-based care created by the physician self-referral law. Currently, certain beneficial arrangements that would advance the transition to value-based care and the coordination of care among providers in both the Federal and commercial sectors may be impermissible under the physician self-referral law. Industry stakeholders have informed us that, because the consequences of noncompliance with the physician self-

referral law are so dire, providers, suppliers, and physicians may be discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth). This proposed rule would address this issue by establishing three new exceptions that would protect certain arrangements for value-based activities between physicians and entities that furnish designated health services in a value-based enterprise. These exceptions would provide critically needed flexibility for physicians and entities to work together while protecting the integrity of the Medicare program. We believe this new flexibility will promote innovation throughout the health care system.

Commenters on the CMS RFI also told us that they currently invest sizeable resources to comply with the physician self-referral law's billing and claims submission prohibitions and thereby avoid its substantial penalties. Our proposals that do not directly address value-based arrangements seek to balance genuine program integrity concerns against this considerable burden. These proposals would reassess our regulations to ensure they appropriately reflect the scope of the statute's reach, establish exceptions for common nonabusive compensation arrangements between physicians and the entities to which they refer Medicare beneficiaries for designated health services, and provide critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral law. We believe these reforms will greatly reduce burden by providing additional flexibility to enable parties to enter into nonabusive arrangements and by making physician self-referral law compliance more straightforward.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule is considered to be economically significant. Pursuant to the Congressional Review Act (5 U.S.C. § 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as a major rule, as defined by 5 U.S.C. § 804(2).

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. For purposes of the RFA, most hospitals and most other providers and suppliers are considered small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. We anticipate that a large portion of affected entities are small based on these standards. The specific affected entities are discussed later in this section. Individuals

and states are not included in the definition of a “small entity.” HHS considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact of revenue on at least five percent of small entities. We are not preparing an analysis for the RFA because we have determined, and the Secretary proposes to certify, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

We determined that this proposed rule does not have a significant impact on small businesses because it would likely reduce, not increase, regulatory burden. This proposed rule would not require existing compliant financial relationships to be restructured. Instead, it would provide important new flexibility to enable parties to create new arrangements that advance the transformation to a value-based health care system and remove regulatory barriers to certain beneficial and nonabusive arrangements, such as the donation of cybersecurity technology and services. It would also reduce burden by clarifying certain key provisions found in current regulations. Also, although we expect entities to incur costs, these costs are estimated to be less than \$1,000 per entity. These costs are unlikely to have an impact of three percent of revenue, and we expect they will be offset by savings resulting from this rule. Overall, this proposed rule is accommodating to legitimate financial relationships while reducing regulatory burden and continuing to protect against program and patient abuse.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that

is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The impact of this rule on small rural hospitals is minimal. In fact, several provisions of the rule benefit small rural hospitals by giving them more flexibility to maintain operations and participate in innovative arrangements that enhance care coordination and advance the transition to a value-based health care system. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. This rule imposes no mandates on state, local, or tribal governments, or on the private sector, and reduces regulatory burden on health care providers and suppliers.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This

proposed rule, if finalized, is expected to be a deregulatory action. We seek comment on the economic impact of this proposed rule, including any potential increase or decrease in utilization, any potential effects due to behavioral changes, or any other potential cost savings or expenses to the Government as a result of this rule.

C. Anticipated Effects

This proposed rule would affect physicians and entities with which they have financial relationships that furnish designated health services payable by Medicare. The following items or services are DHS: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) outpatient speech-language pathology services; (5) radiology and certain other imaging services; (6) radiation therapy services and supplies; (7) durable medical equipment and supplies; (8) parenteral and enteral nutrients, equipment, and supplies; (9) prosthetics, orthotics, and prosthetic devices and supplies; (10) home health services; (11) outpatient prescription drugs; and (12) inpatient and outpatient hospital services. We do not have data on the number of physicians and entities that furnish designated health services payable by Medicare that have financial relationships, but we believe a substantial fraction of Medicare-enrolled physicians, group practices, hospitals, clinical laboratories, and home health agencies are affected by the physician self-referral law. We anticipate that this proposed rule will have significant, ongoing benefits for the affected physicians and entities and the entire health care system.

To estimate the number of entities directly affected by this rule, we use Medicare enrollment data. According to this data, there were 2,039 single or multispecialty clinics or group practices, 3,139 clinical laboratories (billing independently), 2,043 outpatient

physical therapy/speech pathology providers, 2,843 independent diagnostic testing facilities, 11,593 home health agencies, 6,123 inpatient hospitals, 4,233 rural health clinics, 180 comprehensive outpatient rehabilitation facilities, 8,289 federally qualified health centers, and 9,748 medical supply companies enrolled in Medicare in 2017.²⁶ In addition, we estimate that 400 physician practices unassociated with single or multispecialty clinics or group practices will independently review and respond to the rule. We request public comment on the entities affected by the rule.

We anticipate that directly affected entities will review the rule upon finalization in order to determine whether to explore newly permissible value-based arrangements and to take advantage of burden-reducing clarifications provided by the rule. We estimate that all directly affected entities described above that would be eligible to use the proposed rules will review the rule. We estimate that reviewing the final rule will require an average of three hours of time each from the equivalent of a compliance officer and a lawyer.

To estimate the costs associated with this review, we use a 2018 wage rate of \$34.86 for compliance officers and \$69.34 for lawyers from the Bureau of Labor Statistics,²⁷ and we double those wages to account for overhead and benefits. As a result, we estimate total regulatory review costs of \$31.7 million in the first year following finalization of the rule. We seek public comment on these assumptions.

In developing this proposed rule, we have taken great care to ensure that the safeguards against program and patient abuse in our proposed new exceptions impose the

26 CMS Program Statistics, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2017/2017_Providers.html

27 U.S. Department of Labor, Bureau of Labor Statistics, May 2018 National Occupational Employment and Wage Estimates United States, https://www.bls.gov/oes/2018/may/oes_nat.htm.

minimum burden possible while providing full protection against overutilization and other harms against which the physician self-referral law is designed to protect. For example, we believe a value-based enterprise would ordinarily develop a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s), so our requirement would not impose any additional burden. We also believe that parties to an arrangement under which remuneration is paid already keep business records necessary for a variety of purposes, such as income tax filings, records of compliance with state laws (including fee splitting laws), and, for nonprofit entities, justification for tax-exempt status. Therefore, we do not believe the proposed requirement to maintain records of the methodology for determining and the actual amount of remuneration paid under a value-based arrangement for a period of at least 6 years imposes additional burden. In addition, we believe that physicians and entities routinely document their financial arrangements in writing as a common good business practice and so the arrangements can be enforced. For example, we believe that an entity would ordinarily ensure that the details of a shared loss repayment agreement are documented in writing to ensure the arrangement can be enforced under state law. Similarly, we believe that entities that are working together to achieve a purpose would routinely monitor their operations to confirm that their plans are working as intended. We seek comments on these assumptions.

The new exceptions for arrangements that facilitate value-based health care delivery and payment have numerous benefits that would reduce costs and improve quality not only for Medicare and its beneficiaries but to patients and the health care system in general. For example, these new exceptions provide important new flexibility

for physicians and entities to work together to improve patient care and reduce costs. This increased flexibility would provide new opportunities for the private sector to develop and implement cost-saving, quality-improving programs that might currently be impermissible. We anticipate that implementation of improvements and efficiencies such as care redesign protocols resulting from private sector innovation could have a beneficial effect on the care provided to Medicare beneficiaries and thereby result in savings for beneficiaries and the Trust Funds. We believe that these new exceptions would also increase participation in Innovation Center models because, unlike the fraud and abuse waivers that have been issued for certain Innovation Models, the exceptions would not expire and would not be narrowly designed to apply solely to one specific model. We anticipate that this increased participation would bolster the cost savings and quality improvements of Innovation Center models. We also believe that applying the new exceptions would make compliance more straightforward for physicians and entities participating in Innovation Center models, thus resulting in cost savings for these parties. In addition, we believe that the new exceptions for arrangements that facilitate value-based health care delivery and payment would ensure that the physician self-referral law continues to provide meaningful protection against overutilization and other harms, thus preventing increased Medicare expenditures and associated beneficiary liability. We lack data to quantify these effects and seek public comment on these impacts.

We believe that the clarifications and regulatory revisions of key terminology (specifically, the terms “commercially reasonable” and “fair market value,” the volume or value standard, and the other business generated standard) discussed in section II.B. of this proposed rule would have significant, ongoing benefits to all physicians and entities

affected by the physician self-referral law. These terms are used throughout the physician self-referral regulations. Commenters on the CMS RFI indicated that additional guidance on these terms is necessary to reduce the complexity of structuring financial arrangements to comply with the physician self-referral law.

We anticipate that the proposed changes to decouple the physician self-referral law regulations from the anti-kickback statute and federal and state laws or regulations governing billing or claims submission would reduce burden by making compliance more straightforward for physicians and entities. We stress that the anti-kickback statute and billing laws remain in full force and effect, so those laws would continue to protect against program and patient abuse. We anticipate that our proposed changes to the definitions of “designated health services,” “physician,” and “remuneration;” the proposed ownership and investment interest provisions in §411.354(b); and the proposed exception for remuneration unrelated to the provision of designated health services would reduce compliance burden by providing protection for nonabusive financial relationships. Our proposed changes for the exception for payments by a physician and the exception to fair market value would make these exceptions available to protect financial arrangements that must currently be protected by other exceptions that are more complicated and burdensome to meet. We anticipate that this added flexibility would provide substantial burden reduction through reduced compliance costs. We note that RFI commenters expressed concern about the need for regulatory change to reduce burden on many of these matters.

We have also proposed numerous other changes that while relatively minor, would reduce burden. For example, we believe that the modifications to the group

practice rules provide useful clarification to physicians and group practices. We anticipate that even these minor changes would provide a beneficial effect on the burden to comply with the group practice rules. We anticipate that our proposed changes relating to isolated transactions, the period of disallowance, the special rules on compensation arrangements, the exceptions for rental of office space and rental of office equipment, the exception for physician recruitment, and the exception for assistance to compensate a nonphysician practitioner would also have a beneficial impact by reducing the existing burden on physicians and entities through the provision of additional guidance and clarifications. We lack data to quantify these effects and seek public comment on these impacts.

The American Hospital Association estimates compliance costs faced by hospitals.²⁸ They estimate \$350,000²⁹ in annual costs for an average hospital to comply with fraud and abuse regulations, which include the physician self-referral rules. To estimate aggregate fraud and abuse compliance costs, we multiply this figure by the number of Medicare enrolled hospitals, which implies \$2.1 billion in total annual costs across these hospitals. Based on RFI comments, compliance with the physician self-referral regulations comprises a substantial fraction of these costs. Furthermore, we anticipate that clarifications provided in this rule will substantially reduce the complexity of compliance for affected entities, greatly reducing the burden that they face. As a result, we expect this rule will substantially reduce net fraud and abuse compliance burden for affected entities, although we lack data to quantify these estimates.. If this rule reduces this burden for hospitals by 1.5 percent, this burden reduction will offset all

28 <https://www.aha.org/sites/default/files/regulatory-overload-report.pdf>

29 Note that the figure is adjusted for inflation between 2017 and 2018.

first year costs of the rule and generate substantial net savings in subsequent years. We believe it is very likely that burden reduction at hospitals will exceed this level, and therefore tentatively believe that this rule will be considered a deregulatory action. We note that hospitals represent a fraction of entities affected by this rule, and burden is likely to decline substantially for other categories of entities affected by this rule. We seek public comment on the extent to which this rule will reduce compliance burden for hospitals and entities other than hospitals.

Our proposed modifications to the EHR exception are modest and would clarify that protection for certain cybersecurity technology is included as part of an electronic health records arrangement, update provisions regarding interoperability to align with newer CMS and ONC standards in a manner that is not expected to increase costs as a result of this rulemaking, and remove the sunset date. The EHR exception would continue to be available to physicians and entities other than laboratories. We would expect the same entities that are currently using the EHR exception to continue to use the exception. We anticipate that these proposed changes would result in an incremental reduction in compliance burden.

In section II.E. of this proposed rule, we discuss new exceptions for limited remuneration to a physician and cybersecurity technology. We anticipate that the new exception for limited remuneration to a physician would ease compliance burden because it would allow entities to compensate a physician for items or services provided by the physician without being subject to all the documentation and certain other requirements of existing exceptions to the physician self-referral law. We believe this new exception would also provide additional flexibility where these arrangements are not covered by an

existing exception. We anticipate that the cybersecurity exception would be widely used by physicians, group practices, and hospitals. We believe this proposed exception would help to address the growing threat of cyberattacks that infiltrate data systems and corrupt or prevent access to health records and other information essential to the safe and effective delivery of health care. We lack data to quantify these effects and seek public comment on these impacts.

D. Alternatives Considered

We carefully considered the alternative of maintaining the status quo and not pursuing regulatory action. However, we believe that the transition to a value-based healthcare system is urgently needed due to unsustainable costs inherent in the current volume-based system. We believe this proposed rule would address the critical need for additional flexibility that is necessary to advance the transition to value-based care and improve the coordination of care among providers in both the Federal and commercial sectors.

We also considered proposing to limit the new exceptions for arrangements that facilitate value-based health care delivery and payment to CMS- sponsored models or establishing separate exceptions with different criteria for arrangements that exist outside CMS-sponsored models. However, we believe that in their current state, the physician self-referral regulations discourage the development and adoption of rewards that encourage change on a broad scale, across all patient populations and payor types, and over indefinite periods of time. In addition, we considered establishing an exception to protect care coordination activities performed outside of a value-based enterprise. We rejected this alternative due to program integrity concerns that could exist without the

incentives and protections inherent in a value-based enterprise.

We considered including provisions in the proposed exceptions for value-based arrangements that would require compensation to be set in advance, fair market value, and not 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. We are concerned, however, that the inclusion of such requirements would conflict with our goal of dismantling and addressing regulatory barriers to value-based care transformation. We further believe that the disincentives for overutilization, stinting on patient care, and other harms the physician self-referral law was intended to address that are built into the proposed value-based definitions will operate in tandem with the requirements included in the proposed exceptions and be sufficient to protect against program and patient abuse. We are also considering whether to exclude laboratories and DMEPOS suppliers from the definition of VBE participant. It is not clear to us that laboratories and DMEPOS suppliers have the direct patient contacts that would justify their inclusion as parties working under a protected value-based arrangement to achieve the type of patient-centered care that is a core tenet of care coordination and a value-based health care system.

Through our own experience administering the physician self-referral law regulations and our thorough analysis of CMS RFI comments, we recognize the urgent and compelling public policy need for additional guidance on the physician self-referral law. In preparing this rule, we conducted an in-depth review of our existing regulations to identify those matters that might benefit from additional guidance. We have also taken great care to provide this guidance in the clearest, most straightforward manner

possible. For example, we considered addressing the need for guidance on the applicability of the physician self-referral law to referrals for inpatient hospital services after admission through modifying the definition of “referral” rather than the definition of “designated health services.” We are concerned that modifying the definition of “referral” could have a broader effect and would not be as clear. We have also carefully weighed each proposal to ensure that it does not pose a risk of program or patient abuse. For example, we considered whether to protect donations of multi-use technology or services in the proposed cybersecurity exception but are concerned that they may pose a risk of program or patient abuse. We seek comments on these regulatory alternatives.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR part 411 as set forth below:

PART 411--EXCLUSIONS FORM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

1. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, 1395hh, and 1395nn.

Subpart J—Financial Relationships Between Physicians and Entities Furnishing Designated Health Services

2. Amend §411.351 by--
 - a. Revising the introductory text;
 - b. Adding definitions for "Commercially reasonable" and "Cybersecurity";
 - c. In the definition for "Designated health services (DHS)" by revising paragraph (2);
 - d. Removing the definition for "Does not violate the anti-kickback statute";
 - e. Revising the definition for "Electronic health record";
 - f. Revising the definition for "Fair market value";
 - g. Adding the definition for "General market value";
 - h. Revising the definition for "Interoperable";
 - i. Adding the definition for "Isolated financial transaction";
 - j. Removing the definition for "Isolated transaction";
 - k. In the definition for "List of CPT/HCPCS Codes" by removing the term "Web site" is and adding in its place the term " website";
 - l. In the definition for "Locum tenens physician (or substitute physician)" by removing the phrase "is a physician" and adding in its place the phrase "means a physician";

- m. Revising the definition for "Physician";
- n. In the definition of "Referral" by adding paragraph (4);
- o. In the definition for "Remuneration" by revising paragraphs (2) introductory text and (3)(iii);
- p. Adding the definition for "Target patient population";
- q. Revising the definition for "Transaction"; and
- r. Adding definitions for "Value-base activity", "Value-based arrangement", "Value-based enterprise (VBE)", "Value-based purpose", and "VBE participant".

The revisions and additions read as follows:

§411.351 Definitions.

The definitions in this subpart apply only for purposes of section 1877 of the Act and this subpart. As used in this subpart, unless the context indicates otherwise:

* * * * *

Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.

* * * * *

Cybersecurity means the process of protecting information by preventing, detecting, and responding to cyberattacks.

Designated health services (DHS) * * *

(2) Except as otherwise noted in this subpart, the term “designated health services” or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services

that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS).

* * * * *

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.

* * * * *

Fair market value means—

- (1) *General.* The value in an arm's-length transaction, with like parties and under like circumstances, of like assets or services, consistent with the general market value of the subject transaction.

- (2) *Rental of equipment.* With respect to the rental of equipment, the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction.

(3) *Rental of office space.* With respect to the rental of office space, the value in an arm's-length transaction, with like parties and under like circumstances, of rental property for general commercial purposes (not taking into account its intended use), without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

General market value means—

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

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

* * * * *

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 Public Health Service Act.

Isolated financial transaction—(1) Isolated financial transaction means a transaction involving a single payment between two or more persons or a transaction that involves integrally

related installment payments, provided that—

(i) The total aggregate payment is fixed before the first payment is made and does not take into account the volume or value of referrals or other business generated by the physician; and

(ii) The payments are immediately negotiable, guaranteed by a third party, secured by a negotiable promissory note, or subject to a similar mechanism to ensure payment even in the event of default by the purchaser or obligated party.

(2) An isolated financial transaction includes a one-time sale of property or a practice, or similar one-time transaction, but does not include a single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).

* * * * *

Physician has the meaning set forth in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart.

* * * * *

Referral * * *

(4) A referral is not an item or service for purposes of section 1877 of the Act and this subpart.

* * * * *

Remuneration * * *

(2) The furnishing of items, devices, or supplies that are, in fact, used solely for one or more of the following purposes:

* * * * *

(3) * * *

(iii) The amount of the payment is set in advance, does not exceed fair market value, and is not determined in any manner that takes into account the volume or value of any referrals.

* * * * *

Target patient population means an identified patient population selected by a value-based enterprise or its VBE participants based on legitimate and verifiable criteria that—

(1) Are set out in writing in advance of the commencement of the value-based arrangement; and

(2) Further the value-based enterprise's value-based purpose(s).

Transaction means an instance or process of two or more persons or entities doing business.

Value-based activity—(1) Means any of the following activities, provided that the activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise:

- (i) The provision of an item or service;
- (ii) The taking of an action; or
- (iii) The refraining from taking an action.

(2) The making of a referral is not a value-based activity.

Value-based arrangement means an arrangement for the provision of at least one value-based activity for a target patient population between or among—

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

Value-based enterprise (VBE) means two or more VBE participants—

- (1) Collaborating to achieve at least one value-based purpose;

(2) Each of which is a party to a value-based arrangement with the other or at least one other VBE participant in the value-based enterprise;

(3) That have an accountable body or person responsible for financial and operational oversight of the value-based enterprise; and

(4) That have a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose(s).

Value-based purpose means—

(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 means an individual or entity that engages in at least one value-based activity as part of a value-based enterprise.

3. Section 411.352 is amended by revising paragraph (i) to read as follows:

§411.352 Group practice.

* * * * *

(i) *Special rules for profit shares and productivity bonuses.* (1) *Overall profits.*

(i) Notwithstanding paragraph (g) of this section, a physician in the group practice may be paid a share of overall profits of the group that is indirectly related to the volume or value of the physician's referrals.

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

(iii) Overall profits must be divided in a reasonable and verifiable manner. The share of overall profits will be deemed not to relate directly to the volume or value of referrals if one of the following conditions is met:

(A) Overall profits are divided *per capita* (for example, per member of the group or per physician in the group).

(B) Overall profits derived from designated health services are distributed based on the distribution of the group's revenues attributed to services that are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services constitute less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(2) *Productivity bonuses.* (i) Notwithstanding paragraph (g) of this section, a physician in the group may be paid a productivity bonus based on services that he or she has personally performed, or services "incident to" such personally performed services, that is indirectly related to the volume or value of the physician's referrals (except that the bonus may directly relate to the volume or value of referrals by the physician if the referrals are for services "incident to" the physician's personally performed services).

(ii) A productivity bonus must be calculated in a reasonable and verifiable manner. A productivity bonus will be deemed not to relate directly to the volume or value of referrals if one

of the following conditions is met:

(A) The productivity bonus is based on the physician's total patient encounters or the relative value units (RVUs) personally performed by the physician. (The methodology for establishing RVUs is set forth in §414.22 of this chapter.)

(B) The services on which the productivity bonus is based are not designated health services and would not be considered designated health services if they were payable by Medicare.

(C) Revenues derived from designated health services are less than 5 percent of the group's total revenues, and the portion of those revenues distributed to each physician in the group constitutes 5 percent or less of his or her total compensation from the group.

(3) *Value-based enterprise participation.* Profits from designated health services that are directly attributable to a physician's participation in a value-based enterprise, as defined in §411.351, are distributed to the participating physician.

(4) *Supporting documentation.* Supporting documentation verifying the method used to calculate the profit share or productivity bonus under paragraphs (i)(1), (2), and (3) of this section, and the resulting amount of compensation, must be made available to the Secretary upon request.

4. Section 411.353 is amended--

- a. By revising paragraph (c)(1);
- b. In paragraph (f)(1)(i) by removing “;” and adding in its place “; and”;
- c. In paragraph (f)(1)(ii) by removing “; and” and adding in its place a period;
- d. By removing paragraphs (f)(1)(iii) and (g).

The revisions read as follows:

§411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(c) * * *

(1) Except as provided in paragraph (e) of this section, no Medicare payment may be made for a designated health service that is furnished pursuant to a prohibited referral.

* * * * *

5. Section 411.354 is amended--

- a. In paragraph (b)(3)(iv) by removing “; or” and adding in its place “;”;
- b. In paragraph (b)(3)(v) by removing the period at the end of the paragraph and adding in its place “;”;
- c. By adding paragraphs (b)(3)(vi) and (vii);
- d. By revising paragraph (c)(2)(ii);
- e. In paragraph (b)(3)(iv) by removing “.” and adding in its place “;”;
- f. By adding paragraph (c)(4);
- g. By revising paragraphs (d)(2) through (4);
- h. By adding paragraphs (d)(5) and (6); and
- i. Adding paragraph (e)(3).

The additions and revisions read as follows:

§411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(b) * * *

(3) * * *

(vi) A titular ownership or investment interest that excludes the ability or right to receive

the financial benefits of ownership or investment, including, but not limited to, the distribution of profits, dividends, proceeds of sale, or similar returns on investment; or

(vii) An interest in an entity that arises from an employee stock ownership plan (ESOP) that is qualified under Internal Revenue Code section 401(a).

(c) * * *

(2) * * *

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section. If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the nonownership or noninvestment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii));

* * * * *

(4) *Exceptions applicable to indirect compensation arrangements.* (i) *General.* Except as provided in this paragraph (c)(4) of this section, only the exceptions at §§411.355 and 411.357(p) are applicable to indirect compensation arrangements.

(ii) *Special rule for indirect compensation arrangements involving value-based arrangements.* When an unbroken chain described in paragraph (c)(2)(i) of this section includes a value-based arrangement (as defined in §411.351) to which the physician (or the physician organization in whose shoes the physician stands under this paragraph) is a direct party, only the exceptions at §§411.355, 411.357(p), and 411.357(aa) are applicable to the indirect compensation arrangement.

(d) * * *

(2) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account the volume or value of referrals if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals.

(3) Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account other business generated between the parties or other business generated by the referring physician if the compensation is fair market value for items or services actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business (except for services personally performed by the physician, which are not considered “other business generated” by the physician).

(4) If a physician's compensation under a *bona fide* employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, all of the following conditions must be met.

(i) The compensation, or a formula for determining the compensation, is set in advance for the duration of the arrangement. Any changes to the compensation (or the formula for determining the compensation) must be made prospectively.

(ii) The compensation is consistent with the fair market value of the physician's services.

(iii) The compensation arrangement otherwise complies with an applicable exception at §§411.355 or 411.357.

(iv) The compensation arrangement complies with both of the following conditions:

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

(B) The requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment.

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, personal service arrangement, or managed care contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, personal service arrangement, or managed care contract.

(5)(i) Compensation from an entity furnishing designated health services to a physician

(or immediate family member of the physician) takes into account the volume or value of referrals only if—

(A) The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals to the entity; or

(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(ii) Compensation from an entity furnishing designated health services to a physician (or immediate family member of the physician) takes into account the volume or value of other business generated only if—

(A) The formula used to calculate the physician's (or immediate family member's) compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the physician's generation of other business for the entity; or

(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(iii) For purposes of applying this paragraph (d)(5), a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases.

(iv) This paragraph (d)(5) applies only to section 1877 of the Act.

(6)(i) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of referrals only if—

(A) The formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity; or

(B) There is a predetermined, direct correlation between the physician's prior referrals to the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(ii) Compensation from a physician (or immediate family member of the physician) to an entity furnishing designated health services takes into account the volume or value of other business generated only if—

(A) The formula used to calculate the entity's compensation includes other business generated by the physician for the entity as a variable, resulting in an increase or decrease in the entity's compensation that negatively correlates with the physician's generation of other business for the entity; or

(B) There is a predetermined, direct correlation between the other business previously generated by the physician for the entity and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(iii) For purposes of applying this paragraph (d)(6), a negative correlation between two variables exists when one variable increases as the other variable decreases, or when one variable

decreases as the other variable increases.

(iv) This paragraph (d)(6) applies only to section 1877 of the Act.

(e) * * *

(3) *Special rule on writing and signature requirements.* In the case of any requirement in this subpart for a compensation arrangement to be in writing and signed by the parties, the writing requirement or the signature requirement is satisfied if—

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the writing or signature requirement of the exception; and

(ii) The parties obtain the required writing(s) or signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant with the requirements of the applicable exception.

6. Section 411.355 is amended by--

- a. Removing and reserving paragraph (b)(4)(v);
- b. Revising paragraphs (c)(5), and (e)(1)(ii)(C);
- c. Adding paragraph (e)(1)(ii)(D);
- d. Removing and reserving paragraphs (e)(1)(iv), (f)(3), (f)(4), (g)(2), (g)(3), (h)(2), (h)(3), (i)(2), (i)(3), and (j)(1)(iv).

The revisions read as follows:

§411.355 General exceptions to the referral prohibition related to both ownership/investment and compensation.

* * * *

(b) * * *

(4) * * *

(v) [Reserved]

(c) * * *

(5) A coordinated care plan (within the meaning of section 1851(a)(2)(A) of the Act) offered by a Medicare Advantage organization in accordance with a contract with CMS under section 1857 of the Act and part 422 of this chapter.

(e) * * *

(1) * * *

(ii) * * *

(C) The total compensation paid by each academic medical center component is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician within the academic medical center.

(D) If any compensation paid to the referring physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4).

* * * *

(iv) [Reserved]

* * * *

(f) * * *

(3) [Reserved]

(4) [Reserved]

* * * *

(g) * * *

(2) [Reserved]

(3) [Reserved]

* * * *

(h) * * *

(2) [Reserved]

(3) [Reserved]

* * * *

(i) * * *

(2) [Reserved]

(3) [Reserved]

(j) * * *

(1) * * *

(iv) [Reserved]

* * * *

7. Section 411.357 is amended--

- a. By revising paragraphs (a)(3), (a)(5)(i), (b)(2), (b)(4)(i), (c)(2)(ii);
- b. By adding paragraph (c)(5);
- c. By revising paragraph (d)(1)(v);
- d. By adding paragraph (d)(1)(viii);
- e. By revising paragraph (d)(2) introductory text;
- f. By adding paragraph (d)(2)(iv);
- g. By revising paragraphs (e)(1)(iii) and (e)(4)(i) and (v);
- h. By removing paragraph (e)(4)(vii);

- i. By revising paragraphs (e)(6)(i), (f)(1) and (3), (g), and (h)(5);
- j. By adding paragraph (h)(7);
- k. By revising paragraph (i)(2);
- l. Adding paragraph (i)(3);
- m. By removing and reserving paragraph (j)(3);
- n. By removing paragraph (k)(1)(iii);
- o. In paragraph (k)(2), by removing the term "Web site" and adding in its place the term "website";
- p. By revising paragraphs (l) and (m)(1);
- q. In paragraph (m)(2) by removing the term " Web site" and adding in its place the term " website";
- r. In paragraph (m)(3) by removing the term" Web site" and adding in its place the term " website";
- s. In paragraph (m)(5) by removing the term " Web site" and adding in its place the term " website";
- t. By removing and reserving paragraph (m)(7);
- u. By revising paragraph (n);
- v. By removing paragraph (p)(3);
- w. By revising paragraph (r)(2)(iv);
- x. By removing paragraph (r)(2)(x);
- y. By removing and reserving paragraph (s)(5);
- z. By removing paragraph (t)(3)(iv);
- aa. By removing and reserving paragraph (u)(3);

- bb. By revising paragraphs (w) introductory text, (w)(2), (3), and (6) introductory text.
- cc. By removing paragraphs (w)(11) through (13);
- dd. By revising paragraphs (x)(1) and (4);
- ee. In paragraph (x)(7)(ii) introductory text by removing the phrase "patient care services" is adding in its place the phrase "NPP patient care services";
- ff. In paragraph (x)(7)(ii)(A) by removing the phrase "patient care services" and adding in its place the phrase "NPP patient care services";
- gg. By revising paragraph (y)(6)(i);
- hh. By removing and reserving paragraph (y)(8); and
- ii. By adding paragraphs z, aa, and bb.

The revisions and additions read as follows:

§411.357 Exceptions to the referral prohibition related to compensation arrangements.

(a) * * *

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. For purposes of this paragraph (a), exclusive use means that the lessee (and any other lessees of the same office space) uses the office space to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an

invitee of the lessee to use the office space.

* * * * *

(5) * * *

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

* * * * *

(b) * * *

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor). For purposes of this paragraph (b), exclusive use means that the lessee (and any other lessees of the same equipment) uses the equipment to the exclusion of the lessor (or any person or entity related to the lessor). The lessor (or any person or entity related to the lessor) may not be an invitee of the lessee to use the equipment.

* * * * *

(4) * * *

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

* * * * *

(c) * * *

(2) * * *

(ii) Except as provided in paragraph (c)(4) of this section, is not determined in any manner that takes into account the volume or value of referrals by the referring physician.

* * * * *

(5) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4).

(d) * * *

(1) * * *

(v) The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined in §411.351), is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

* * * * *

(viii) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4).

(2) *Physician incentive plan exception.* In the case of a physician incentive plan (as defined at §411.351) between a physician and an entity (or downstream contractor), the compensation may be determined in any manner (through a withhold, capitation, bonus, or otherwise) that takes into account the volume or value of referrals or other business generated between the parties, if the plan meets the following requirements:

* * * * *

(iv) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4).

(e) * * *

(1) * * *

(iii) The amount of remuneration under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the physician or other business generated between the parties; and

* * * *

(4) * * *

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice if the remuneration is provided indirectly to the physician through payments made to the physician practice and the physician practice does not pass directly through to the physician all of the remuneration from the hospital.

* * * *

(v) The remuneration from the hospital under the arrangement is not determined in any manner that takes into account the volume or value of actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital.

* * * *

(6) * * *

(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

* * * *

(f) * * *

(1) The amount of remuneration under the isolated financial transaction is—

(i) Consistent with the fair market value of the isolated financial transaction; and

(ii) Not determined in any manner that takes into account the volume or value of referrals by the referring physician or other business generated between the parties.

* * * * *

(3) There are no additional transactions between the parties for 6 months after the isolated financial transaction, except for transactions that are specifically excepted under the other provisions in §§411.355 through 411.357 and except for commercially reasonable post-closing adjustments that do not take into account the volume or value of referrals or other business generated by the referring physician.

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

(1) The remuneration is not determined in any manner that takes into account the volume or value of the physician's referrals; and

(2) The remuneration is for an item or service that is not related to the provision of patient care services.

(3) For purposes of this 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.

(h) * * *

(5) The compensation paid over the term of the agreement is consistent with fair market value, and the compensation per unit of service is fixed in advance and is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

* * * *

(7) If remuneration to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the arrangement satisfies the requirements of §411.354(d)(4).

(i) * * *

(2) To an entity as compensation for any other items or services—

(i) That are furnished at a price that is consistent with fair market value; and

(ii) To which the exceptions in paragraphs (a) through (h) of this section are not applicable.

(3) For purposes of this paragraph (i), “services” means services of any kind (not merely those defined as “services” for purposes of the Medicare program in §400.202 of this chapter).

* * * *

(j) * * *

(3) [Reserved]

* * * *

(l) *Fair market value compensation.* Compensation resulting from an arrangement

between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in §411.352) for the provision of items or services or for the use of office space or equipment, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items, services, office space, or equipment, all of which are specified in writing.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items, services, office space, or equipment during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items, services, office space, or equipment do not change.

(3) The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of office space or equipment may not be determined using a formula based on—

(i) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(ii) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(4) The arrangement is commercially reasonable (taking into account the nature and scope of the transaction).

(5) [Reserved]

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

(7) The arrangement satisfies the requirements of §411.354(d)(4) in the case of—

(i) Remuneration to the physician that is conditioned on the physician's referrals to a particular provider, practitioner, or supplier; or

(ii) Remuneration paid to the group of physicians that is conditioned on one of the group's physician's referrals to a particular provider, practitioner, or supplier.

(m) * * *

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in any manner that takes into account the volume or value of referrals or other business generated between the parties.

* * * * *

(7) [Reserved]

* * * * *

(n) *Risk-sharing arrangements.* Compensation pursuant to a risk-sharing arrangement (including, but not limited to, withholds, bonuses, and risk pools) between a MCO or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan. For purposes of this paragraph (n), "health plan" and "enrollees" have the meanings set forth in §1001.952(l) of this title.

* * * * *

(r) * * *

(2) * * *

(iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in any manner that takes into account the volume or value of referrals by the physician or other business generated between the parties.

* * * *

(s) * * *

(5) [Reserved]

* * * *

(u) * * *

(3) [Reserved]

* * * *

(w) *Electronic health records items and services.* Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, including certain cybersecurity software and services) necessary and used predominantly to create, maintain, transmit, receive, or protect electronic health records, if all of the following conditions are met:

* * * *

(2) The software is interoperable (as defined in §411.351) at the time it is provided to the physician. For purposes of this paragraph (w), software is deemed to be interoperable if, on the date it is provided to the physician, it is certified by a certifying body authorized by the National Coordinator for Health Information Technology to electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.

(3) The donor (or any person on the donor's behalf) does not engage in a practice

constituting information blocking, as defined in section 3022 of the Public Health Service Act, in connection with the donated items or services.

* * * * *

(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph (w), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

* * * * *

(x) * * *

(1) Remuneration provided by a hospital to a physician to compensate a nonphysician practitioner to provide NPP patient care services, if all of the following conditions are met:

(i) The arrangement—

(A) Is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner; and

(B) Commences before the physician (or the physician organization in whose shoes the physician stands under §411.354(c)) enters into the compensation arrangement described in paragraph (x)(1)(vi)(A) of this section.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's NPP referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); and

(B) Is not determined in any manner that takes into account the volume or value of actual or anticipated—

(1) Referrals by the physician (or any physician in the physician's practice) or other business generated between the parties; or

(2) NPP referrals by the nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The compensation, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the NPP patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under §411.354(c))—

(A) Furnished NPP patient care services in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide NPP patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished NPP patient care services at the medical practice site located in the geographic area served by the hospital.

(vi)(A) The nonphysician practitioner has a compensation arrangement directly with the

physician or the physician organization in whose shoes the physician stands under §411.354(c); and

(B) Substantially all of the NPP patient care services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide NPP patient care services in the geographic area served by the hospital.

(viii) [Reserved]

* * * * *

(4) For purposes of this paragraph (x), the following terms have the meanings indicated.

(i) "NPP patient care services" means direct patient care services furnished by a nonphysician practitioner that address the medical needs of specific patients or any task performed by a nonphysician practitioner that promotes the care of patients of the physician or physician organization with which the nonphysician practitioner has a compensation arrangement.

(ii) "NPP referral" means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but does not include any designated health service personally performed or provided by the nonphysician practitioner.

* * * * *

(y) * * *

(6) * * *

(i) In any manner that takes into account the volume or value of referrals or other business generated between the parties; or

* * * *

(8) [Reserved]

* * * *

(z) *Limited remuneration to a physician*—(1) Remuneration from an entity to a physician for the provision of items or services provided by the physician to the entity that does not exceed an aggregate of \$3,500 per calendar year, as adjusted for inflation in accordance with paragraph (z)(2) of this section, if all of the following conditions are satisfied:

(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician.

(ii) The compensation does not exceed the fair market value of the items or services.

(iii) The arrangement is commercially reasonable.

(iv) Compensation for the lease of office space or equipment is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(v) Compensation for the use of premises, equipment, personnel, items, supplies, or

services is not determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(2) The annual remuneration limit in this paragraph (z) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI-U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI-U for the 12-month period and the new remuneration limit on the physician self-referral website at http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.

(aa) *Arrangements that facilitate value-based health care delivery and payment.*

(1) *Full financial risk*—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met:

(i) The value-based enterprise is at full financial risk (or is contractually obligated to be at full financial risk within the 6 months following the commencement of the value-based arrangement) during the entire duration of the value-based arrangement.

(ii) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(iii) The remuneration is not an inducement to reduce or limit medically necessary items

or services to any patient.

(iv) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(v) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).

(vi) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(vii) For purposes of this paragraph (aa), "full financial risk" means that the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time. For purposes of this paragraph (aa), "prospective basis" means that the value-based enterprise has assumed financial responsibility for the cost of all patient care items and services covered by the applicable payor prior to providing patient care items and services to patients in the target patient population.

(2) *Value-based arrangements with meaningful downside financial risk to the physician*—Remuneration paid under a value-based arrangement, as defined in §411.351, if the following conditions are met:

(i) The physician is at meaningful downside financial risk for failure to achieve the value-based purpose(s) of the value-based enterprise during the entire duration of the value-based arrangement.

(ii) A description of the nature and extent of the physician's downside financial risk is

set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(ix) For purposes of this paragraph (aa), "meaningful downside financial risk" means that the physician—

(A) Is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement; or

(B) Is financially responsible to the entity on a prospective basis for the cost of all or a defined set of patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time.

(3) *Value-based arrangements*—Remuneration paid under a value-based arrangement, as

defined in §411.351, if the following conditions are met:

(i) The arrangement is set forth in writing and signed by the parties. The writing includes a description of—

(A) The value-based activities to be undertaken under the arrangement;

(B) How the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise;

(C) The target patient population for the arrangement;

(D) The type or nature of the remuneration;

(E) The methodology used to determine the remuneration; and

(F) The performance or quality standards against which the recipient will be measured, if any.

(ii) The performance or quality standards against which the recipient will be measured, if any, are objective and measurable, and any changes to the performance or quality standards must be made prospectively and set forth in writing.

(iii) The methodology used to determine the amount of the remuneration is set in advance of the undertaking of value-based activities for which the remuneration is paid.

(iv) The remuneration is for or results from value-based activities undertaken by the recipient of the remuneration for patients in the target patient population.

(v) The remuneration is not an inducement to reduce or limit medically necessary items or services to any patient.

(vi) The remuneration is not conditioned on referrals of patients who are not part of the target patient population or business not covered under the value-based arrangement.

(vii) If the remuneration paid to the physician is conditioned on the physician's referrals

to a particular provider, practitioner, or supplier, the value-based arrangement satisfies the requirements of §411.354(d)(4)(iv).

(viii) Records of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(bb) *Cybersecurity technology and related services*—(1) Nonmonetary remuneration (consisting of certain types of technology and services), if all of the following conditions are met:

(i) The technology and services are necessary and used predominantly to implement, maintain, or reestablish cybersecurity.

(ii) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.

(iii) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business with the donor.

(iv) The arrangement is documented in writing.

(2) For purposes of this paragraph (bb), "technology" means any software or other types of information technology other than hardware.

§411.362 [Amended]

8. Section 411.362 is amended in paragraphs (b)(3)(ii)(C), (c)(2)(iv), (c)(2)(v), and (c)(5) introductory text by removing the term "Web site" each time it appears and adding in its place the term "website".

§411.372 [Amended]

9. Section 411.372 is amended in paragraph (a) by removing the term "Web site" and adding in its place the term "website".

§411.384 [Amended]

10. Section 411.384 is amended in paragraph (b) by removing the term "Web site" and adding in its place the term "website".

Dated: September 26, 2019.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: September 27, 2019.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.