



The Healthcare Law Section Presents

# Stark Law: Highlights of the New Regulations

**Wednesday, June 16, 2021**

5:00 - 6:30 P.M.

Via Zoom

1.5 hours Gen. CLE Credit

Provider #36

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# PROGRAM EVALUATION FORM

Stark Law: Highlights of the New Regulations

Program Title

Healthcare Law

Section/Committee

Wednesday, June 16, 2021

Zoom Webinar

Program Date and Time

Event Location

Participant Name

State Bar Number

Profession, if not a lawyer

- Please rate by circling the appropriate number ( 5 = highest rating; 1 = lowest rating )

**Speakers**

**Usefulness of Information**

**Speaking ability**

Daniel Eliav \_\_\_\_\_

5 4 3 2 1

5 4 3 2 1

Robert Homchick \_\_\_\_\_

5 4 3 2 1

5 4 3 2 1

Charles Oppenheim \_\_\_\_\_

5 4 3 2 1

5 4 3 2 1

- Overall program rating ..... 5 4 3 2 1

- Contribution of written materials to the learning experience (Consider whether the material contained significant, current intellectual or practical content) ..... 5 4 3 2 1

- Contribution of the location/environment to the learning experience ..... 5 4 3 2 1

- Did the program meet your expectations?  Yes  No

If no, Please explain \_\_\_\_\_

- Did the promotional materials accurately describe the program?  Yes  No

If no, Please explain \_\_\_\_\_

- How did you hear about the program?

E-Mail  Brochure  LACBA Website  LACBA Publications  Other

If other, Please explain \_\_\_\_\_

- Please rank the factors that influenced your attendance at this program.

<b>Topic</b>	5	4	3	2	1	<b>Location</b>	5	4	3	2	1	<b>Price</b>	5	4	3	2	1
<b>Time</b>	5	4	3	2	1	<b>Materials</b>	5	4	3	2	1	<b>Speakers</b>	5	4	3	2	1

Other \_\_\_\_\_

• Number of years in practice \_\_\_\_\_ Number of lawyers in firm \_\_\_\_\_

• List of your area(s) of practice/interest \_\_\_\_\_  
\_\_\_\_\_

• Who recommends/authorizes CLE attendance in your firm?

Managing partner       Recruiting officer       Other \_\_\_\_\_  
 Department Head       Self

• What program length do you prefer?

1 Hour       2 Hours       3 Hours       All-day

• What time of day do you prefer to attend program?

Weekday before 10 a.m.       Weekday lunch       Weekday evening  
 Weekend       Other \_\_\_\_\_

Comments \_\_\_\_\_  
\_\_\_\_\_

You may use my comments for future promotional purposes

You may not use my comments

Signature \_\_\_\_\_

Date \_\_\_\_\_

# The Stark Law: Highlights of the New Regulations



Los Angeles County Bar Association  
Health Law Section Webinar  
June 16, 2021

Daniel Eliav, Nelson Hardiman  
Robert G. Homchick, Davis Wright Tremaine LLP  
Charles Oppenheim, Hooper Lundy & Bookman, PC

# Regulatory Sprint To Coordinated Care

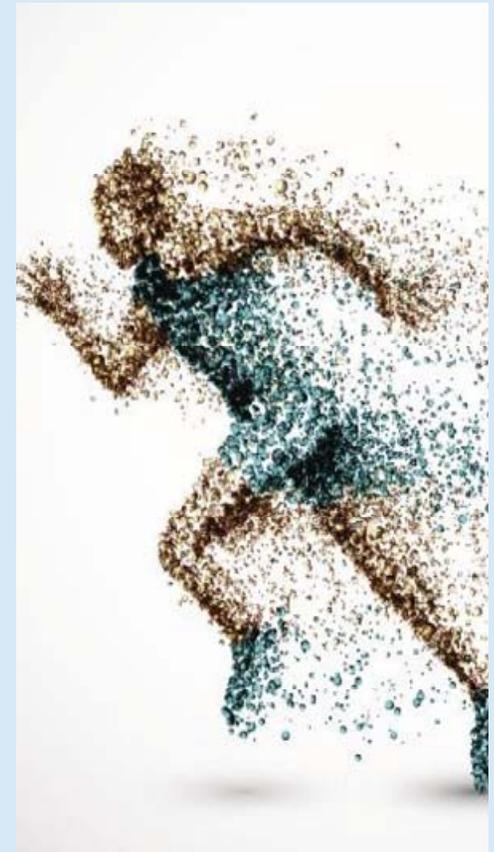
Sprint launched in 2018 – Reduce regulatory barriers and accelerate transformation of the healthcare system into one that better pays for value and promotes care coordination

CMS issued Request for Information regarding Stark  
OIG issued Request for Information regarding AKS and Civil Money Penalty Law

October 17, 2019, CMS and OIG issue Proposed Sprint Regs

December 2, 2020 CMS and OIG publish Final Sprint Regs

- Effective January 19, 2021 (with limited exceptions)





## -Based Rules

- 3 new Stark exceptions and 3 new AKS safe harbors
- Basics: two or more VBE participants
  - Collaborate to achieve a value-based purpose
  - By participating in value-based activities in a valued-based arrangement
  - Relating to a target patient population
  - Have an accountable body or person responsible for oversight
  - Governing documents describe the VBE and how the VBE participants intend to achieve the VBE's value-based purpose(s)

# Risk and the Value-Based Exceptions

- New AKS Safe Harbors
  - Full financial risk
  - Substantial downside financial risk
  - Care coordination arrangements (limited to in-kind remuneration)
- New Stark Exceptions
  - Full Financial Risk
  - Meaningful downside financial risk to physician
  - Value-based arrangements
- The less risk the parties assume, the more regulatory safeguards



## Stark Sprint Regulations: The Big 3



Updated definitions for:

- Fair Market Value
- Volume or Value
- Commercial Reasonableness

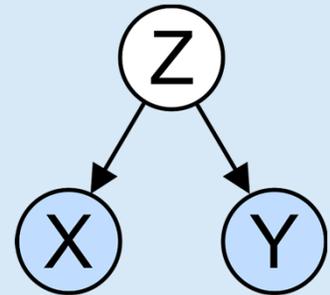
# Fair Market Value



- **Fair Market Value** the “value in an arm’s length transaction, consistent with general market value of the subject transaction.” (42 CFR 411.351).
  - The fair market value of equipment and office space leases are determined without taking into account intend use or, in the case of office space, proximity to the lessor if the lessor is a potential source of referrals.
- **General Market Value** “the price that assets or services would bring as the result of *bona fide* bargaining between well informed parties that are not otherwise in a position to generate business for each other.”
- New definition recognizes that FMV is an individualized determination

## Volume or Value

- CMS is striving for a bright line test
- Compensation will be considered to take into account the volume or value of referrals or other business generated only if the formula includes the volume or value of referrals or other business generated as a variable, either increasing or decreasing the amount of compensation in a way that directly correlates the compensation with the physician's referrals or other business generated
  - “correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases” 42 CFR 411.354 (d)(5), (6)
- Commentary specifically rejects the 4<sup>th</sup> Circuit's *Toumey* opinion (again); payments based on personally performed services do not run afoul the volume or value of referrals prohibition simply because the performance of the service will also generate a hospital facility charge



# Commercial Reasonableness

- Commercial Reasonableness: finally defined!
- An arrangement is “commercially reasonable” if it furthers a legitimate business purpose and is sensible in light of the characteristics of the parties, including their size, type, scope and specialty.
  - “Legitimate business purpose” is not specifically defined but conduct that violates AKS (paying for referrals) would not qualify
  - Regulation specifically states an arrangement can be commercially reasonable even if it does not result in a profit for one or more of the parties
    - Direct response to DOJ arguments and judicial decisions that take the position that it is not commercially reasonable for a hospital to pay a physician in excess of his/her total professional collections

# Indirect Compensation Arrangement Definition



- Sprint Regulations modify the definition of Indirect Compensation Arrangement
- Second prong of test changed to eliminate the reference to special rules on compensation
- New approach requires that
  - (1) the compensation to the physician must vary with the volume or value of the referrals or other business generated by the physician for the DHS entity and
  - (2) the individual unit of compensation must be either not fair market value or calculated using a formula that uses the physician's referrals or other business generated as a variable that positively correlates compensation with volume or value of referrals or other business generated
- Net Result is that the new definition should reduce the number of arrangements that qualify as Indirect Compensation Arrangements under Stark

## Writing Requirement

- Many Stark exceptions require terms of the arrangement be in writing
- Sprint Regulations establish a new 90 day grace period to satisfy the writing requirement
  - Very similar to the alternative means of compliance with signature requirement



## Set in Advance: Permitting prospective changes to compensation

- **Set in Advance** - special rule on compensation changed to permit compensation to be modified at any time during the course of the arrangement, provided:
  - 1) all requirements of an applicable exception are met on the effective date of the modified compensation;
  - 2) the modified compensation is determined before the furnishing of items, service, space or equipment for which the modified compensation is to be paid;
  - 3) before the furnishing of the items, service, space or equipment for which the modified compensation is to be paid the compensation is set forth in writing such that it can be objectively verified.

## Fixing Mistakes– New Special Rule for Reconciling Compensation

Proposed Regulations included an important clarification on the ability of parties to cure an oversight or error during the term of the arrangement

Final Sprint Rules include new “special rule for reconciling compensation” (42 CFR 411.353(h))

Permits submission of claim for DHS if no later than 90 days following termination of the arrangement, the parties reconcile all discrepancies

Parties can cure mistakes during the term and for a period of 90 days following termination



## Required or Directed Referrals



- A special rule on compensation allows an entity to include in employment agreements, personal services agreements or managed care contracts a provision requiring the physician to refer within a designated network or system. However, the referral requirement must include exceptions to honor patient choice, a physician's clinical judgment and payor preferences. (42 CFR 411.354(d) (4))
- Emphasizing patient choice, the Sprint Regulations make this provision an explicit element in the exceptions for academic medical centers, employment, personal services arrangements, physician incentive plans, group practice arrangements with a hospital, fair market value compensation, and indirect compensation arrangements.

## Exception Z Limited Remuneration

- New exception for limited remuneration to physicians
  - No more than \$5,000 per calendar year in the aggregate
  - Must be FMV, not based on volume or value, and commercially reasonable
  - HOWEVER – no writing or signatures required and compensation does not have to be set in advance
- May be used to protect an arrangement that fails to qualify for another exception for part of a year
  - For example, arrangement that fails to satisfy the FMV arrangement exception because it was not reduced to writing during first few months or the parties' signatures were not secured within 90 days

