# Proposed Changes to Stark, Anti-Kickback Statute, and Civil Monetary Penalties Law

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(11/19)

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# HHS'S REGULATORY SPRINT TO COORDINATED CARE

- On October 17, 2019, HHS published proposed changes to regulations implementing:
  - Anti-Kickback Statute, 42 USC 1320a-7b(b)
    - 42 CFR 1001.952
    - 84 FR 55694
  - Ethics in Patient Referrals Act ("Stark"), 42 USC 1395nn
    - 42 CFR 411.351 et seq.
    - 84 FR 55766
  - Civil Monetary Penalties Law re beneficiary inducements, 42 USC 1320a-7a(a)(5)
    - 42 CFR 1003.110
    - 94 FR 55694
- Comments due December 31, 2019.

# DISCLAIMER

- I'm going to focus on what I consider to be the most important changes.
  - Proposed rules contain other technical or relatively esoteric changes.
  - Existing rules contain other terms that I will not address.
- These are proposed rules.
  - Presumably, final rules will issue next year.
  - Not sure what the final rules will include.
- Proposed rules and commentary may give insight into agency interpretation and enforcement.

# ANTI-KICKBACK STATUTE

# ANTI-KICKBACK STATUTE

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by government program unless transaction fits within a regulatory safe harbor.

(42 USC 1320a-7b(b); 42 CFR 1003.300(d))

- "One purpose" test

(*US v. Greber*, 760 F.2d 68 (1985))

Penalties

- 10 years in prison
- $100,000 criminal fine
- $100,000 civil penalty
- 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR 1003.310; 45 CFR 102.3)

- Automatic False Claims Act violation

(42 USC 1320a-7a(a)(7))


# OUTCOME-BASED SERVICES SAFE HARBOR

- Outcomes-based payment arrangements to:
  - Improve quality of care, and/or
  - Reduce costs while improving or maintaining quality of care.
- Based on clinical evidence or credible medical support.
- Payment methodology is
  - Set in advance;
  - Commercially reasonable;
  - Consistent with FMV; and
  - Not based on the volume or value of referrals or other business payable by federal healthcare programs.
- Agreement does not create incentive to act against patient's best interest or limit medically necessary items or services.
- Agreement for at least 1 year.
- Written agreement specifying required terms.
- Policies to immediately address deficiencies in quality of care.

(42 CFR 1001.952(d)(2))


# VALUE-BASED ARRANGEMENT SAFE HARBORS

- New safe harbors for care coordination and value-based arrangements.
  - (ee) Care coordination arrangements
  - (ff) Value-based arrangements with substantial downside financial risk
  - (gg) Value-based arrangements with full financial risk
  - (hh) Arrangements for patient engagement and support to improve quality, health outcomes and efficiency
  - (ii) CMS-sponsored model arrangements and model patient incentives.
  - (jj) Cybersecurity technology and related services.
  - (kk) ACO beneficiary incentive program

(42 CFR 1001.952(ee)-(kk))

# VALUE-BASED DEFINITIONS

- "Value-based purpose" =
  - Coordinating and managing the care of a target patient population;
  - Improving quality of care for a target patient population;
  - Appropriately reducing the costs to, or growth in expenditures of, payors without reducing the quality of care for a target patient population; or
  - Transitioning from health care delivery and payment based on the volume to quality of care an control of costs for a target patient population.

(42 CFR 1001.952(ee))

# VALUE-BASED DEFINITIONS

- "Value-based enterprise" ("VBE") = 2+ participants
  - Collaborating to achieve at least one value-based purpose;
  - Each of which is a party to a value-based arrangement with other(s) in the VBE to achieve at least one value-based activity for a target population;
  - Have an accountable body or person responsible for financial and operational oversight of the VBE; and
  - Have governing document that describes the VBE and how participants intend to achieve value-based purposes.

(42 CFR 1001.952(ee))

# VALUE-BASED DEFINITIONS

- "Value-based activity" = any of the following provided that the activity is reasonably designed to achieve at least one value-based purpose of the VBE:
  - Provision of an item or service;
  - Taking of an action; or
  - Refraining from taking an action.
- Making a referral is not a value-based activity.

(42 CFR 1001.952(ee))

# VALUE-BASED DEFINITIONS

- "Value-based arrangement" = provision of at least one value-based activity for a target patient population between:
  - The VBE and one or more VBE participants; or
  - VBE participants in the same value-based enterprise.
- "Target population" = identified patient population selected by the VBE using criteria that
  - Are set out in writing in advance, and
  - Further the VBE's value-based purposes.

(42 CFR 1001.952(ee))


# CARE COORDINATION SAFE HARBOR

- Value-based arrangement using evidenced-based measures that advance coordination and management of target patient population.
- Arrangement is commercially reasonable.
- Written agreement specifying terms.
- Remuneration is:
  - In-kind.
  - Used to promote value-based activities.
  - Does not induce medically unnecessary services or reduce or limit services.
  - Not funded by third parties.
- Arrangement not based on referrals or business not covered by value-based arrangement.
- Recipient pays at least 15% of in-kind remuneration.

(42 CFR 1001.952(ee))

# CARE COORDINATION SAFE HARBOR (CONT.)

- Arrangement does not:
  - Limit provider's ability to make decisions in best interest of patient.
  - Require referrals to particular provider if:
    - Patient wants to elsewhere, or
    - Payer determines provider.
  - Include marketing to patients or patient recruitment activities.
- Monitor and report on the VBE performance.
- Terminate within 60 days if VBE's accountable body determines it is not working.
- Remuneration not to be diverted, resold, or used for unlawful purpose.
- VBE makes info available to HHS upon request.

(42 CFR 1001.952(ee) (cont.))

# CARE COORDINATION DEFINITIONS

- "Care coordination and management" = deliberate organization of patient care activities an sharing info between to or more value-based enterprise ("VBE") participants or patients tailored to improve health outcomes of the target population and achieve safer and more effective care for the target population.

(42 CFR 1001.952(ee))


# VALUE-BASED ARRANGEMENT: SUBSTANTIAL DOWNSIDE

- VBE has (or will assume in next 6 months) substantial downside financial risk.
- VBE participants share risk, e.g., through payment, capitation, or payment under Stark's value-based safe harbor.
- Payments between VBE and VBE participants:
  - Are used for value-based activities and purposes;
  - Do not limit medically necessary items or services;
  - Does not take into account referrals; and
  - Satisfies other conditions.
- Writing setting terms in advance.
- Does not induce or limit participants ability to make decisions in best interest of patient.
- Make records available to HHS upon request.

(42 CFR 1001.952(ff))


# VALUE-BASED ARRANGEMENT: FULL FINANCIAL RISK

- VBE has (or will assume in next 6 months) full financial risk for cost of providing care for at least 1 year.
- Writing signed by parties specifying terms.
- Payments between VBE and VBE participants:
  - Are used for value-based activities and purposes;
  - Do not limit medically necessary items or services;
  - Does not take into account referrals; and
  - Satisfies other conditions.
- VBE provides quality assurance.
- No marketing to or recruiting patients.
- Make records available to HHS upon request.
- Other conditions.

(42 CFR 1001.952(gg))


# ARRANGEMENTS FOR PATIENT ENGAGEMENT, QUALITY, OUTCOMES, EFFICIENCY

- Patient engagement tools or support furnished by VBE participant to patient if:
  - No outsider funds or contributes to provision of the tool or service.
  - In-kind tool or support that furthers specific health-related goals (e.g., monitoring, preventive, etc.); not cash or cash-equivalent or marketing.
  - Item not to be diverted, sold or used improperly.
  - Aggregate retail value ≤ $500/year.
  - Make records available to HHS upon request.

(42 CFR 1001.952(hh))


# CMS-SPONSORED PROGRAMS

- Remuneration between parties in a CMS-sponsored model arrangement or incentive program if:
  - Does not induce medically unnecessary services, or reduce medically necessary services.
  - No payments to induce referrals outside the CMS-sponsored program.
  - Signed writing sets forth terms in advance.
  - Records provided to HHS upon request.
  - Comply with CMS program requirements.

(42 CFR 1001.952(ii))


# CYBERSECURITY DONATION SAFE HARBOR

- Nonmonetary technology and services if:
  - Predominantly for cybersecurity.
  - Not hardware.
  - Donor does not:
    - Take into account referrals when determining eligibility, amount or nature of tech or services; and
    - Condition donation on referrals.
  - Recipient does not make the donation a condition of doing business with donor.
  - Written signed agreement describing:
    - Tech and services provided, and
    - Recipient's contribution, if any.
  - Donor does not shift costs to any federal program.

(42 CFR 1001.952(jj))


# ACO BENEFICIARY INCENTIVE PROGRAM

- Incentive payments made by an ACO to an assigned beneficiary under a beneficiary incentive program established by CMS so long as payment is made in accordance with the requirements of the program.

(42 CFR 1001.952(kk))

# PERSONAL SERVICES SAFE HARBOR

- Not required to specify schedule for periodic services arrangements.
- Compensation methodology need only be set in advance, not the aggregate compensation.

(42 CFR 1001.952(d)(1))

# EHR SUPPORT SAFE HARBOR

- Now includes cybersecurity software or services.
- EHR donor does not engage in information blocking re donated items or services.
- Beneficiary may have the equivalent items or services.

(42 CFR 1001.952(y))

# LOCAL TRANSPORTATION SAFE HARBOR

- Extends mileage limit.
  - For rural patients, extends to 75 miles.
  - No mileage limit if patient is being discharged from inpatient facility and transported to patient's residence or another residence.
- Define:
  - Eligible entity.
  - Established penalty.
  - Shuttle service.
  - Urban area.
  - Rural area.

(42 CFR 1001.952(y))

# WARRANTIES SAFE HARBOR

- Modified requirements.

(42 CFR 1001.952(g))

# Ethics in Patient Referrals Act ("Stark")

# ETHICS IN PATIENT REFERRALS ACT ("STARK")

- If physician (or family member) has financial relationship with entity:
  - Physician may not refer patients to entity for designated health services ("DHS"), and
  - Entity may not bill Medicare or Medicaid for such DHS

  unless arrangement fits within a regulatory exception.

(42 USC 1395nn; 42 CFR 411.353 and 1003.300)

## Penalties

- No payment for services provided per improper referral.
- Repayment w/in 60 days.
- Civil penalties.
  - $24,748 per claim submitted
  - $164,992 per scheme

(42 CFR 411.353, 1003.310; 45 CFR 102.3)

- Likely False Claims Act violation
- Likely Anti-Kickback Statute violation

# PERIOD OF DISALLOWANCE

- Removed the regulations concerning the "period of disallowance."

(42 CFR 411.353(c))

- *Time when violation ends is determined on a case by case basis, depending on the particular facts.*
- *"An entity that detects a problem in an active financial relationship and corrects the problem while the 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 the arrangement has ended, we believe the parties cannot retroactively 'cure' previous noncompliance by recovering or repaying problematic compensation."*

# DEFINITION OF "PHYSICIAN"

- As defined in 42 USC 1395x(r), i.e.,
  - MD
  - DO
  - DDS or DMD
  - DPM
  - OD
  - DCM
  - DC

  who are legally authorized and practices within the scope of licensure in the relevant state.

(42 CFR 411.351)

# DEFINITION OF "DESIGNATED HEALTH SERVICES"

- DHS only applies to services payable by Medicare, not Medicaid.
- "For services furnished to inpatients by a hospital, a service is not a designated health service payable … by Medicare if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the [IPPS]."

(42 CFR 411.351)

# OWNERSHIP OR INVESTMENT INTERESTS

- "Ownership and investment interests" do not include:
  - Titular ownership or investment without the ability or right to receive financial benefits of ownership or investment, e.g., profits, dividends, sale proceeds, or similar return on investment.
  - Interest arising from an employee stock ownership plan ("ESOP").

(42 CFR 411.354(b))

# DEFINITION OF "FAIR MARKET VALUE"

- In general: "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."
- Rental of space/equipment: "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."
- "General market value" = price that items would bring as result of bona fide bargaining at the time of the agreement.

(42 CFR 411.351)

# DEFINITION OF "COMMERCIALLY REASONABLE"

- "Commercially reasonable" =
  - 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 a profit for one or more of the parties.

(42 CFR 411.351)

➢ *Still may not take into account referrals.*

➢ *Not reasonable if arrangement is illegal or duplicative.*

# "VOLUME OR VALUE OF REFERRALS"

- Generally removes reference to "directly or indirectly".
- Compensation by entity to physician (or family member) takes into account volume or value of referrals only if:
  - Formula used to calculate compensation includes the physician's referrals to the entity as a variable, resulting in increase/decrease in compensation that positively correlates with the number or value of the physician's referrals, or
  - There is predetermined, direct correlation between 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 compensation is to be determined.

(42 CFR 411.354(d)(5))

- Similar terms apply to compensation by physician to entity.

(42 CFR 411.354(d)(6))


# REMUNERATION < $3,500 SAFE HARBOR

- New safe harbor for remuneration to a physician for items or services provided by a physician that do not exceed $3,500 per calendar year
  - Compensation not determined in any manner that takes into account volume or value of referrals.
  - Compensation does not exceed FMV.
  - Arrangement is commercially reasonable.
  - Compensation for use of space, equipment personnel, items, supplies or services not based on:
    - % of revenue attributable to such use; or
    - Per-unit of service fee that are not time-based to extent they reflect services referred by the party granting permission to use the space, equipment, personnel, items, supplies or services.
- $3,500 adjusted annually based on CPI.

(42 CFR 411.357(z))

➢ *Not required to be in writing, signed, or set in advance.*


# VALUE-BASED ARRANGEMENTS SAFE HARBORS

- New safe harbor for value-based arrangements.

(42 CFR 411.357(aa))

- Definitions parallel Anti-Kickback definitions above:
  - Value-based arrangement
  - Value-based enterprise ("VBE")
  - Value-based activity
  - Value-based purpose
  - Target population

(42 CFR 411.351)


# VALUE-BASED ARRANGEMENTS: FULL FINANCIAL RISK

- VBE is at "full financial risk" (or will be in 6 months), i.e.,
  - VBE is financially responsible on prospective bases for cost of care of patients in target population.
- Remuneration:
  - Is for value-based activities;
  - Does not induce reduction of medically necessary items or services; and
  - Not conditioned on referrals of patients who are not part of the value-based arrangement.
- Records of arrangement kept for 6 years.

(42 CFR 411.357(aa)(1))


# VALUE-BASED ARRANGEMENTS: DOWNSIDE FINANCIAL RISK

- Physician has "meaningful downside financial risk" for failure to meet value-based purposes of the VBE, i.e.,
  - Physician is responsible to pay no less than 25% of remuneration; or
  - Is financially responsible on prospective basis for cost of defined set of patient care items or services.
- Writing sets forth nature and extent of risk.
- Remuneration:
  - Methodology is set in advance;
  - For value-based activities;
  - Does not induce reduction of medically necessary items or services; and
  - Not conditioned on referrals of patients who are not part of the value-based arrangement;
- Records of arrangement kept for 6 years.

(42 CFR 411.357(aa)(2))


# VALUE-BASED ARRANGEMENTS: GENERAL

- Value-based arrangement is:
  - Writing signed by parties covering:
    - Value-based activities to be performed;
    - How value-based activities will further the value-based purposes;
    - Target patient population;
    - Type or nature of remuneration;
    - Methodology for remuneration set in advance; and
    - Performance or quality standards set in advance.
  - Remuneration
    - For value-based activities;
    - Does not induce reduction of medically necessary items or services; and
    - Not conditioned on referrals of patients who are not part of the value-based arrangement;
  - Records of arrangement kept for 6 years.

(42 CFR 411.357(aa)(3))


# CYBERSECURITY DONATIONS SAFE HARBOR

- Non-monetary services, software or information technology other than hardware.
- Necessary and used predominantly for cybersecurity.
- Eligibility, amount, and nature of services not determined on referrals.
- Physician does not make the tech or services a condition of doing business.
- Writing documenting the arrangement.

(42 CFR 411.351)

# EHR DONATIONS SAFE HARBOR

- Expands EHR safe harbor to certain cybersecurity software and services.
- Donor cannot engage in a practice constituting information blocking as defined in the Public Health Service Act § 3022 in connection with the donated item or service.
- Deleted December 31, 2021 sunset provision.

(42 CFR 411.357(w))

# FAIR MARKET VALUE SAFE HARBOR

- Extends FMV safe harbor to also include use of office space.
- Compensation cannot be based on percentage of revenue attributable to services performed or generated through the space.

(45 CFR 411.357(l))

# PAYMENTS BY A PHYSICIAN SAFE HARBOR

- Safe harbor applies to payment by a physician (or family member) to any entity as compensation for any items or services:
  - That are furnished at a price consistent with FMV, and
  - To which safe harbors in .357(a)-(h) are not applicable, e.g.,
    - Leases
    - Employment
    - Personal service arrangement
    - Recruitment
    - Isolated transactions
    - Group practice arrangements with hospital

(42 CFR 411.357(i))

# REMUNERATION UNRELATED TO DHS SAFE HARBOR

- Safe harbor for remuneration provided by hospital to physician if remuneration is "unrelated to the provision of DHS", i.e.,
  - Remuneration is not determined in a manner that takes into account the volume or value of physician's referrals; and
  - Remuneration is for an item or service that is "not related to the provision of patient care services."
    - "Items related to patient care services" means item, supply, device, equipment, or space used in diagnosis or treatment of patient and any tech used to communicate with patients re patient care services.
    - Services that could be provided by a person who is not a licensed medical professional are deemed not to be "related to provision of patient care services."

(42 CFR 411.357(g))

# LEASES
# SAFE HARBORS

- Space and equipment leases normally require that the lessee have "exclusive use" of the leased space or equipment.
- "Exclusive use" means that the lessee uses the leased 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 space or equipment.

(42 CFR 411.357(a), (b))

# PHYSICIAN RECRUITMENT SAFE HARBOR

- If recruit physician into a group practice, only need to have the practice sign the recruitment agreement if:
  - The remuneration is provided indirectly to the physician through payments made to the practice; and
  - Practice does not pass directly through to the physician all of the remuneration from the hospital.

(42 CFR 411.357(e))

# NON-PHYSICIAN RECRUITMENT SAFE HARBOR

- Recruitment agreement must be executed before the NPP enters a compensation agreement with the physician or physician group.
- Physician or group must engage the NPP to provide direct patient care services that address the medical needs of specific patients or any task performed by a NPP that promotes the care of patients of the physician or physician organization with which the NPP has a compensation arrangement.

(42 CFR 411.357(x))

# ISOLATED TRANSACTIONS SAFE HARBOR

- Single payment, or
- Integrally related installment payments if:
  - Total aggregate payment fixed before first payment is made and does not take into account volume or value of referrals or otherwise generated by the physician; and
  - Payments are immediately negotiable, guaranteed, secured by negotiable promissory note, or otherwise ensures payment if default.
- Includes one-time sale of property, practice, etc., but not single payment for multiple or repeated services (such as a payment for services previously provided but not yet compensated).

(42 CFR 411.351)

➢ *Can't be used to cure past violations.*

# GROUP PRACTICE COMPENSATION: SHARE OF PROFITS

- Physicians in group practice may be paid share of overall profits subject to conditions.
  - "Overall profits" =
    - If ≤ 5 physicians in group: profits derived from DHS of the entire group.
    - If > 5 physicians in group: Profits derived from DHS of any component of the group with at least 5 physicians.
  - Share may be indirectly related to the volume or volume or value of the physician's referrals.
  - Share may be based on group's revenues from services that are not DHS and would not be DHS if payable by Medicare.

(42 CFR 411.352(i))

# GROUP PRACTICE COMPENSATION: PRODUCTIVITY BONUS

- Physicians in group practice may be paid based on services they personally perform.
  - May pay based on services that are "incident to" physician's services.
  - May pay based on services that are not DHS and would not be DHS if payable by Medicare.

(42 CFR 411.352(i))

# GROUP PRACTICE COMPENSATION: VALUE BASED PROGRAM

- May pay profits from DHS that are directly attributable to a physician's participation in a value-based enterprise as defined in 411.351.

(42 CFR 411.352(i))

# INDIRECT COMPENSATION ARRANGEMENTS

- In general, the only safe harbors applicable to indirect compensation arrangements are:
  - Exceptions that are applicable to both ownership and compensation arrangements per 411.355.
  - Indirect compensation exception per 411.357(p).
  - Value-based compensation arrangements per 411.357(aa).

(42 CFR 411.354(c))

# CONDITIONING COMPENSATION ON REFERRALS

- May condition physician's compensation in employment, personal services arrangement, or management contract if satisfy conditions, including but not limited to:
  - Compensation or formula is set in advance for the duration of the arrangement; any changes to the compensation or formula must be made prospectively.
  - Compensation must be fair market value for the physician's services.

(42 CFR 411.354(d))

- If compensation is conditioned on referrals, must satisfy requirements in 411.354(d)(5)).

(*See, e.g.*, 42 CFR 411.355(e), .357(c), (d), (l), (aa))

# WRITING AND SIGNATURE REQUIREMENT

- If safe harbor requires writing signed by the parties, the requirement is met if:
  - Arrangement fully complies with the safe harbor except for the writing or signature requirement, and
  - The parties obtained the writing or signature within 90 calendar days immediately following the date the arrangement became noncompliant with the requirements of the applicable safe harbor.

(42 CFR 411.354(e))

- *90-day grace period applies to both writing and signature.*
- *Must still comply with other terms, including set in advance when required.*

# REFERENCES TO THE ANTI-KICKBACK STATUTE

- Eliminates the requirement in several safe harbors that the arrangement:
  - Does not violate the anti-kickback statute, and
  - Billings and claim submissions does not violate federal or state laws or regulations governing billing or claims submissions.

(42 CFR 411.351, .355)

# NOT IN RULE, BUT HELPFUL COMMENTARY

- Productivity bonuses based on personally performed services do not take into account the volume or value of referrals even if they generate a facility fee.

# Civil Monetary Penalties Law

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# CIVIL MONETARY PENALTIES LAW

- Prohibits offering remuneration to a Medicare/Medicaid beneficiary if know or should know that it is likely to influence such beneficiary to order or receive services from a particular provider or supplier.

(42 USC 1320a-7a(5); 42 CFR 1003.1000(a))

Penalties

- $20,000 per violation.
- Exclusion from Medicare and Medicaid

(42 CFR 1003.1010(a); 45 CFR 102.3)

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# TELEHEALTH FOR END STAGE RENAL DISEASE

- Prohibited "remuneration" does not include the provision of telehealth audio visual tech by a provider or renal dialysis facility to person with ESRD if:
  - Person receiving home dialysis paid under Medicare Part B;
  - Not offered as part of an advertisement or solicitation;
  - Telehealth tech:
    - Contributes substantially to telehealth for ESRD;
    - Not of excessive value;
    - Not supplicative of tech that beneficiary already owns;
  - Provider/facility does not:
    - Bill fed healthcare programs, other payers, or individuals;
    - Claim bad debt
    - Otherwise shift burden to fed programs, payers, or individuals.

(42 CFR 1003.110(10))

# Questions?

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