

What You Can Learn from a Stark Investigation: Practical Tips

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Agenda

- VERY short Stark summary.
- Overview of a Stark FMV investigation.
- Tips for government investigations generally.
- Lessons from Stark investigations.

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Stark History

- Study: Owners of scanners are more likely to order scans.
- Named for Pete Stark, D-CA.
- Original Stark: 1989. Lab only.
- Stark II: Adds 11 “designated health services.”

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Mind the Gap

- 4 cases discuss Medicare Manual language from 1992 that was “written with Stark in mind.”
- The discussion relates to hospital services.
- Stark I (1989) only applied to laboratories. Hospital services were added in Stark II.

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Regulatory Framework

- Statute: § 1877 of the SSA/42 USC 1395.
- Regulations: 42 CFR 411.351-389.
- Federal Register preamble.
- Annual list of Designated Health Services (DHS) in the Medicare Physician Fee Schedule.

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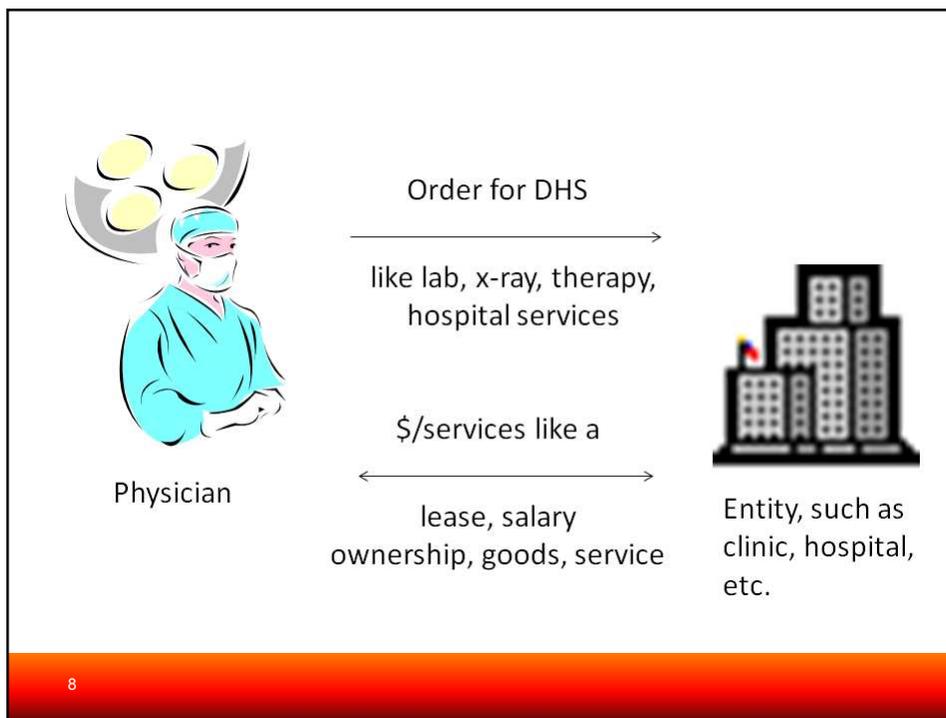
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The Big Picture

- If a physician (or immediate family member) has a financial relationship with an organization that provides DHS ordered by the physician, Stark applies.
- Any value will do it, needn't relate to DHS.

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The Big Picture

- Financial relationships can be ownership or compensation.
- 3 exceptions protect both ownership and compensation. The others only protect one or the other.
- Intent doesn't matter.*

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*Does Intent Matter??

“In some cases, relationships clearly will not involve a transfer of remuneration and thus will not trigger [Stark]. In others, activity might involve transfer of remuneration and there may be no readily apparent exception. We expect that questions of [this] kind will arise with some frequency. Parties may submit advisory opinion requests...”

- 72 FR 51058

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“Designated Health Services”

- Clinical laboratory.
- Physical therapy.
- Occupational therapy.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrition.
- Prosthetics and orthotics.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.
- Outpatient SLP services.

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What About the Anti-Kickback Statute?

- For employees there is the statutory employment exception: 42 USC § 1320a-7b(b)(3)(B).
- It exempts “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer).”
- Often overlooked preamble for payments within an entity.

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Anti-Kickback Inapplicable Internally

“Comment: Many commenters requested the OIG to clarify that payments between corporations which have common ownership are not subject to the statute. Commenters cited as examples intracorporate discounts and payments between two wholly-owned subsidiaries. Some commenters argued that referral arrangements between two related corporations do not constitute "referrals" within the meaning of the statute, and suggested that the OIG define the word "referral" to exclude such activity.

Response: We agree that much of the activity described in these comments is either not covered by the statute or deserves safe harbor protection. **We believe that the statute is not implicated when payments are transferred within a single entity, for example, from one division to another. Thus, no explicit safe harbor protection is needed for such payments.”**

- 56 F.R. 35952 (July 29, 1991)

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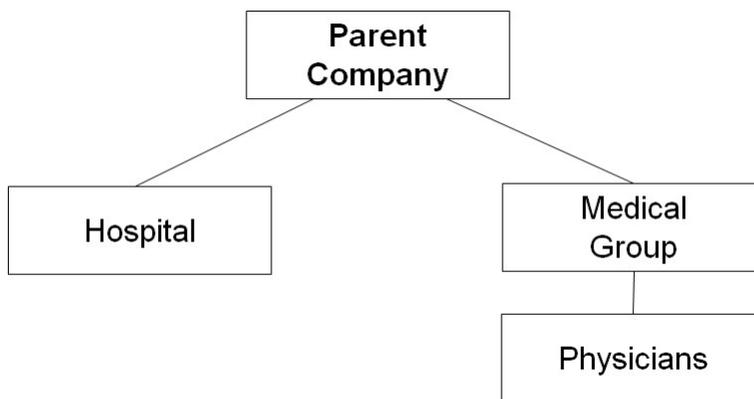
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What Happened?

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Tips for Government Investigations

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Government's Interests/Constraints

- Public Safety
- Thoroughness
- Fairness
- Efficiency
- Constituencies

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Government's Constituencies

- Who decides within the USAO?
- DOJ Civil Frauds involved?
- HHS OIG
- CMS
- When to ask to “talk to your supervisor?”
- When to raise issues about CIAs?

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Types of USAO-Civil Frauds Arrangements

- Delegated:
 - USAO has full authority to resolve the case
 - Single damages must be less than \$10M
- Monitored:
 - USAO has primary responsibility, but Civil Frauds must approve suit, declination, or settlement
- Joint:
 - USAO and Civil Frauds jointly handle investigation, including all litigation decisions
 - Usually for single damages over \$10M

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Defense Counsel's Approach

- Who are some of the most successful lawyers? Hint: this one may be really hard to answer.
- Is your counsel bragging about how they have been involved in some of the “biggest cases ever”?
- How do you choose counsel for an investigation (or anything else for that matter!)?

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Initial Interactions

- When do you call the government? Who calls? What do you say in the initial call? Is it a call or visit?
- Is it reasonable to ask to narrow the subpoena?
- What can you do that will help with the resolution?
- What can you do early on that will get you in trouble with the government?

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Interrogatories

- What can the government seek?
- What should counsel do if they don't know an answer?
- What happens if an answer later proves to be wrong?
- Can interrogatory responses be better than documents?

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Witness Interviews

- Internal and external communication: What can/should you say to former employees?
- Do you make employees available to the government?
- Should they be under oath?
- Who can/should participate in interviews? What is "participation?"

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Experts

- How do you choose consultants?
(Note: what you do pre-investigation matters!)
- When do you present expert reports?
Must it be a trade?

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Communication

- When does the government want to hear from us?
- In person, email or phone?
- Should defense counsel ever include the DOJ and OIG?

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How to Approach an Investigation

- Document retention.
- Pros and cons of making changes during the investigation.

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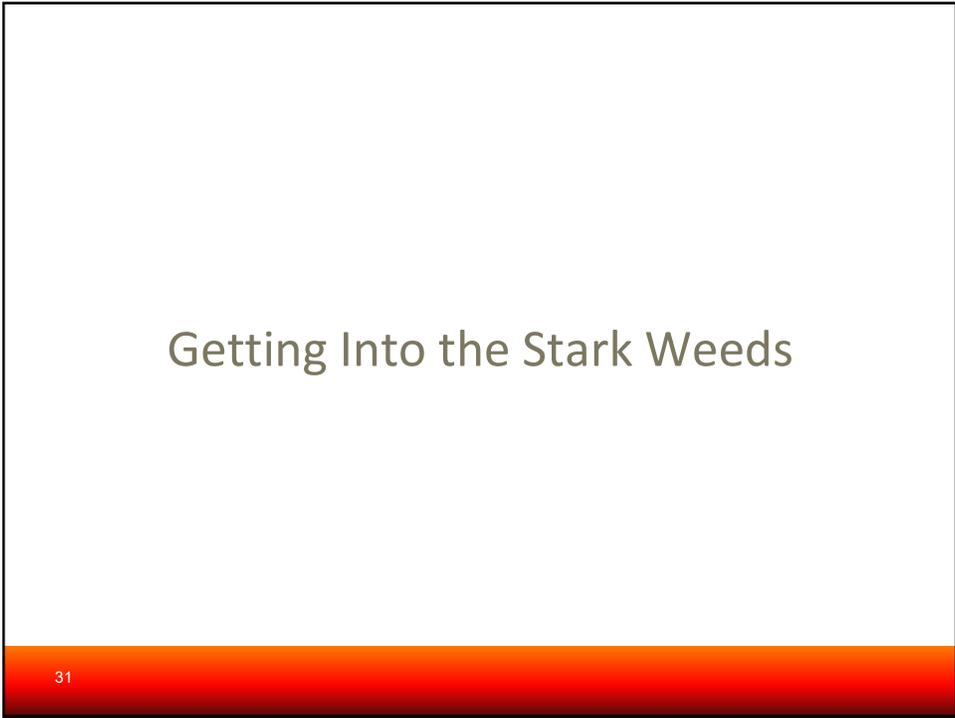
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Defense Considerations

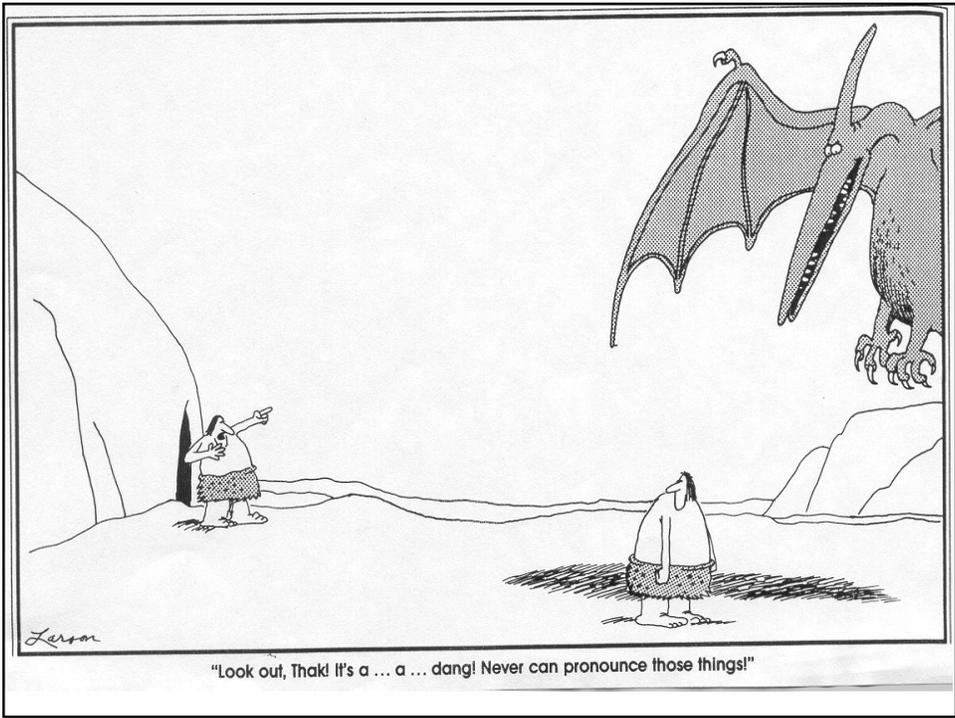
- Patience is valuable.
- Do you conduct a parallel investigation while the government does its thing?
- Did you consider insurance coverage?

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Indirect Compensation Requires:

- (i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships . . . between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);
- (ii) **The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the *entity furnishing the DHS* . . . ; and**
- (iii) **The entity furnishing DHS has actual knowledge** of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.*

42 C.F.R. § 411.354(c)(2)

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*Note that "FMV" does not appear here at all!

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Indirect Comp: Plain English

- Does the payment “take into account” the volume or value of referrals?
- Mathematical question, but also a metaphysical one.
- FMV doesn’t appear in the definition, but courts consider “anticipated referrals” as “taking into account” referrals, and analyze FMV.

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Indirect Compensation: *Tuomey* Instruction

“An indirect compensation arrangement means that the referring physician receives aggregate compensation from the entity in the chain with which the physician has a direct financial relationship that varies with, or otherwise takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing services.”

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Indirect Compensation Exception

- Consistent with FMV and **not determined in a manner that takes into account directly or indirectly the volume or value of any referrals.**
- Commercially reasonable even if no referrals are made to the hospital.
- In writing, signed by the parties, specifying the services covered by the arrangement.
 - Except *bona fide* employment relationship (must be for identifiable services and commercially reasonable if no referrals, but need not be written).
- Does not violate Anti-Kickback Statute.

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Indirect Compensation Exception

(1) (i) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and **not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.**

(ii) Compensation for the rental of office space or equipment may not be determined using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

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Indirect Compensation Exception

(B) Per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

(3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

- 42 CFR § 411.357(p)

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How is Compensation Sliced?

- 42 CFR § 411.354(c)(2)(ii) states that indirect compensation arrangements examine “**aggregate** compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship.”
- Compensation is considered in its entirety (aggregate).
- There is no temporal demarcation.

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Key Points

- Indirect comp exists only if pay is linked to physician referrals to the hospitals.
- Can compensate physicians for personally performed work, and other things that do not “take into account” the value/volume of DHS.
- If you credit for E&M in the inpatient or outpatient setting, does that “take into account”?
- Can you credit physicians for work by physician extenders?

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Proposed Stark Changes

- <https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>
- 84 FR 55766, published 10/17/19.
- Only proposed, but....

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Proposed Stark Changes

- Significant changes to definitions, including commercially reasonable, fair market value, general market value, value-based activity and more.
- Would change comp. formula exceptions, including the ability to give credit for “DHS” for non-Medicare/caid patients.

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Proposed Stark Changes

- Important changes to the definition of “takes into account.”
- Compensation “takes into account” referrals if “compensation includes the physician’s referrals to the entity as a variable, resulting in an increase or decrease in the physician’s (or immediate family member’s) compensation that positively correlates with the number or value of referrals.”
(underlining in original)

• 84 FR 55793.

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Proposed Stark Changes

- Focus on the word “variable.” A variable is part of a mathematical formula.
- Consider the difference between a compensation formula that says “if you have 5 years of experience your hourly rate is 1.2 times higher” and “we often pay more for experienced workers.”
- Rejects the reasoning of *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.* See 84 FR 55795

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Proposed Stark Changes

However, for clarity, we reaffirm the position we took in the Phase II regulation. With respect to employed physicians, a productivity bonus will not take into account the volume or value of the physician's referrals solely because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service. We are also clarifying that our guidance extends to compensation arrangements that do not rely on the exception for bona fide employment relationships at § 411.357(c), and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, provided that the compensation meets the conditions in the special rule at § 411.354(d)(2). That is, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula— even when the entity bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals if the compensation meets the conditions of the special rule at § 411.354(d)(2) (see 69 FR 16067). 84 FR 55795

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Scienter

- Is Stark “strict liability?” Do you need intent? Does DOJ enforce Stark directly or under the FCA?
- “Substantial risk that the contracts violated the Stark law, and was deliberately ignorant of, or recklessly disregarded risk.” *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 376 (4th Cir. 2015) (*Tuomey II*).
- Reckless disregard: compliance reviews at the time of the agreement, how was the agreement monitored? What records were kept?

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Stark: Burden of Proof

- The government will have the burden of proving that the compensation meets the definition of indirect compensation.
- “Once the government has established the proof of each element of a violation under the Act, the burden shifts to the defendant to establish that the conduct was protected by an exception.” *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009).

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What Are “Referrals?”

- “Referral” very specific: “a request by a physician for, or ordering of, DHS” 42 CFR § 411.351.
- Note “operating” vs. “attending.”
- Only referrals/business (i.e. in/outpatient services) from physicians for designated health services matter. Many professional services are not DHS.

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Survey Data

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What Is the Relevance of Survey Data?

- Is there a FMV ceiling? 50th percentile? 75th? 90th?
- What is the quality of the survey data? Number, quality of respondents.
- How does call pay, medical director comp, etc. factor in?
- How to view survey data in light of all other circumstances in the case?

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Real World Example

- 90th Percentile Interventional Cardiology 2012:
AMGA: \$102.06 MGMA: \$86.47
- 90th Percentile RVU:

2009	16,758
2010	18,316
2011	16,136
2012	15,208 (20% swing from 2010!)

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“We Lost Money on Every Physician.”

- If true, is this a problem?
- Is it true?
 - How is overhead calculated and allocated?
 - How is revenue allocated?
- What about ancillaries?

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Identifiable Services

- The employment exception requires “Identifiable” services. What does that mean?
- Must the be “identified” in advance?

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Questions?



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