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Antikickback Statute, Civil Monetary Penalty Law, and Stark Law – 2020 Final Rules

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Purpose and Agenda

- Not a comprehensive summary of every provision in the two final rules (403 pages!)
- Background information
- Issue-spotting and discussion of selected key provisions
- Additional resources

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BACKGROUND

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"The Stark law was created to address a risk in an FFS payment model. The financial incentives that trigger overutilization concerns in an FFS payment model are largely or entirely eliminated in alternative payment models."

"Why Stark, Why Now?" Senate Finance Committee Majority Staff Report (2016)

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Reform Implementation Timeline - Part I

Date	Event
4/24/2009; 6/30/2009	AHLA "Convener" on Stark Law Reform
12/10/2015; 6/30/2016; 7/12/2016	Senate Finance Committee Roundtable, Report/White Paper, and Hearing on Stark Law Reform
7/24/2017	House Ways & Means Committee, Medicare Red Tape Relief Project began
6/25/2018	HHS "Regulatory Sprint to Coordinated Care" announced; CMS issues RFI seeking comment on how to address "undue regulatory impact and burden" of Stark Law
8/27/2018	OIG issued RFI seeking comment on regulatory provisions (AKS safe harbors, beneficiary inducements CMP) that may "act as barrier to coordinated care or value-based care."

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Reform Implementation Timeline – Part II

10/17/2019	CMS and OIG issue NPRMs
6/30/2020	HHS announced in Spring 2020 Unified Agenda intention to issue Stark Law final rule in August 2020
8/27/2020	CMS announces extension of timeline for publication of Stark Law Final Rule extended to August 2021 because CMS was "still working through the complexity of issues raised by comments on the proposed rule."
11/20/2020	CMS and OIG announce Final Rules
12/2/2020	CMS and OIG Final Rules published in Federal Register
1/19/2021	Effective dates for OIG and CMS Final Rules (with exception noted below)
1/1/2022	Effective date for CMS amendments to definition of a group practice to update Special rule for productivity bonuses and profit share (42 C.F.R. § 411.352(i))

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DISCUSSION – SELECTED KEY PROVISIONS

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Selected Key Provisions

<u>CMS Final Rule</u>

- Value-based care
- Non-monetary donations of cybersecurity technology
- Revised definitions – e.g., commercially reasonable; volume/value; fair market value
- Pass-through arrangements
- Updated definition of "overall profits" for special rules on profit sharing
- ESOP
- Limited remuneration to physician
- Changes to signature and writing requirements

<u>OIG Final Rule</u>

- Value-based arrangements
- Non-monetary donations of cybersecurity technology
- Patient engagement and support
- PSA Safe Harbor and outcomes-based payments
- Bundled warranty arrangements
- Local transportation
- Telehealth technologies related to in-home dialysis

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CMS and OIG Final Rules - Value-Based Care/ Arrangements

- For legal and compliance professionals who are involved in reviewing (or creating) value-based care arrangements and payment models, it may be obvious what these terms mean and why changes were needed to AKS and Stark regulations to facilitate further adoption of these models
- For those who are not involved in VBC on day-to-day basis, VBC may seem a bit more unclear.
- VBC ties reimbursement to quality of care and rewards efficiency and effectiveness. FFS bases reimbursement on volume of care; government has viewed FFS as improperly incentivizing health care providers in some circumstances
  - Same underlying concerns existed spurring transition from cost-based reimbursement to FFS when that occurred beginning in the 1980s.

CMS and OIG Final Rules - Value-Based Care/Value-Based Arrangements

- Types of value-based arrangements include:
  - Alternative payment models
    - Specific clinical condition
    - Specific care episode
    - Specific population
  - Bundled Payments
  - Pay for performance
  - Shared savings programs
  - Risk-bearing arrangements
  - Accountable care organizations
  - Global payment and capitation models

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CMS and OIG Final Rules - Value-Based Care/Value-Based Arrangements

- CMS and OIG have used waivers and new statutory authorities to create the original and other value-based programs (beginning in 2012 and continuing through present):
  - ESRD Quality Incentive Program
  - Hospital Value-Based Purchasing Program
  - Hospital Readmission Reduction Program
  - Value Modifier Program (or Physician Value-Based Modifier)
  - Hospital Acquired Conditions Reduction Program
  - Skilled Nursing Facility Value-Based Program
  - Home Health Value Based Program

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CMS and OIG Final Rules - Value-Based Care/Value-Based Arrangements

- Final Rules create permanent exceptions to permit VBA
- CMS and OIG believe rule changes will also result in greater adoption of VBA in private and commercial markets
  - Study released in December 2019 found that VBP increased from 10.9% in 2012 to 53% in 2017, but 90% based on FFS payment systems. Only 6% from APM that includes downside financial risk for providers.

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CMS and OIG Final Rules - Value-Based Care/Value-Based Arrangements

- Primary focus of both CMS and OIG rules and major impetus for reform
- Deliberate and significant differences between CMS and OIG rules: OIG's VBA safe harbors protect a narrower universe of arrangements than CMS rules
  - Stark exceptions mandatory because Stark law is strict liability
  - AKS safe harbors are not required and can use facts and circumstances test to protect arrangements
  - Knowledge/Intent required for criminal, civil and administrative enforcement of AKS

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CMS and OIG Final Rules - Value-Based Care/Value-Based Arrangements

- Tiered structure prominent in OIG Final Rule - flexibility increases as parties assume more downside financial risk
  - Care Coordination Arrangements
  - Substantial Downside Financial Risk
  - Full Financial Risk
- OIG's Final Rule does not prohibit entities with common ownership from forming VBE (contrast GPO safe harbor)
- VBE participants can include excluded entities (like pharma manufacturers) under OIG Final Rule, but cannot receive safe harbor protection

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CMS and OIG Final Rules - Nonmonetary Donations of Cybersecurity Technology

- Donations must be "necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity."
- Written agreement
- No value/volume
- No monetary cap (but OIG had considered)
- OIG - No restrictions on types of individuals or entities eligible as donors or recipients

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SELECTED KEY PROVISIONS – STARK FINAL RULE

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Other Selected Key Provisions – Stark Final Rule

- Revised definitions – e.g., commercially reasonable; volume/value; Fair market value
- Pass-through arrangement – does not create compensation relationship
- Updated definition of "overall profits" for special rules for profit shares and productivity bonuses
  - All DHS of group; No distribution on service-by-service basis
- ESOP – Not ownership or investment interest
- Limited remuneration to physician – Aggregate of $5,000 adjusted annually for inflation
- Changes to signature and writing requirements; 90 calendar days

SELECTED KEY PROVISIONS - OIG FINAL RULE

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Other Selected Key Provisions - OIG Final Rule

- Patient engagement and support
- Bundled warranty arrangements
- Local transportation
- Telehealth technologies related to in-home dialysis
- CMS-sponsored model arrangements and patient initiatives
- Amendments to EHR safe harbor, including removing sunset provision
- PSA Safe Harbor and outcomes-based payments

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OIG Final Rule – PSA Safe Harbor and Outcomes-Based Payments

- Increased flexibility for part-time or sporadic arrangements
- Increased flexibility for arrangements for which aggregate compensation cannot be determined in advance
- Outcomes-based payments – periodic re-assessment and revised benchmarks and remuneration required
- Exclusion of certain entities from outcomes-based payment exception (e.g., pharma manufacturers)

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Political Considerations

- Rule changes were backed by broad bipartisan support and long history of reform efforts
- Rules subject of significant commentary and interest by American Hospital Association, American Medical Association, Federal of American Hospitals, PhRMA, and other organizations
- Some lingering perception that the rules were rushed through final review post-election (especially since CMS had previously announced delay until August 2021 for publication)
- Continuing interest in Congress to implement additional statutory changes to further simplify AKS and Stark
  - Particular interest in re-evaluating entities OIG deemed ineligible for safe harbor protections -- pharmaceutical manufacturers in particular.

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ADDITIONAL RESOURCES

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Additional Resources

- CMS Fact Sheet, https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f (11/20/2020)
- CMS Final Rule, https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf (12/2/2020)
- OIG Fact Sheet, https://oig.hhs.gov/reports-and-publications/federal-register-notices/factsheet-rule-beneficiary-inducements.pdf (11/20/2020)
- OIG Final Rule, https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf (12/2/2020)

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Additional Resources (cont.)

- Alston Health Care Advisory on Final Rule (11/25/2020) https://www.alston.com/en/insights/publications/2020/11/cms-and-oig-significantly-update
- Alston Health Care Advisory on Proposed Rule (12/19/2019) https://www.alston.com/en/insights/publications/2019/12/cms-and-oig-release-proposed-rules
- Article by Seema Verma & Kim Brandt, Updates to Stark Law Regulations Will Drive Value in the Health Care System 12/9/2020) https://www.healthaffairs.org/do/10.1377/hblog20201208.472326/full/

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Questions?

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