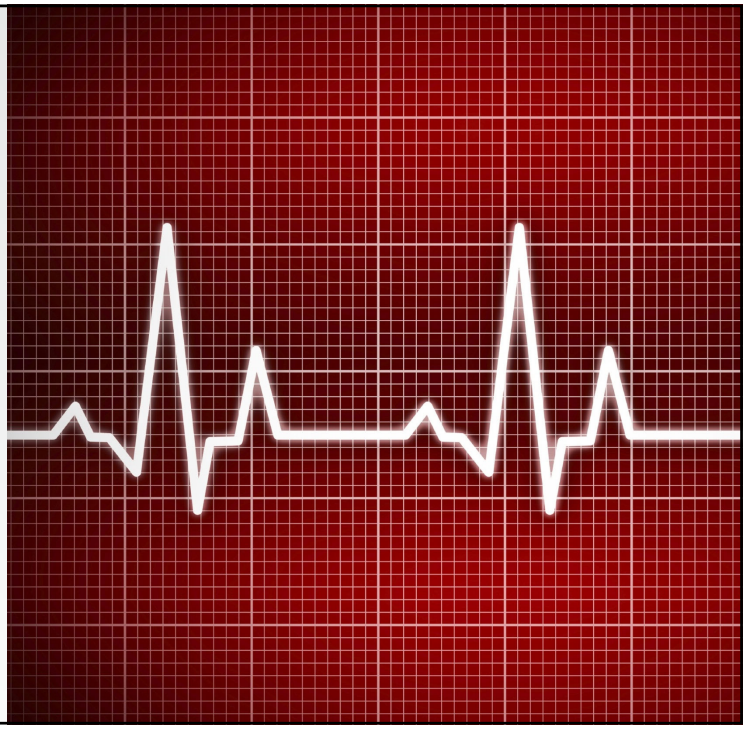
Best Practice Approaches to Building an Effective Research Billing Compliance Audit Program

SESSION P6 – JUNE 8, 2022

HCCA RESEARCH COMPLIANCE CONFERENCE



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Disclosure

- We have no conflicts of interest related to this presentation.
- The opinions expressed are our own and do not necessarily reflect the views of our employers, colleagues, or friends.
- The information, thoughts, and opinions provided here are not legal advice: consult your institution's legal, compliance, and other appropriate leaders and, at their discretion, your local Medicare Administrative Contractor (MAC), for any specific billing questions or issues.

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Objectives

- Identify the necessary operational front-end and back-end processes to set the foundation for successful research billing compliance audit outcomes.
- Describe how collaboration is key to building an effective audit program.
- Discuss strategies to identify red flags and hot issues that could put your site at risk for research billing non-compliance before being discovered in an audit.

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Poll

- Does your institution have an established Research Billing Compliance Audit Program?

a. Yes
b. No
c. I do not know

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Wasn't Built in a DAY!!!

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Poll

- What Keeps YOU Up at Night?

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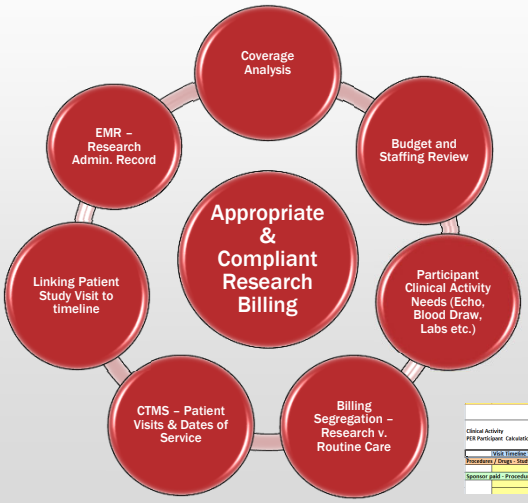
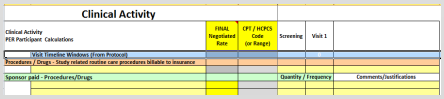
Important Operational Touchpoints

EMR

CTMS





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What we do to mitigate RISKS?

We use an all-encompassing info, staffing, budget, clinical activities spreadsheet:

- Coverage Analysis

We use our Clinical Trial Management System (if you have one):

- An electronic tool to track patient visits, billing types, notes, etc

We use our Electronic Health/Medical Record:

- Tracking of visits, patients, notes, research billing/coding

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False Claims Act

False Claims Act prohibits

- knowingly filing a false claim
- causing the filing of a false claim
- creating a false record to get a claim paid, or
- concealing an obligation to repay money to the federal government

"Knowingly" means:

- Has actual knowledge of the information;
- Acts in deliberate ignorance of the information;
- Acts in reckless disregard of the truth or falsity of the information.

Proof of specific intent to defraud is not required

Violations subject to

- Treble damages, civil penalties starting at $11,665 to $23,331 per line item on a claim and higher; jail time

***Qui Tam suits* (Whistleblowers)**

- Plaintiff can receive 15%-30% of the total recovery from the defendant = BIG INCENTIVE $$$

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WHY? The Future of Healthcare

$$$

- Respect for persons: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent
- Beneficence: the philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects; and
- Justice: the fair distribution of costs and benefits to potential research participants — and equally (subject selection)

Think *compliance*, not just *ethics*,
Relate billing to justice, beneficence, and respect for persons

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Why a Coverage Analysis spreadsheet?

Coverage Analysis (CA) or (a.k.a. Medicare Coverage Analysis) is:

- A systematic review to determine if a research study is a qualifying clinical trial
- Distinguishes between routine patient care costs and research-only costs
- An important document within research administration protecting your organization, research department and your patients
- Our place to "show our work" for the decisions we make

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MORE on Coverage Analysis

It's a home for determinations, justifications and comments addressing:

- Support for routine care Coverage under NCD, IDE or standard Billing Rules;
- Routine costs to be justified as Conventional Care with appropriate reference; Administration of Investigational Item or Service; Monitor and Manage Complications with source identified (protocol, IDB, ICF)
- Additional support or Limitation on Coverage as referenced in appropriate NCD or LCD

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Who Uses this Awesome Thing?

Who:

- Research Coordinators/Nurses/PI's
- Sponsored Programs teams
- Research Finance Analysts
- Coverage Analysis Liaison (i.e. CA Expert)
- Compliance/Research Integrity
- Research Sponsors
- Any institution conducting a research billing compliance audit

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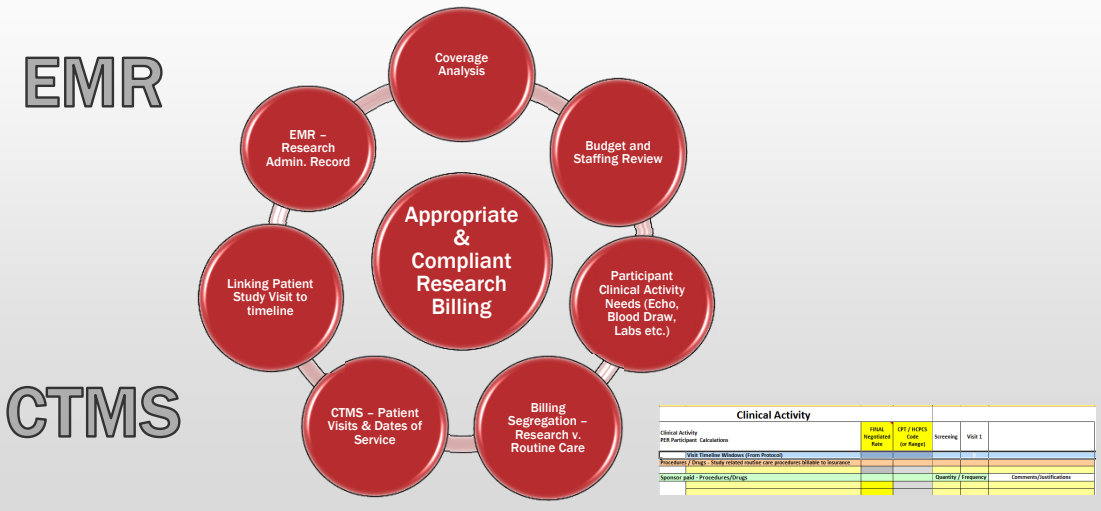
Important Operational Touchpoints - Recap



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Diving Deeper into Processes

- Technology
- Operational Workflows

When should compliance be at the table?

Do you know what is going on at your institution?

Do you have access to the right systems, contacts?

Institutional Mergers/Integrations

- What happens when institutions merge?
- Are research practices siloed and not centralized?
- Do you centralize?
- Who will retain or gain oversight?

The WHY Behind Research Billing Audits

- Billing is Complex –
  - **Research Billing is more Complex**
- Operations often siloed
- Manual processes
- Clinical Operations do NOT always consider Research Needs
- Billing system design
- Electronic Systems for Research
  - Often, do not talk to each other
  - Who has oversight?
  - Automation
- False Claims Act
- Protect the Patient
- Level-set Risk Profile

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[Errors vs Errors vs Error] X Risk Profile

- Level-set:
  - Compliance risk always has a local variable
  - Consider a starting framework for consideration
- Compliance Auditing lacks national consensus error and risk stratification unlike Internal Auditing standards
  - **Research Billing has very little national discussion on error result stratification**
- Not All Errors are Equal
  - Some errors produce overpayments, some are close misses, and some do not produce overpayments but are poor processes
  - **Risk Profile**: The institution's risk profile may adjust the following risk levels "up"

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Types of Errors

- Incident versus Financial
  - Incident – number of errors without respect to impact
  - Financial – Charge Error
  - Financial - (Receipts)
    - Overpayments divided by total payments (receipts not charges)
- Life of Research Billing
  - Coverage Analysis/CTA Accuracy
  - CTMS Build
  - Charge Review
  - Information Flow

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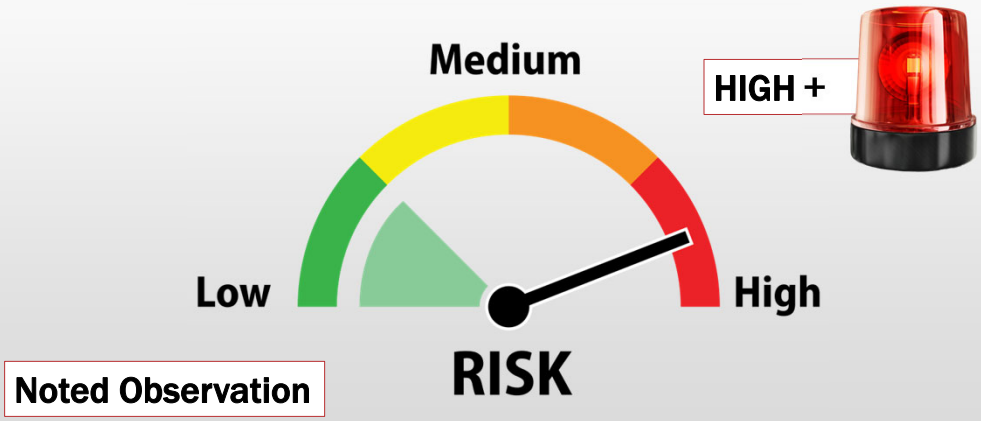
Risk Profile Stratification



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Risk Stratification

HIGH+

- A control previously designed to prevent overpayments or errors has systemically failed (recidivism)

HIGH

- Overpayments were identified and not random
- Controls give appearance of an issue that could result in an overpayment or error
- CA Accuracy: CA error leading to overpayment or errors through improper charge review

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Risk Stratification

MEDIUM

- Charge Review – Random overpayment was identified but without receipt
  - Attention could result in an overpayment for other activities

LOW

- Errors occur that do not produce overpayments but is an area needing oversight, improvement, or technical compliance

OBSERVATION

- Process Improvements
- File Maintenance
- SOP or Workflow Clarity

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Fire exit
Fire exit

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Roles & Responsibilities
Bill Holds
Claim Edits
Reconciliation
Coverage Analysis Development
Subject Tracking
Charge Capture & Review
Payments
Internal Budget Development and Negotiations
Subject Enrollment
Pre-authorizations
Denials
CTA and ICF Cost Sections
Document Concordance
Billing Rule Scenarios
Documentation

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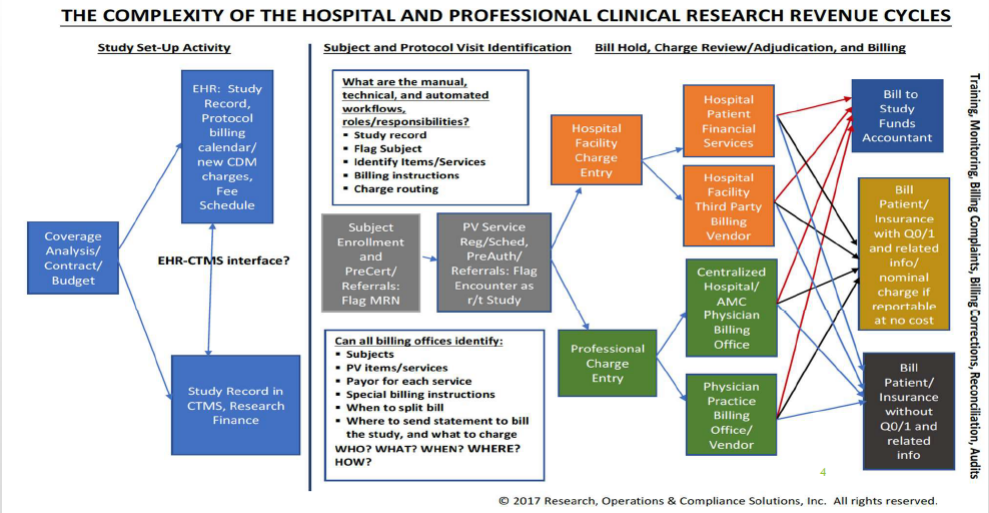

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Foundations to Successful Auditing

- **Leadership Buy In/C Suite Support**
  - Needs to come from the top!
  - Organizational culture
- **Communication & Collaboration**
- **Written Policies & Procedures**
  - Are they updated?
  - Who reviews them?
- **Training & Education**
  - Do staff know what to do?
  - Who tracks training & education?
- **Enforcement**
- **Response & Corrective Actions**
  - Periodic Reviews
- **Monitoring & Auditing**

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Monitoring vs. Auditing

Monitoring

- Less formal
- Conducted by operations
- *Examples*:
  - •Monitoring Core
  - •Departmental QA
  - •Internal Audits

Auditing

- More formalized structure
- Conducted by individuals
- *Examples*:
  - •Internal & External Audits
  - •Research Revenue Lifecycle
    - First Patient Review
    - Risk-Based
    - Focused
      - Process Review
      - OIG Workplans

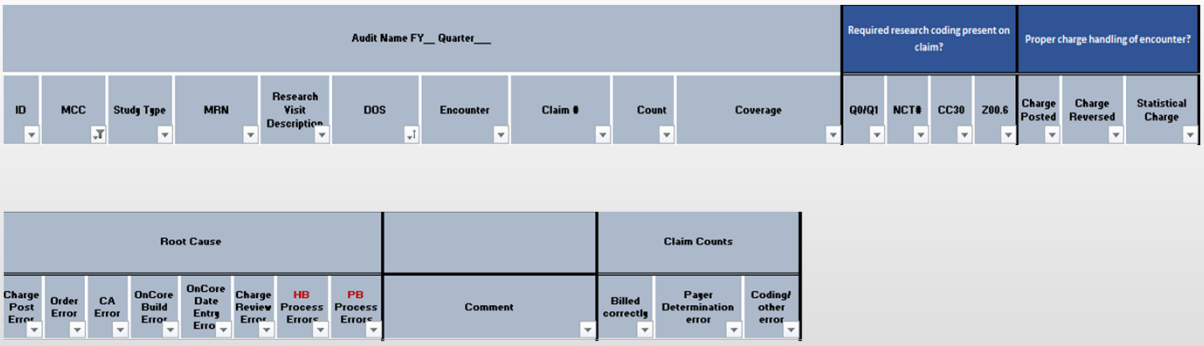
Goals of the Research Billing Audit

- Testing only risk controls (similar to classic Internal Audit);
- Binary review of overpayments versus no overpayments;
- Life of CRB (information flow/CA accuracy/charge review);
- Financial Overview;
- For-Cause;
- First Patient in Reviews;
- System or Human Error
- Identify Process Gaps
- Documentation of Quality Assurance

- Could be a ***risk assessment*** to level-set stratification for the future due to:
  - Never audited; or
  - Significant institutional change & first status of corrective action controls post-change

Combination of all the above

Claims Audit Example Headings



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Identify Standards

- Risk Assessment of Entire Process
- Skill Set Parallel with Content
- Define Scope
- Compare to Minimum Necessary to Achieve Compliance
  - Based on Risk Profile
  - When Does the Office of General Counsel Need Consulted?
- Time span
  - Process improvement?
  - For Cause or a Specific Time point?
  - What Snapshot in Time?
- Sample Size
  - Significant sample?
  - Number of Studies?
  - Billing Review – # of Patients or Claims?
- Interviews and Assistants
  - Dependent on Scope
  - Leadership Channel Considerations

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Risk Assessment Scoring Matrix						
	Impact to the Organization			Vulnerability		Controls
Score	Reputation	Financial	Legal	Likelihood of Risk	Detectability	Controls
1	Slight reputation risk. Possible bad press but no significant patient, physician, constituent consequences.	Slight loss of gross revenue or expense.	Technical violation of law and Civil fines and/or penalties possible, but little risk of exclusion, CIA, loss of accreditation/ licensure.	Slight risk, historical industry experience shows some likelihood however not experienced in organization to date; simple well understood process; competency demonstrated - less likely to fail.	Slight risk that failure will not be detected - process failures; moderate safeguards in place; partially automated process with moderate management oversight.	Routinely audited and/or tested. Performance metrics are established, routinely reviewed and show little variation. Current policies and procedures exist. Employee training and competency established. Well-prepared to manage this risk appropriately based on implemented risk management plans.
2	Moderate reputation risk. Probable bad press. Probable modest physician, patient and/or constituent fallout.	Moderate loss of gross revenue or expense.	Civil fines and/or penalties probable. Modest risk of exclusion, CIA possible.	Moderate risk of occurrence. Slightly complex or partially manual process.	Moderate risk that failure will not be detected. Limited safeguards in place to identify failure prior to occurrence. Partially automated process with limited management oversight.	Periodically audited and/or tested. Corrective action plans developed and tested for effectiveness. Limited performance metrics established. Limited policies and procedures exist.
3	Significant and/or extensive and prolonged negative press coverage. Significant sponsor/board questions of management. Extensive patient, physician, and/or constituent fallout.	Significant loss of gross revenue or expense.	Criminal conviction and/or exclusion of hospital or System probable. Fines, penalties and or legal exposure. Exclusion and/or CIA most likely.	High risk of occurrence. Complex and/or totally manual process. Relies on extensive specialized skills.	Significantly or extremely hard to detect prior to failure. Little to no automated processes with little or no human intervention, oversight or control. Few built-in safeguards, cross-checks, or other mechanisms to identify errors/failures prior to submission/completion.	Process not audited or tested or infrequently audited or tested. Little to no policy or procedure guidance.

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Planning & Conducting the Audit

Scope

- What type of Audit?
- Reason for the Audit?
- Payer Selection
- Invoicing
- Denials

Audit Steps

- Standard Steps
- Create an Audit Plan
- Sample Selection
- Consistency Checklist (handout)
- Request and Review Documents
- Perform Interviews & Testing
- Write a Report

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GCP	RBC
Subjects given study assessments not approved by the sponsor	Billed to payer with incorrect coding; billed to sponsor; loss of revenue
Discrepancies in drug reconciliation	Incorrect quantity charged to payer or sponsor
Treating physician not listed, not recognized or compensated	Inappropriate allocation of funds
Wrong dates entered for screening tests and/or other study related assessments	Triggers billing that could go to wrong payer with incorrect coding; loss or revenue
Not certifying/documenting visits	Delays in Revenue Cycle Reviews, potential for incorrect billing and payers, increases risk of double billing
Tests not required for study that are done anyway	Incorrect billing; loss of revenue
Pregnancy test done on women of none childbearing potential, i.e. hysterectomy	Unnecessary service; not billable to Medicare
Discrepancies/unable to find drug administration start/stop	Sponsor paid items could get billed to a payer incorrectly
Items and services that are "confirmatory"	Imaging done to confirm tumor progression or response outside of recommendations in guidelines - could trigger incorrect billing
Identify items and services unnecessarily repeated to fit the protocol's screening or other windows	If a patient has had a procedure that is "just outside" the protocol window, not billable without sponsor approval (should be in the CTA)
Missing source documentation	Verification missing; incorrect billing
Using an unapproved or inaccurate ICF	Billing review inconsistencies leading to incorrect billing
Missed scans/procedures	Invoicing issues; incorrect billing; loss of revenue
DOA Log Discrepancy	Incorrect billing or funds transfers

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Common Findings

- Provider not notified of clinical trial / subject
- Under budgeting
- Large residual balances
- Claims submission errors
  - Double billing – misdirection of charges
  - Denials – no pre-authorization, investigational article
  - Coding errors
    - IDE, NCT numbers on claim with no Q-modifiers or CC
    - IV Administration with no study drug
  - No Follow Up on denials; write-offs
- Charges Not Posted
- Pro and Tech Fees Not Coordinated
  - Billed differently
- Patient Refunds Not Tracked or Paid
- Research Order Errors
- Visits Not Certified Timely
  - Impacts Timely Filing
  - Data Quality

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Post Audit

- Submit Corrections
  - Track process through completion
- Establish Policies and Procedures
- Renegotiate Contract/Budget
- Training and Education
- Enforcement of Corrective Action Plans
- Changes to Workflows
- Establish Benchmarking and Metrics
- Collaboration & Communication !

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Alone we can do so little,
together we can do so much." –

Helen Keller

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