Centers for Medicare & Medicaid Services
Special Open Door Forum: Physician Self-Referral Law
Moderator: Jill Darling
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Coordinator: Welcome and thank you for standing by. Today's call is being recorded. If you have any objections you may disconnect at this time. All participants are in listen only mode. I'd like to now pass it over to Ms. Jill Darling. You may begin.

Jill Darling: Great. Thank you, (Lynne). Good morning and good afternoon, everyone. I'm Jill Darling in the CMS Office of Communications and welcome to today's special open door forum, the Physician Self-Referral Law, also known as the Stark law.

Before we get into today's presentation, I have one brief announcement. This special open door forum is open to everyone, but if you are a member of the press you may listen in, but please refrain from asking questions during the Q&A portion of the call. If you do have any inquiries, please contact CMS at press@CMS.HHS.gov.

And now I would like to hand the call off to Kim Brandt, who's the Principal Deputy Administrator for Policy and Operations at CMS.

Kim Brandt: Great. Thanks, Jill and good afternoon, everyone. Very excited to be here with the team today to talk to you about the rule that we announced on November 20, updating our regulations under the Stark law. As you all know, this is something that we've been working on for a long time and in fact, this rule represents the culmination of many years of work at CMS.

It started back in 2017 with our patients over paperwork initiative. When we launched that patients over paperwork initiative, we put out a formal request for information to hear directly from providers on the front lines about which regulations inhibited their ability to care for patients. And time after time, they pointed to the regulations that interpret the Stark law as one of the ones that they found to be more difficult to comply with.

So, under that initiative, we've already saved the medical community $6.6 billion and about 42 million burden hours, and today's work will extend the historic success even further.

So, the Stark law was enacted back in 1989. The regulations implementing it have been mostly outdated in many ways, despite a bunch of good updates from the team here at CMS but too often they hinder, rather than advance the cause of affordable quality health care for patients.

So, the law was originally intended to address a legitimate problem then and now, which is the possibility that a profit motive might influence physicians to order services based on their financial self-interest, rather than the good of the patient. And it's for this reason, that the Stark law prohibits a physician from making referrals for certain health care services payable by Medicare if the physician or an immediate family member has a financial interest with that entity performing the service.

However, Medicare can't pay for any service resulting from a prohibited referral. And the law made sense then, and in many cases, it makes sense today. But back in 1989, Medicare was almost exclusively a fee for service payment model. And since then, the value-based payment models in which providers are paid on the basis of the results and quality they deliver to

patients, rather than the value of the volume of the services have emerged. And in these models, the self-referral incentive represents less of a threat.

In such value-based situations the regulations under the Stark law can actually stand in the way of innovation and sometimes impose needless costs on providers. Unfortunately, the looming threat of liability under the Stark law has discouraged many providers from entering into value-based arrangements in the first place. Arrangements that have been trying to deliver patients higher quality health care at lower costs--and that's why this rule is so needed. It modernizes our regulations to account for the present-day realities, it reduces burdens, and it promotes value. 1989 was three decades ago; times have changed, and so must our approach.

So, these are the main goals that we've had, as we put in this new final rule and there are three main ways that our final Stark regulation reduces burden and promotes value.

First, and most importantly, it finalizes permanent exceptions to the law's prohibitions in order to permit legitimate value-based arrangements. Under the current law, flexibility for value-based care already exists, but only for participants in some of Medicare's own value-based care programs such as the Medicare Shared Savings Program.

The law provides this flexibility to the entire healthcare system, thereby removing the dampening effect on innovation both inside and outside of Medicare. It also frees healthcare providers to design and enter into legitimate value-based arrangements designed by the private sector without fear that their value-based activities will violate the Stark law.

Second, the rule implements a new exception for the donation of certain cybersecurity technology in both a fee-for-service and a value-based payment system. For instance, a hospital that wants to protect patient electronic health records and other data may currently be worried about providing cybersecurity software to reduce (inaudible) *(fee to physicians)* using the system because of concerns about the Stark law

If the physicians can't afford the cybersecurity software, the hospital has to choose between risking attacks from a hacker and denying access to its electronic system. Our final rule allows for such common sense arrangements, while assuring that the physician wouldn't be obligated to make any referrals.

And then third, the rule offers clarity and guidance for providers to help them ensure that they don't violate the Stark law. We heard from providers all over the country that they shell out huge sums of money on compliance with the Stark law, money that increases administrative costs and the cost of care simply to comply with the law.

This final rule codifies the policy regarding prohibitions on compensation that takes into account volume or value of referrals, clarifies when an arrangement meets the commercially reasonable standard, and revises the regulatory definition of fair market value.

The new guidance will help reduce administrative burdens and bring down overall costs by making it easier to comply with these rules across the industry. And most importantly, these updates maintain important protections against inappropriate self-interested referrals.

We take our responsibility to ensure providers are not abusing the system at the expense of patients and taxpayers very seriously. And in the case of a

doctor that stands to gain financially from a given referral, a referral that is not made with the good of the patient in mind, the Stark law will still continue to come down in full force, and the effort to crack down on bad actors will continue unabated.

So, with that overview, I'm going to hand it over to Lisa Ohrin Wilson and the rest of the team to walk you through all the details of this important new regulation. Thank you.

Lisa Ohrin Wilson: Thanks, Kim. Good afternoon. As Kim mentioned, my name is Lisa Ohrin Wilson and I am a Senior Technical Advisor with CMS, focusing primarily on the agency's physician self-referral policy.

For the rest of the hour, we're going to take the opportunity to provide an introduction to our final rule, Modernizing and Clarifying the Physician Self-referral Regulations, published today in the Federal Register and found at 85 Federal Register, 77492. It is a whopping 191 pages reading pleasure for you.

First, we'll get through the very highlights of that today. Then, right after this is Cathy Martin, a Senior Technical Advisor and she's going to walk through our new policies that are intended to further the transitions to a healthcare system that pays for outcomes and health rather than the volume of procedures and services furnished.

After that, Matt Edgar, a technical advisor to the agency, and I will discuss new regulations and updates to existing regulations that are intended to clarify the agency's policy on issues related to physician self-referral law, as well as establish new flexibilities to enhance and meet compliance with the law’s requirements.

For the scope of our presentation today, we do not expect to be able to take questions. With that, I'm going to turn things over to Cathy Martin.

Cathy Martin: Thanks, Lisa. As Kim discussed, the physician self-referral law has been identified as a barrier to the transition to value-based care, impacting parties participating or considering participating in integrated care delivery models, alternative payment models, and arrangements designed to incentivize improvements in outcomes and reductions in cost.

To alleviate these barriers and facilitate the transition to value-based care while protecting the Medicare programs and beneficiaries, the final rule creates an inner woven fabric of definitions and three new exceptions that work together to provide important program integrity safeguards.

This final rule provides critically needed flexibility for physicians and entities to work together and promote innovation, improve quality outcomes, produce health system efficiencies and lower costs without sacrificing program integrity. I'm going to provide you with a general overview of the value-based definitions and exceptions, but first, I'd like to mention a few important points.

In this final rule, we recognize that requiring compensation under some value-based arrangements to be fair market value simply will not work. Therefore, the value-based exceptions do not include a fair market value requirement.

However, and importantly, they do include other safeguards to protect the integrity of the Medicare program and our beneficiaries. To illustrate this point, historically, providing free or below cost telehealth equipment physicians for use in their private practice would not be permitted under the physician self-referral law, because the existing applicable exceptions all require that compensation to a physician must be fair market value.

These exceptions recognize that the free of the low cost telehealth equipment provided to the physician could be utilized for value-based activities that further important value-based purposes, such as consults with donor -- with a donor hospital to avoid unnecessary ambulance transfers or ER visits or to be used by primary care physicians to obtain immediate input from specialists while a patient is present in the primary care physician's office.

The exceptions also do not require that compensation be sent in advance or determined in a manner that does not take into account the volume or value of the physicians' referrals or other business generated by the physician. Like fair market value these requirements often do not fit the way compensation is structured in value-based arrangements. There is however, a requirement that the value-based arrangement itself must be commercially reasonable.

The exceptions apply regardless of whether the arrangement relates to care furnished to Medicare beneficiaries, non-Medicare patients or combination of both. The right to freedom of choice of providers is expressed and reinforced in almost every aspect of the Medicare program. It is protected here as well. And finally, remuneration may not be an inducement to reduce or limit medically necessary items or services to any patient.

Moving on now to the value-based definition. For purposes of applying the exceptions, we finalized new definitions for the following terms, value-based activity, value-based arrangement, value-based enterprise value-based purpose, VBE participants and target patient population.

And to put these definitions in context, the exceptions for value-based arrangements permit the provision of both cash and in-kind remuneration between a physician and an entity to which he or she refers Medicare

beneficiaries for designated health services where the parties to the compensation arrangement are engaging in value-based activities designed to achieve at least one value-based purpose for a target patient population as part of the same value-based enterprise.

So, let's walk through these definitions. First, a value-based enterprise. A value-based enterprise is essentially a network of two or more 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, increased efficiencies in the delivery of care and improved outcomes for patients.

They must have an accountable body or person responsible for financial and operational oversight, which is necessary for transparency, and a governing document that describes the value-based enterprise and how the VBE participants intend to achieve its value-based purpose. Importantly, this definition focuses on the functions of the enterprise. It does not dictate or limit how parties establish the enterprise, but rather provided flexibility in this regard.

VBE participants. A VBE participant is a person or entity engaged in value-based activities as part of the value-based enterprise. Importantly, the definition of VBE participant does not exclude any specific persons, entities, or organizations from qualifying as a VBE participant.

Value-based purpose. At least one of these four purposes must anchor the activities undertaken as part of the value-based arrangement, and these are set forth in the regulations. The value-based purposes are coordinating and managing the care of a target patient population, improving the quality of care for a target patient population, appropriately reducing the cost to or growth

and expenditures of payors without reducing the quality of care for a target patient population, or 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 cost of care for target patient population.

Value-based activities. Value-based activities are the activities undertaken by the parties to a compensation arrangement that are key to the arrangement qualifying as a value-based arrangement. The value-based activities must be reasonably designed to achieve at least one value-based purpose of the value-based enterprise.

And I just want to highlight that furthering the purpose of the arrangement itself is not what is required. The focus here is on the purpose of the value-based enterprise.

Value-based arrangement. This is relatively straightforward, but it's an arrangement for at least one value-based activity for the target patient population.

And then finally, target patient population. Basically, this is the group of individuals for whom the parties to the value-based arrangement are undertaking value-based activities. The criteria for selecting the target patient population must be legitimate and verifiable and the selection cannot be driven by profit motive or purely financial concerns.

The definitions are central to the application of the exceptions, which 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. Again, you must satisfy the definition to access the value-based exceptions.

Now that we've covered the definitions, let's walk through the value-based exceptions. In recognition of the fact that a large aspect of the industry is not yet well positioned to move directly into two-sided risk arrangements, the value-based exceptions include varying levels of requirements depending on the type of payment risk undertaken by the enterprise and/or the specific parties to the compensation arrangement. The greater the risk, the greater the flexibility afforded by the exception.

The first exception is the full financial risk exception. Here the value-based enterprise, not the parties to the arrangement, must assume full financial risk or be contractually obligated to be at full financial risk within 12 months following commencement of the value-based arrangement between the parties for all patient care services covered by the applicable payor for the entire duration of the value-based arrangement.

Note this exception includes a 12-month previous timeframe that is available to protect value-based arrangements entered into, in preparation for the implementation of the value-based enterprises financial risk payor contract.

As I mentioned, the greater the risk the greater the flexibility. Here, full financial risk for all patient care services diminishes traditional fraud abuse risk such as incentives to order unnecessary services, or steer patients to higher-cost sites of service. For this reason, this exception includes only essential program integrity safeguards.

Examples of full financial risk include but are not limited to a capitation payment from the payer, whereby the value-based enterprise agrees to a

predetermined payment per patient per month, or a global budget payment from a payor to a value-based enterprise for all patient care items and services provided to the identified target patient population for a set period of time.

The next exception is the meaningful downside financial risk exception. This exception is focused on the risk taken on by the physician participating in the specific value-based arrangement. Here it is, the physician who is at meaningful downside financial risk under the value-based arrangement for failing to achieve the value-based purpose of the value-based enterprise.

Note here as well that the focus is on what the value-based enterprise was formed to do and not the physician's specific performance. Meaningful downside financial risk means the physician must be responsible to repay the entity no less than 10% of the value of the remuneration the physician receives under the value-based arrangement or forgo no less than 10% of the remuneration available to the physician under the arrangement.

And financial risk can take many forms including but not limited to incentive payments tied to achieving quality or performance metrics, claw back arrangements, withholds or reduction and compensation. I'm just going to give you a few examples of some of the different forms of financial risk.

With an incentive payment, you could have an arrangement where a physician is entitled to a base payment of $50,000 with the ability to earn an additional $25,000 for performing certain value-based activities that are designed to further the value-based purposes of the value-based enterprise.

To set up a withhold, the physicians total potential compensation under the value-based arrangement could be set at $100,000, but you hold back or withhold $10,000 payable only upon successfully completing the value-based

activities called for under the arrangement and achievement of the value-based purposes of the value-based enterprise.

Under a claw back or repayment, if a hospital provides a physician with in-kind infrastructure support for the physician's practice, such as imaging equipment to be used for the target patient population under shared care protocols, the value-based enterprise in which the hospital and physician participate does not achieve the enterprise's value-based purposes, the physician must repay at least 10% of the value the infrastructure or potentially return the equipment.

The final exception is the value-based arrangements exception. This exception which we sometimes refer to as, the no risk exception applies to value-based arrangements regardless of the level of risk assumed by the value-based enterprise or the parties to the arrangement. The no risk exception could cover both monetary and non-monetary remuneration between the parties when all requirements of the exception are satisfied.

Among other things, this exception requires that the arrangement is documented in writing and includes an explicit monitoring requirement. Under this exception, parties must monitor the value-based arrangements no less frequently than annually or at least once during the term of the arrangement, if the arrangement has a duration of less than one year to determine whether the parties have furnished the value-based activities required under the arrangement, and whether and how continuation of the value- based activities is expected to further the value-based purposes of the value-based enterprise.

In addition, if the arrangement includes outcome measures against which the recipient of the remuneration will be assessed, the parties must monitor

progress towards the attainment of the outcome measures. We expect that this exception will be widely used by entities and physicians wishing to enter into the value-based healthcare space. This is consistent with commenters who told us that this exception is critical to the transition to a value-based health care delivery and payment system.

Commenters also told us that this exception will be particularly useful with respect to value-based arrangements undertaken as part of the CMS-sponsored payment models that currently rely on model specific fraud and abuse waivers as there is not a separate exception specific to CMS- sponsored payment models.

And just a few examples of value-based arrangements that could be structured under this exception. A hospital provides staff and other resources to physicians for free or at below fair market value to help with patient education, through admission evaluations and post procedure follow-up and monitoring to help improve patient compliance and outcomes, reduce complications and reduce readmission.

Another example is a specialty physician practice or other entity that provides free data analytic services to a primary care physician practice with which it works closely. The data analytics could for example, identify practice patterns that deviate from evidence-based protocols, or determine whether follow-up care recommended by the specialty physician practice is being sought by patients.

And finally, a hospital could enter into a value-based arrangement with its orthopedic surgeons, whereby the hospital agrees to share a portion of the internal cost savings generated through product standardization.

Now, we know that this is a lot to digest with our new policies that facilitate the transition to a health care system that pays for value rather than volume. Today, we're providing highlights of our new definitions and exceptions.

The preamble of the final regulations provide additional insight into the policies we're finalizing, and we refer stakeholders to the preamble for more details. Now I'll turn things over to Lisa Wilson to discuss some of our important final policies that do not relate to value-based health care delivery and payment.

Lisa Ohrin Wilson: Thanks, Cathy. Before we start, let's set the stage to discuss some of these final policies, especially those that characterize the key terminology of the physician self-referral law's exception.

So, let's remember that many of the statutory and regulatory exceptions to the physician self-referral law include one, two or all of the following requirements.

First, that the compensation arrangement itself is commercially reasonable. Second, the amount of compensation paid under the arrangement is fair market value. And third, 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.

Our final rule codifies a new definition of commercially reasonable, it codifies new regulations stating when compensation takes into account the final value referrals or takes into account the volume or value of other business generated by a physician, and it revises the regulatory definition of fair market value.

So, let me start in that order. When developing the proposed definition of commercially reasonable, we considered a very basic question, does the arrangement make sense as a means to accomplish the party's goals? And the final definition of commercially reasonable is built on this. For the purpose of the physician self-referral law--no other law, not the kickback statute or any other state law, but for purposes of the federal physician self-referral law--commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty.

Also, we clarified what appears to be a misconception of CMS policy based on the comments we received on our July 2018 requests for information and October 2019 proposal. The final definition of commercially reasonable also provides that an arrangement may be commercially reasonable, even if it does not result in profit for one or more of the parties.

As we stated in our summary of the proposed rule and in our response to comments in the final rule, there are numerous reasons why an arrangment might not be profitable for one or more the parties, but nonetheless further a legitimate business purpose to the parties and be sensible considering their characteristics.

Second, we also asked ourselves, how did the parties calculate the remuneration paid under the arrangement? And we used that question to establish policy regarding the volume and value and other business generated standards. We asked the question to establish a clear, objective, bright line rule that states exactly when compensation takes into account the volume or value of a physician's referrals or takes into account the other business generated by a physician.

Under the final rule, we applied a mathematical approach to assess whether compensation is determined in a manner that takes into account the volume or value of referrals or business generated by physicians. That is, if this amount of compensation paid to a physician increases, as the number or value of the physician referrals or the generation of other business increases, the compensation takes into account, the volume and value of the physician referrals or the other business generated by the physician. For example, if the physician is paid $100 each time he admits a patient to the hospital.

Second, if the amount of compensation paid by a physician decreases, as the number or value of the physician's referrals or the generation of other business increases, the compensation takes into account the volume or the value of the physician's referrals or the other business generated by the physician. There's a negative correlation there. For example, if the physician pays $2,000 per month to rent office space if the physician orders less than 20 MRIs per month, and the payment is $1,800 dollars per month if the physician orders more than 20 MRIs per month.

The rule is not universal though. Many commenters pointed out that mathematical formulas do not readily translate to the provision of in-kind remuneration and the assessment whether this type of compensation takes into account the volume or value of physician referrals or the other business generates.

And for the most part, we agreed with that and the final regulations on the volume or value and other business generated standards do not apply for purposes of the exception for medical staff incidental benefits, professional courtesy, community-wide health information systems, electronic prescribing items and services, electronic health records items and services, and the new

exception for cybersecurity technology and related services that Matt Edgar is going to talk to you about in a minute.

And then, finally, we also with respect to the volume and value standards, we confirm in the preamble discussion that, under longstanding CMS policy prior to this final rule, productivity compensation based solely on a physician's personally performed services would not have been considered to take into account the volume or value of the physician's referrals for other business generated by the physician, provided that the unit based compensation met the conditions of the special rules and our regulations at Section 411.354(d)(2) or (d)(3).

And this is true even when the entity with which the physician has the direct or indirect compensation arrangement bills for designated health services that correspond to such personally performed services or bills for other business generated that corresponds to such personally performed services.

Under the final rule, we see a similar result. Because the compensation formula would not include designated health services as a variable or other business generated as a variable, such compensation would not take into account the volume or value of the physicians referral's or other business generated by the physician.

And then finally, we have some policies related to the fair market value definition. We also asked whether the calculation of compensation results in compensation that is fair market value for the asset, items, service, or rental property. And we use that question to guide our revisions to the physician self-referral regulatory definition of fair market value.

And, like the definition of commercially reasonable, and also with our policies that relate to the volume and value standard, the definition of fair market value applies only for purposes of the federal physician self-referral law. It does not apply for any other purpose, including purposes of the IRS, Office of the Inspector General, or any state that has its own physician self-referral (Baby star) or anti-kickback statute.

So, as we noted in the final rule, a careful reading of the physician self-referral statute shows that the fair market value requirement is separate and distinct from the volume or value standard and other business generated standard.

Therefore, the final rule revised the regulatory definition of fair market value to remove all references to compensation that is not determined in any manner that takes into account the volume or value of anticipated or actual referrals. That language is included in current definition, but when the final rule becomes effective, it will no longer be there.

In addition, we restructured the definition of fair market value to provide for a general definition and definitions that are specific to the rental of equipment and the rental of office space. That corresponds better to the way the statute is set out.

And we also separated the definition of general market value from its previous inclusion in the definition of fair market value. However, at the end of the day, we did not finalize all of our proposals related to these two terms.

And then finally, also related to these general policies, because the final regulations interpreting the volume and value standard and the other business generated standard rely on positive and negative correlation between the amount of compensation paid to or from a physician and variables in that

compensation formula, we made revisions to certain exceptions and other regulations to reinforce our policies regarding patient choice, and the conditions under which an entity may direct the referrals of the physician with whom it has a compensation arrangement.

These policies were formerly expressed as an interpretation of the volume or value standard. Now, they are separate regulations and affirmative obligations.

So, under this final regulation, where compensation is paid to physician in exchange for the physician's personal services and the physician's referrals are directed to a particular provider, practitioner, or supplier, the compensation arrangement and the compensation itself must satisfy the conditions of the regulation set forth in 411.354(d)(4).

The final rule also establishes a new condition in this section that prohibits making the existence of a compensation arrangement or the amount of a physician's compensation contingent on the number or value of the physician's referrals to the particular provider, practitioner, or supplier.

For example, if the compensation arrangement would be terminated if the physician failed to refer a sufficient number of patients for designated health services, a direct referral requirement will be impermissible. The physician's referrals and billing for those designated health services that the physician refers to the entity would also be prohibited. Or, if the value of the physician's referrals of designated health services failed to achieve the target established under the direct referral requirement, that direct referral requirement will be impermissible.

And, likewise, the physician's referrals for DHS, as well as the billing for those designated health services would be prohibited. And, although we could

spend much more time putting you to sleep and unpacking the "big three" terminology as we affectionately call it here at CMS, we do have lots to cover today.

I'm going to turn things over to Matt Edgar to discuss two new exceptions to the referral and billing provisions of the physician self-referral law.

Matt Edgar: Thank you, Lisa. I'm going to start with the new exception for cybersecurity technology and related services.

In 2017, the Health Care Industry Cybersecurity Task Force recommended the creation of a new exception for donations of cybersecurity technology and services, modeled on the existing exception to the physician self-referral law for electronic health record items and services, which I'm going to refer to as the EHR exception.

Since 2017, as commenters have informed us, the need for such an exception has become more apparent as numerous cybersecurity attacks have struck health care providers and suppliers in the United States.

As noted by the Task Force, healthcare providers and suppliers who have not invested in adequate cybersecurity technology are vulnerable to cyber-attacks, and they also represent a risk to other healthcare providers and suppliers with whom they share data and electronic information.

The new cybersecurity exception permits an entity to donate cybersecurity technology and services to a physician at no cost or below fair market value costs, which may facilitate bolstering cybersecurity throughout the healthcare sector.

Specifically, the new cybersecurity exception permits non-monetary, that is, in-kind remuneration in the form of donations of cybersecurity technology and services that are necessary and used predominantly to implement, maintain, or re-establish cybersecurity. The exception incorporates a broad, industry-neutral definition of cyber security and it is neutral with respect to the types of technology that may be donated under the exception.

The goal underlying the expansive scope of the exception is to avoid being overly prescriptive and ensure that the exception does not become obsolete over time. As such, the exception covers a broad range of existing and yet to be developed technologies and services and allows for the donation of hardware, provided that the hardware is necessary and use predominantly for cybersecurity.

There's a detailed list of various technologies and services that may be covered under the exception in the preamble, and I urge folks to look at that list carefully. The list is illustrated only and is not exhaustive of the types of technologies or services that may be donated under the exception.

Lastly, the donated technology or services may have multiple uses, but the core functionality of the technology or services must be cybersecurity and the cybersecurity use must predominate. The technology or services must also be necessary for cybersecurity.

The cybersecurity exception incorporates certain requirements of the existing EHR exception. Donors are not permitted to directly take into account the volume or value of a physician's referrals, or the other business generated by the physician, in determining the eligibility of a physician to receive the donation or the nature or the amount of the donation.

Physician practices may not make the receipt of cybersecurity technology or services or the nature or amount of the technology or services a condition of doing business with the donor, and the arrangement must be in writing. Unlike the EHR exception, however, there's no requirement that the physician recipient pay 15% of the cost of the donated technology or services. Donors are permitted but not required to charge the recipient the contribution amount.

As we noted in the final rule, we are concerned that a contribution requirement could chill beneficial donations that contribute to the cybersecurity of the entire healthcare ecosystem.

With that, I'll turn now to the new exception for limited remuneration to a physician. Several commonly used exceptions for compensation arrangements require that the arrange – require the arrangement to be signed and in writing, and the amount of compensation must be set in advance, that is, determined before a physician provides items or services.

However, we are aware that it is not uncommon for physicians to provide items or services to hospitals on an infrequent or one-off basis or under exigent circumstances, before the parties have had an opportunity to work out the financial details of the arrangement and document the arrangement in writing.

The new exception for limited remuneration to a physician provides flexibility for such arrangements. Specifically, the exception permits remuneration from an entity to a physician that does not exceed an aggregate of $5,000 per year as adjusted for inflation, for items or services actually provided by the physician to the entity.

The exception also stipulates that a physician may provide items or services through an employee that a physician has hired for the purpose of performing the services, a wholly owned entity or through a local tenens physician. Payments made to a physician for services provided by the physician's employees, wholly owned entities, or local tenens physicians are counted towards the physician's annual aggregate remuneration limit.

The exception does not cover payments to a physician's immediate family member for items or services provided by the family member. The new exception includes the traditional big three requirements discussed earlier by Lisa, that is, compensation may not be determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; compensation may not exceed the fair market value of the items or services; and the arrangement must be commercially reasonable even if no referrals were made between the parties.

The new exception also includes the following requirements: per click or percentage based compensation formulas for the lease of office space or equipment or the non-leasehold use of premises or equipment are not permitted. And, if the arrangement includes a directed referral requirement, the arrangement and the compensation itself must also satisfy the conditions related to directing a physician's referrals to a particular provider, practitioner, or supplier. Importantly, the new extension does not require the arrangement to be in writing and signed by the parties or the amount of compensation to be set in advance.

The new exception can be used in conjunction or in succession with other exceptions. For example, parties may rely on the exception for limited remuneration to a physician at the outset of an arrangement before the parties

have documented the arrangement or set the amount of compensation in advance.

Once the parties have documented the arrangement and determined the compensation amount, the parties may rely on another exception that does not include an annual limit to except the arrangement on a going forward basis. It's important to note here that compensation to a physician that fully satisfies all the requirements of another exception to the physician self- referral law, such as the exception for personal service arrangements, is not counted towards the physician's annual aggregate remuneration limit.

During any calendar year, the exception for limited remuneration to a physician may be applied to the provision of different types of items or services, including personal services, office space and equipment. The annual aggregate remuneration limit is determined by adding compensation for all of the various items and services provided by the physician under the exception for limited remuneration to a physician.

To illustrate these concepts, assume an entity pays a physician $500 for equipment rental and $1,000 for a shift of call coverage during a calendar year, relying on the exception for limited remuneration to a physician. Assume also that the entity paid the physician $12,000 in a calendar year for medical directorship services, under an arrangement that satisfies all the requirements of the exception for personal service arrangements.

Assuming no other compensation arrangements between the parties, the amount counted towards the annual aggregate remuneration limit for this calendar year would be $1,500. The annual aggregate remuneration limit resets each calendar year. For arrangements that straddle a calendar year,

remuneration should be allocated to the annual aggregate remuneration limit of a calendar year based on the date that the items or services are provided.

So, this completes my review of the new exception for cybersecurity technology and related services and the new exception for limited remuneration to a physician. Lisa will now discuss some of the new additional flexibilities under the final rule.

Lisa Ohrin Wilson: Thanks, Matt. There are a number of revisions and clarifications that we made to provide for new flexibilities, to help folks stay in compliance with the physician self-referral law or to more readily achieve compliance. We picked out a few to talk about today and as time permits, we may add more to the end. But for now, we want to talk about some of the more important ones that we think are more significant and a significant portion of the rule actually relates to these kind of policy clarifications and these new flexibilities.

As I said, they are intended to assist stakeholders in their efforts to comply with the physician self-referral law. Some of the more significant of these flexibilities include regulations that allow for the correction of payment discrepancies during the term of an arrangement and up to 90 days following its expiration or termination.

Prior to this final rule, CMS policy allowed the reconciliation of payment discrepancies during the term of a “live” or ongoing arrangement without jeopardizing compliance with the requirements of an applicable exception.

The thinking behind that, of course, is that you're still in the arrangement and if you were supposed to pay $2,000 a month and the check was written for $2,100 a month, you need to recover that extra $100 per month that was paid to the physician or from the physician and you have time to get those

accounting errors corrected, so it didn't result in non-compliance simply because things didn't go according to plan. We've always had this policy and shared it with the public.

In this final rule, we've actually codified that policy but also extended that timeframe to no later than 90 consecutive calendar days following the expiration or termination of the compensation arrangement.

This policy will allow the parties to remain in compliance with the physician self- referral law, if all payment discrepancies are reconciled, such that the entire amount of remuneration for items and services have been paid as required under the terms and conditions of the arrangement. You can't just fix some of your problems and call it a day. You must actually operate the arrangement as intended with respect to the financial terms.

And then, second, except for the payment discrepancies, the arrangement fully complies with the applicable exceptions. You cannot consider yourself as complying with the physician self-referral or satisfying all requirements of an exception if you fail to get your arrangement in writing when that was a requirement as well.

The final rule--moving on to other policy updates--makes more flexible CMS policy on modifying the compensation terms of an arrangement. Under the final rule, there is no minimum amount of time than a modified compensation formula or modified compensation terms have to remain in place.

Instead, the compensation or formula for determining the compensation may be modified at any time at all during the course of the compensation arrangement and still satisfy the requirement that it is set in advance, which is what this relates to.

The arrangement must satisfy all requirements of an applicable exception on the effective date of a modification, and the modified compensation or the formula for determining modified compensation must be determined before the furnishing of the items, services, office space or equipment--before the modified compensation has to be paid and before the furnishing of those items, services, office space, or equipment for which the modified compensation is be paid.

The formula is set forth in writing in sufficient detail so that it can be objectively verified. Two things to note, there is no grace period for obtaining that in writing when you're modifying the financial terms the compensation terms of an arrangement.

And the first item that I mentioned--that the arrangement has to satisfy all requirements in the applicable exception on the effective date of the modification--is very important. Because the policy allows for modifications, as frequently or as many as you'd like, in the term of an arrangement, you have to remember, compensation must generally, for most of the arrangements that we're talking about here, still needs to be fair market value and not take into account the volume or value of referrals or other business generated.

If you modify the compensation terms of an arrangement too frequently, you may start to call into question the ability to comply with those other requirements of the exception. So, it's very important to remember that all requirements of an applicable exception have to be met as of the effective date of the modification.

And then also, another flexibility under the final rule. Under current law parties have 90 consecutive calendar days to obtain required signatures, and

still be considered to have met the signature requirement of an applicable exception at the time that signature requirement was required.

The final rule extends that flexibility to the writing requirement of the physician self-referral law exceptions. And in either case, the compensation arrangement must still comply with the requirements of the exception, except with respect to signature or writing requirements.

And as long as whichever one is missing, or both are missing, if they are obtained within 90 consecutive calendar days of the date they are required, you will remain, you'll be considered to be compliant as of the date those were required.

I wasn't going to get into this, but I'm going to do a quick reminder of how to satisfy the writing requirement--we have codified this in regulation and it's in the statute--but we want to remind parties that we are very flexible as to how writing requirements can be met, including a compilation of contemporaneous documentation.

It doesn't have to be in a single four-square (or within the pages of a) written agreement, it can be any kind of--as we like to call it--a pile of paper that is available and provides a reasonable person the ability to understand what that arrangement is about. And it has to be compiled in time for either the first referral under the arrangement, the first payment—or, of course, within 90 consecutive calendar days, when this final rule becomes effective.

And then also, importantly, in response to stakeholder inquiries, the final rule also codifies CMS policy--I'm saying it codifies CMS policy--that the signature requirements of exception may be satisfied by an electronic or other signature that is valid under applicable federal or state law.

There is no prescribed type of signature that we require for purposes of satisfying signature requirements of the physician self-referral law. As long as that signature is valid under federal or state law--and it can be electronic or any other way--then it will also be sufficient for satisfying the requirements under the applicable exception.

So now I'm going to turn things back to Matt Edgar to discuss a few more of the significant clarifications and flexibilities in this rule, and if we do end up with some time at the end, we have a couple others to touch on, that we didn't necessarily include in today's presentation.

So, you know, at least we will get through these next really important ones, and if we find some time, we'll add in a few more.

Matt Edgar: Okay, thank you, Lisa. I'm going to start with our expansion of the applicability of the exception for payments by a physician. So, the exception for payments by a physician is an exception established by statute that permits physicians to make fair market value payments to an entity such as a hospital for items or services furnished by the entity. That is, the compensation and the physician referrals are going in the same direction—to the entity.

The statutory exception does not require the arrangement to be in writing or the amount of compensation to be sent in advance. Under prior regulations, the exception was not available if any other exception, including exceptions established by regulation, were applicable to the arrangement.

Under the final rule, the exception is still not available for arrangements that are specifically addressed by another statutory exception, such as the exceptions for the rental of office space or equipment. But the exception is

available for all other arrangements, even if another exception established by regulation is also applicable to the arrangement.

For example, the exception is not available to protect a physician's payments to an entity for the rental of office space, but it is available to protect a physician's fair market value payments to an entity for storage space, or residential space. Next, I'm going to address the expansion of the fair market value compensation exception.

Under our prior regulation, the only exception available for direct compensation arrangements between an entity and a physician for the rental of office space was the rental of office space exception, which requires a term of at least one year. The final rule makes the exception for fair market value compensation available for rental of office space arrangements as well, thus making rental of office space arrangements with rental terms of less than one year permissible.

Now, I'm going to move to revisions to the electronic, the exception for electronic health records items or services. Once again, I'm going to refer to this as the EHR exception.

The final rule removes the sunset date from the EHR exception, making it permanent. Prior to this, the exception was available only through December 31, 2021. Revisions of the final rule permit an entity such as a hospital to donate equivalent or replacement EHR items or services, even if the physician recipient already has certain EHR items or services. Under the prior exception, donations of equivalent technology were not permitted.

The final rule also clarifies that the EHR exception is applicable and has always been applicable to donations of certain cybersecurity software and

services. Specifically, the final rule provides that the exception is applicable to cybersecurity software and services that are necessary and used predominantly to protect electronic health records.

Now, the EHR exception in the final rule retains the 15% contribution requirement for all donations of EHR items or services, but provides some flexibilities for the timing of payments. Specifically, for updates or patches to previously donated items or services, the physician is not required to pay in advance of receipt as was formerly required. Rather, the physician must now pay the required contribution at reasonable intervals, for example, monthly or quarterly.

For donations of new EHR items or services or replacement items or services, the physician payment must still be made in advance of receipt of items or services.

Now we're going to briefly touch on our revised definition of designated health services. The final rule modifies the definition of designated health services to provide that a service furnished to an inpatient by an acute care hospital, inpatient rehabilitation facility, inpatient psychiatric facility, or a long term care hospital is not a designated health service if the service does not increase the amount of Medicare's payment to the hospital under the applicable prospective payment system.

To illustrate, assume that Dr. Jones refers a patient to the hospital for an inpatient admission, which is a designated health service. After the patient is admitted, but while still an inpatient, Dr. Smith furnishes a cardiology consult, and orders several diagnostic tests, all of which are hospital services and under current regulation, designated health services.

Under the revised definition of designated health services, if the diagnostic tests ordered by Dr. Smith do not increase the amount of Medicare's payment to the hospital under the applicable prospective payment system, the referral for the services is not prohibited, even if the hospital has a financial arrangement with Dr. Smith that does not satisfy all the requirements of an applicable exception.

The last thing I'm going to talk, touch briefly on the clarifications and changes to how a group practice may distribute profits and pay productivity bonuses. The final rule makes clarifying revisions to our regulations regarding the distribution of overall profits of a group practice and payment of productivity bonuses to physicians in a group practice.

In addition, we made non-substantive changes to restructure these regulations to more closely align with the language of the physician self-referral statute. Specifically, the final rule permits group practices to distribute profits from designated health services that are directly attributable to a physician’s participation in the value-based enterprise, which Cathy discussed earlier, to the participating physician. Such a distribution will not be considered to directly relate to (or take into account) the volume or value of the physician’s referrals.

The final rule also revises the regulations that permit the distribution of overall profits to clarify that such profits must be from all the designated health services of the group practice. To put it another way, the profit from all the designated health services of a group practice or any component of at least five physicians in a group practice must be aggregated before distribution.

A physician practice that wishes to qualify as a group practice may not distribute profits from designated health services on a service-by-service

basis. In recognition of concerns raised in the comments on the proposed rule regarding the amount of time it may take group practices to revise their compensation formulas for physicians in the group practice, we are delaying the effective date of the changes to the group practice regulation.

The final rule is effective January 19, 2021, except for revisions to the group practice regulations at 42 CFR 411.352, which are effective January 1, 2022. That concludes my presentation.

Lisa Ohrin Wilson: Thanks, Matt. I don't think we're actually going to have any time to talk about some more clarifications that we made, but we do refer folks to the final rule. All of the regulations are published there. We also wanted to point out that, for the ease of readers, we have published our regulations in full. Essentially, 411.351, which starts with our definitions, all the way through the exceptions at 411.357, so that there is a comprehensive and complete set of regulations for your reference.

No real redlining is necessary, and you don't have to go back, figure out which word changed. We republished everything together, so--we hope--that will provide some convenience for the reader. Again, as Matt said, these final regulations are effective on January 19, 2021, except for the changes to the group practice regulations.

We are giving folks an extra amount of time to restructure any compensation arrangements that they might have to. We did have some commenters, in response to our proposals, letting us know that that might be necessary.

Those changes will be effective January 1, 2022, but they are published in today's Federal Register, so you can see what they're going to be and you can compare today's rules with next January’s rules or I'm sorry, January 19, 2021,

rules with the January 1, 2022 rules. It's all in one document for your convenience.

So, we do appreciate you joining us today and we hope that you found this informative. Again, we just hit some of the highlights on these rules. As I said, it's 191 pages in the Federal Register and we expect there's plenty more for you to unpack and we are here if you need us. There's contact information in the rule, and we also have a physician call center email box that you are welcome to submit questions to.

You can find that email address on our physician's webpage on the CMS webpage. However, just if you wanted to write it down right now, I can tell you what it is. You can send your questions to the CMS1877 Call Center.

I'm sorry that's the 1877callcenter@CMS.HHS.gov. So that's all you need to type in. 1-8-7-7-C-A-L-L-C-E-N-T-E-R at CMS dot HHS dot gov and feel free to send us any questions you have and we have a team that will respond to them at the earliest convenience, as soon as they are able to.

So again, thanks for your participation today and we appreciate you listening.

Coordinator: Thank you for participating in today's conference. You may disconnect at this time. Speakers, please stand by.

End