Stark Law Overhaul

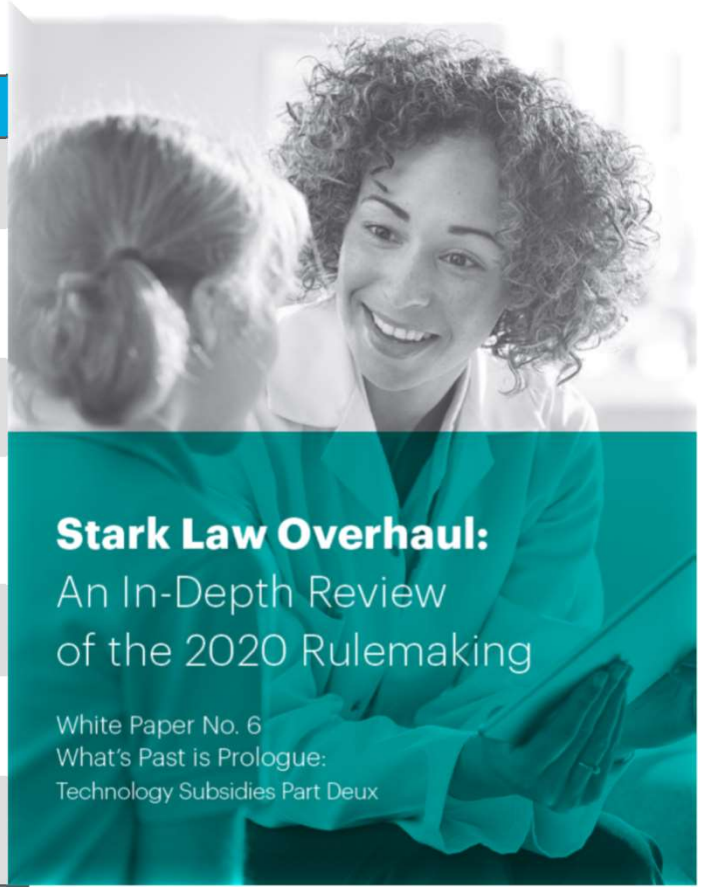
An In-Depth Series on CMS's New Final Rule

Webinar 6

What's Past is Prologue: Technology Subsidies Part Deux

Stark Law Overhaul Series

Date	Topic
March 18	Rolling Up Our Sleeves: A Stark Law Refresher (and Clearing the Brush)
April 1	Separating the Wheat From the Chaff: Technical Requirements, Low-Dollar Violations, and Payment Discrepancies
April 15	Key Standards (Part I): The 'Volume or Value' Standard
April 29	Key Standards (Part II): The 'Fair Market Value' and 'Commercial Reasonableness' Standards, and Indirect Compensation Arrangements
May 13	New Wine in Old Bottles: Providing Greater Flexibility Under Existing Exceptions
May 27	**What's Past is Prologue: Technology Subsidies Part Deux**
June 10	The Problem of the Square Peg and the Round Hole: When FFS and Managed Care Collide



Agenda

- Introduction
- Exception for Electronic Health Records Items and Services ("EHR Exception")
  - 42 C.F.R. § 411.357(w)
- Exception for Cybersecurity Technology and Related Services ("Cybersecurity Exception")
  - 42 C.F.R. § 411.357(bb)
- Q&A

Introduction

- There are now 40 separate and distinct Stark Law exceptions. More than two-thirds of these (28) are intended to protect **compensation arrangements** specifically.
- Many of these exceptions envision a **fair market value** exchange between the parties. For example:
  - Space Rental Exception
  - Equipment Rental Exception
  - Employment Exception
  - Personal Services Exception
- In theory, a fair market value exchange helps ensure that the DHS Entity is not incentivizing referrals.
  - DHS Entity pays Physician $200,000 for services worth $150,000. **What's the extra $50,000 for?**
  - Physician Pays DHS Entity $15/sqft for office space worth $20/sqft. **What's the $5/sqft discount for?**

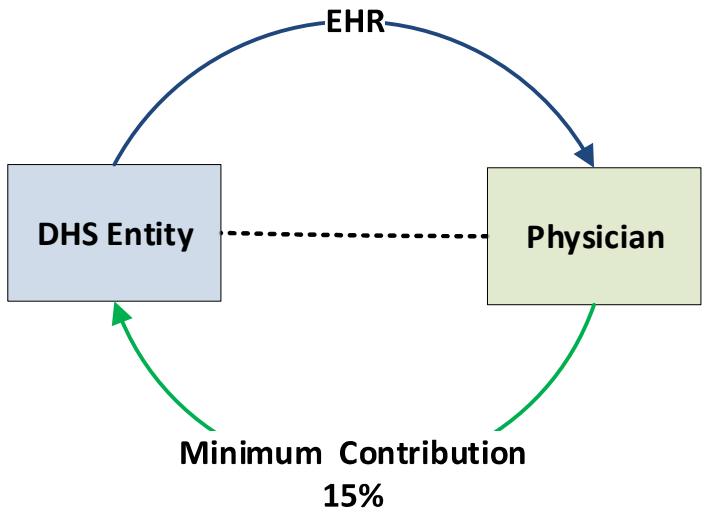
Introduction (cont.)

- Under a few circumstances, however, CMS permits DHS Entities to give physicians items and/or services for free or at a discount.
- In some cases, CMS rationalizes these non-FMV exchanges on the ground that the amounts permitted are **de minimis** and, as such, are not likely to impact referral patterns. For example:
  - Non-Monetary Compensation Exception ($429/year in CY 2021).
  - Medical Staff Incidental Benefits Exception (less than $37 per occurrence in CY 2021).
- In other cases, the amounts at issue are not de minimis but CMS permits the arrangements nonetheless. Why? **The Stark Law is being used as a tool to achieve public policy objectives having nothing whatever to do with preventing (i) overutilization, (ii) patient steering, or (iii) unfair competition**.
- The (2006) EHR Exception and (2021) Cybersecurity Exception are prime examples.

EHR Exception

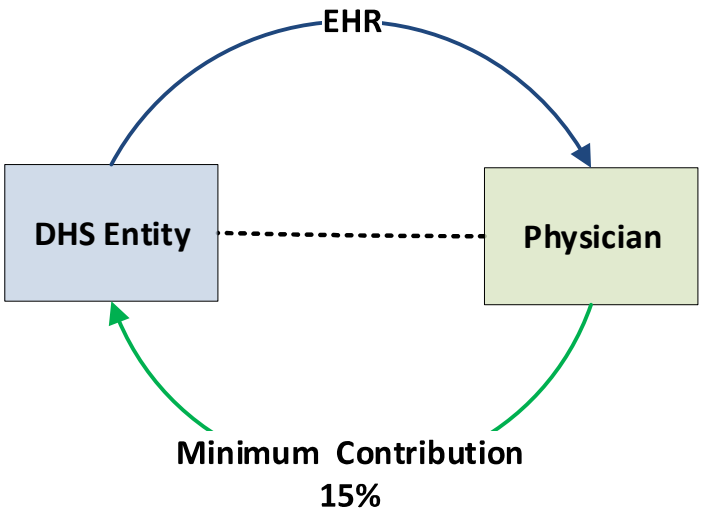
Key Conditions (Historically)

1. Nonmonetary remuneration (e.g, items/services necessary and used predominately to create/maintain/transmit/receive EHR).
2. Provided by DHS Entity (except Lab) to a physician.
3. Software is interoperable (at time provided).
4. Donor does not take any action to limit use/ compatibility/interoperability.
5. Before receipt of items/services, physician pays at least 15% of donor's cost.



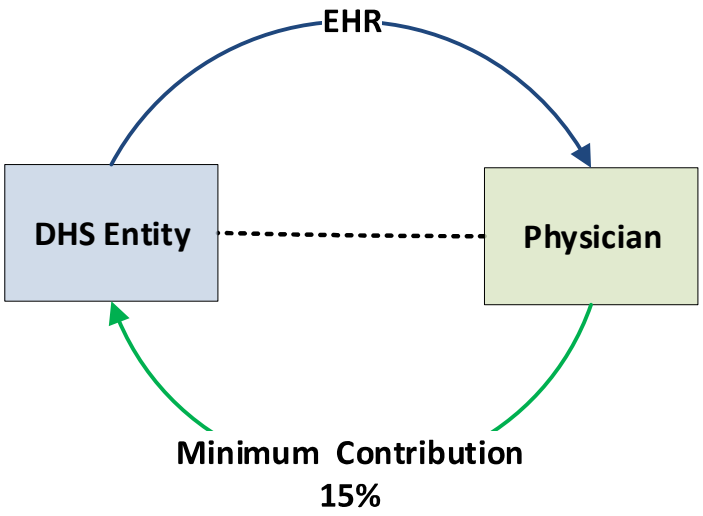
Key Conditions (Historically) (cont.)

6. Physician does not make receipt of items/services a condition of doing business with donor.
7. Donor does not finance physician's payment or loan funds for same.
8. Eligibility and amount/nature of items/services satisfies Volume/Value Standard.
9. Arrangement is in writing, signed by parties, and specifies (i) items and services, (ii) donor's cost, and (iii) amount of physician contribution.
10. Donor does not have actual knowledge (or act in reckless disregard) of fact that physician possesses equivalent items/services.



Key Conditions (Historically) (cont.)

11. Donor does not limit physician's ability to use items/services for any patient.
12. Items/services do not include staffing of physician offices and are not used primarily to conduct business unrelated to physician's medical practice.
13. Arrangement does not violate AKS or any law governing billing or claims submission.
14. Transfer of items/services occurs and all conditions satisfied on or before December 31, 2013 (later extended to December 31, 2021).



Change 1: Elimination of Sunset Date

Pre-Final Rule

Transfer of the items or services occurs and all conditions of the EHR Exception are satisfied on or before December 31, 2021.

Final Rule

Commenters

Lobbied CMS to eliminate Sunset Date.

CMS

Considered simply extending Sunset Date but ultimately decided to make the exception permanent by removing the Sunset Date altogether.

Takeaways

- Certainty with respect to contribution costs for physicians.
- Facilitation of EHR adoption by new entrants or those who may have postponed adoption.
- Preservation of gains already made.

Change 2: Clarification of Scope

Pre-Final Rule	Final Rule
Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records…	Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services, **including cybersecurity software and services**) necessary and used predominantly to create, maintain, transmit, or receive, **or protect** electronic health records…

- According to CMS, EHR Exception always protected donation of certain cybersecurity software and services. Exception amended to make this explicit.
- Definition of cybersecurity is the same for EHR Exception and new Cybersecurity Exception, but scope is narrower under EHR Exception:
  - Cybersecurity software and services limited to those that are necessary and used predominantly to protect electronic health records.
  - Cost sharing requirement applies.

Change 3: Replacement Technology

Pre-Final Rule	Final Rule
Donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that physician possesses or has obtained items or services equivalent to those provided by the donor.	**Commenters** Requested CMS remove limitation on donation of replacement technology. **CMS** Eliminates prohibition on donation of replacement technology.

- CMS sympathetic to concerns of being locked into vendor even if dissatisfied with EHR.
- CMS acknowledges legitimate business and clinical reasons to replace existing EHR (e.g., advancements in EHR technology is continuous and rapid, replacement EHR may be prohibitively expensive).
- EHR Exception continues to have safeguards against donors inappropriately offering or recipients inappropriately soliciting EHR (e.g., all requirements of the Exception apply to replacement technology, including 15% contribution).

Change 4: Modernize Interoperability Requirements - Definition

Pre-Final Rule	Final Rule
Interoperable means able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.	Interoperable means (1) Able to securely exchange data with and use data from other health information technology; and (2) Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law.

- Definition updated to align with statutory definition added by Cures Act.
- Revised definition does not include two proposed revisions in the Proposed Rule:
  - "Without special effort on the part of the user."
  - "Does not constitute information blocking."

Change 4: Modernize Interoperability Requirements - Deeming

Pre-Final Rule	Final Rule
Software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170 [covering health information technology]	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 certification criteria identified in the then-applicable version of 45 CFR part 170 [covering health information technology]

- Certification must be current and active at the time of donation.
- CMS clarifies that EHR Exception only requires that EHR **be** interoperable; it does not prescribe the **method** for confirming interoperability.
- Bottom line: Deeming provision is **available** to those who seek to take advantage of it, but not **required** to establish interoperability.

Change 5: Information Blocking

Pre-Final Rule	Final Rule
The donor… does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems…	Removes requirement in its entirety.

- Original language designed to (i) prevent misuse of Exception that results in data and referral lock-in and (ii) encourage free exchange of data.
  - CMS no longer believes the requirement is an effective way to achieve the policy goals.
  - CMS receptive to concerns about which party bears responsibility for information blocking.
- Subsequent statutory and regulatory initiatives have clearly defined and established penalties for engaging in information blocking.
  - These newer and separate authorities are better suited to deter information blocking and hold individuals/entities accountable.

Change 6: Recipient Contribution Requirement

- Cost sharing requirement intended to address program integrity risks inherent in unlimited EHR donations.
- In Proposed Rule, CMS offered two alternatives:
  - Alternative 1. Eliminate or reduce contribution requirement for small or rural physician organizations (with comments solicited on how to define small or rural physician organization).
  - Alternative 2. Eliminate contribution requirement altogether (with comments solicited on use/adoption impact and program integrity concerns).
- CMS also sought comments on whether to modify/eliminate contribution requirement for **updates** to previously donated EHR.

Change 6: Recipient Contribution Requirement (cont.)

Pre-Final Rule	Final Rule
Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services.	Before receipt of the **initial donation of items and services or the donation of replacement** items and services, the physician pays 15 percent of the donor's cost for the items and services.

- In the Final Rule, CMS went in a third direction.
- Retains (i) cost sharing for initial donations and donations of replacement items/services and (ii) requirement that physicians pay 15 percent in advance of receipt of items/services.
- With respect to updates to initial or replacement EHR, Final Rule permits physicians to pay their contribution amounts at “reasonable intervals.”
    - Reasonable intervals left undefined.
    - Requirement that donor not finance physician’s payment or loan funds to physician to pay for the items/services continues to apply.

Summary of Key Changes

- Eliminates Sunset Date of December 31, 2021, making EHR Exception permanent.
- Clarifies that donation of cybersecurity fits within EHR exception so long as donated items are "necessary and used predominately to … protect electronic health records."
- Eliminates restriction on donation of "equivalent technology," allowing for protection of donations of replacement technology.
- Modernizes interoperability requirements by clarifying definition of interoperable and the circumstances under which EHR technology will be deemed interoperable.
- Eliminates prohibition around information blocking (as such prohibited conduct will now be regulated under the Information Blocking Rule).
- Retains 15% recipient contribution requirement and clarifies that it applies to new and replacement EHRs.

Cybersecurity Exception

Background

- **Pre-Final Rule**. No Stark Law exception existed for donations of cybersecurity technology or related services.
- **Agency's Concern**. Cyberattacks ultimately are borne by health care ecosystem imposing high costs on the health care industry, causing disclosures of protected health information, and endangering patients.
- **Agency's Goal**. "[I]mprove 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."

Proposed Rule: “Cybersecurity” Defined

- Defined as “the process of protecting information by preventing, detecting, and responding to cyberattacks.”
- Definition drawn from the National Institute for Standards and Technology Framework for Improving Critical Infrastructure.
- CMS requested comment on whether this proposed definition was sufficiently tailored to the needs of the health care industry.
- The definition also would apply for purposes of the EHR Exception.

Proposed Rule: “Technology” Defined

- Defined as “any software or other type of information technology *other than hardware*.”
- Definition would apply only to Cybersecurity Exception.
- **Hardware Exclusion.**
  - Hardware is often expensive and can be used for purposes other than cybersecurity.
  - Such donations “present a risk that the donation is being made to influence referrals” and, as such, create a risk of Medicare program and/or beneficiary abuse.
- **Alternative Approaches.**
  - Permit donation of stand-alone (i.e., non-integrated) hardware serving **exclusively** cybersecurity purposes; or
  - Permit donation of hardware determined to be necessary based on donor/recipient-specific **risk assessments**.

Proposed Rule: Four Requirements

- **"Necessary" and "Used Predominantly."** Exception would apply only to technology and services that are "necessary and used predominantly to implement, maintain, or reestablish cybersecurity."
- **Volume/Value Standard.** Donations of technology or services could not be determined in a manner that "takes into account the volume or value of referrals or other business generated between the parties."
- **Conditional.** Neither the physician nor the physician's practice could make the donations of technology or services "a condition of doing business with the donor."
- **Documentation.** Arrangement must be "documented in writing."

Proposed Rule: Comments Requested

- CMS elicited comments on different aspects of the four requirements:
  - **Deeming Provisions.**
    - Deeming provision to establish certain arrangements that would satisfy the "necessary and used predominantly" requirement (e.g., by conforming to a widely-recognized cybersecurity framework).
    - Deeming provision consisting of a list of selection criteria that, if met, would result in the arrangement being deemed not to directly take into account the volume or value of referrals.
  - **Donor Types.** Restrict the types of entities that could be donors under the exception.
  - **Minimum Contribution.** Require a minimum contribution from the recipient to the donor for the cost of the donation.
  - **Writing.** Specify the terms required for a writing documenting the donation arrangement.

Final Rule

- Adopted the Cybersecurity Exception as proposed, with only one substantive modification.
- **"Hardware" Ban Removed**. CMS removed "other than hardware" from the definition of "technology."
  - "Increasingly blurred" lines between hardware, software services, and other technology.
  - Multiple components are frequently part of a bundled package.
- **Clarifications.**
  - Definition of "technology" is specific to the Cybersecurity Exception, and not intended to affect meaning of the (i) "information technology" used in other regulations or (ii) "technology" appearing in EHR Exception.
  - Parties encouraged to perform risk assessments to determine donor and recipient vulnerability to cyberattacks and to create their own cybersecurity programs.

Final Rule (cont.)

- **No deeming provisions.** CMS did not establish "deeming" provisions.
  - Level of specificity that would be required for them to be triggered could result in confusion.
  - Provisions could be interpreted as prescriptive requirements that would prevent parties from making beneficial cybersecurity improvements.
- **No changes to cybersecurity definition**. CMS rejected proposed changes to definition of cybersecurity that would have:
  - expressly included all data analytics and reporting functionality,
  - covered processes such as "identifying" or "recovering" from cyberattacks, and
  - limited definition to "effective" cybersecurity measures designed to protect a particular subject.
- **No specific documentation requirements**. CMS declined to establish specific requirements for documenting the donation arrangement.
  - CMS noted that documentation in the form of a signed agreement would be a "best practice."

Final Rule (cont.)

- **No substantial negative effects.** CMS rejected concerns that the Cybersecurity Exception could:
  - have anti-competitive effects or limit physician autonomy because large health care entities could offer larger donations, or
  - result in inappropriate information blocking.
- **No alternatives to "necessary and predominantly."** CMS declined to adopt alternatives to the "necessary and predominantly" terminology, such as requiring the technology or services to:
  - have a "clear nexus" to cybersecurity, or
  - "[s]ubstantially further the interests of strengthening technology."

Final Rule Text

(1) Nonmonetary remuneration (consisting of technology and services) **necessary and used predominantly** to implement, maintain, or reestablish cybersecurity, if all of the following conditions are met:

  (i) Neither the eligibility of a physician for the technology or services, nor the amount or nature of the technology or services, is **determined in any manner that directly takes into account the volume or value of referrals or other business generated** between the parties.

  (ii) Neither the physician nor the physician's practice (including employees and staff members) **makes the receipt of technology or services, or the amount or nature of the technology or services, a condition of doing business** with the donor.

  (iii) The arrangement is **documented in writing**.

(2) For purposes of this paragraph (bb), "technology" means any software or other types of information technology.

Q&A

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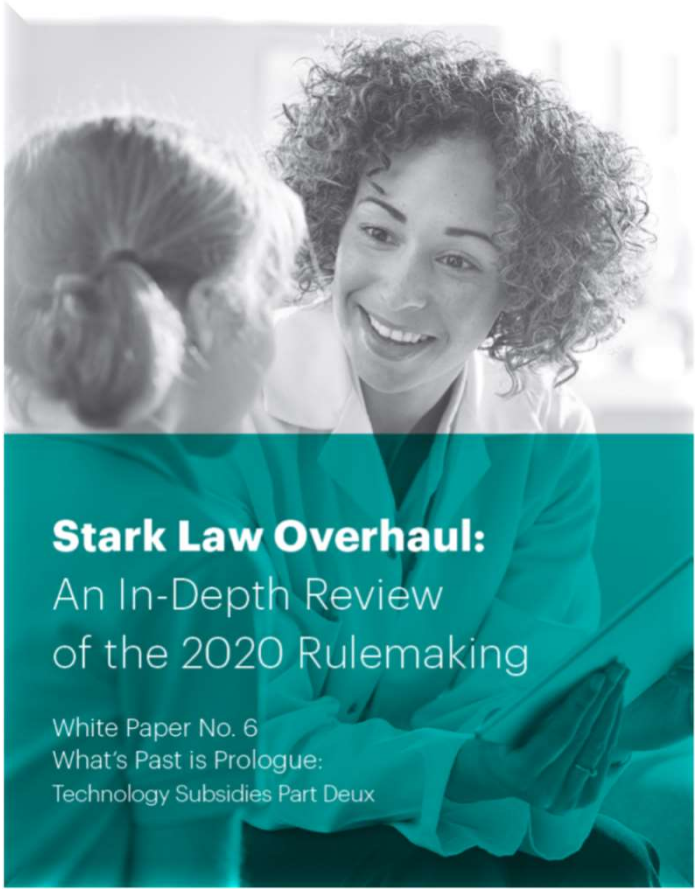

Thank you

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