



Stress Testing Your Transparency Program

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What is your role in transparency reporting?

- a. Day-to-day responsibility
- b. Manage the program
- c. Lead the compliance department
- d. Responsible for report audit
- e. Not involved at all



Have you ever been through an internal or CMS audit?

- a. Yes
- b. No

Do you feel that your transparency program is audit-ready?

- a. **Very** confident
- b. **Somewhat** confident
- c. **Not** confident

Select all that apply to your current transparency program.

- a. Roles and responsibilities are clearly defined
- b. We have documented end-to-end processes
- c. We perform routine data validation
- d. We reconcile all third-party data for completeness
- e. Our assumptions are documented and cover all topics
- f. I don't know what those words above mean





- Cumulative \$1.15M maximum penalty
- Applicable to each entity that qualifies as a covered manufacturer

Enforcement Action so Far

Paid **\$1.11m** to settle allegations of improper and unreported payments

Paid over **\$900k** in fines for false statements to CMS regarding Open Payments

Medtronic



spinefrontier

Dr. Kingsley Chin
CEO of SpineFrontier



Risk-based and random selections

History of non-compliance
Data anomalies and trends
Credible third-party tips

Year 1 Audits (2024 – 2025) are complete

Year 2 selections were planned for 2H2025

12 selections include voluntary audits
Appears to be on hold

CMS now sending letters for specific transactions

CMS requires a 5-year record retention requirement after public disclosure

What did/does a CMS Audit Look Like?

Contracted auditors with minimal Sunshine experience



Questionnaires on internal controls, processes, and risk mitigation followed by transactional data requests



Amenable scope, negotiate with counsel



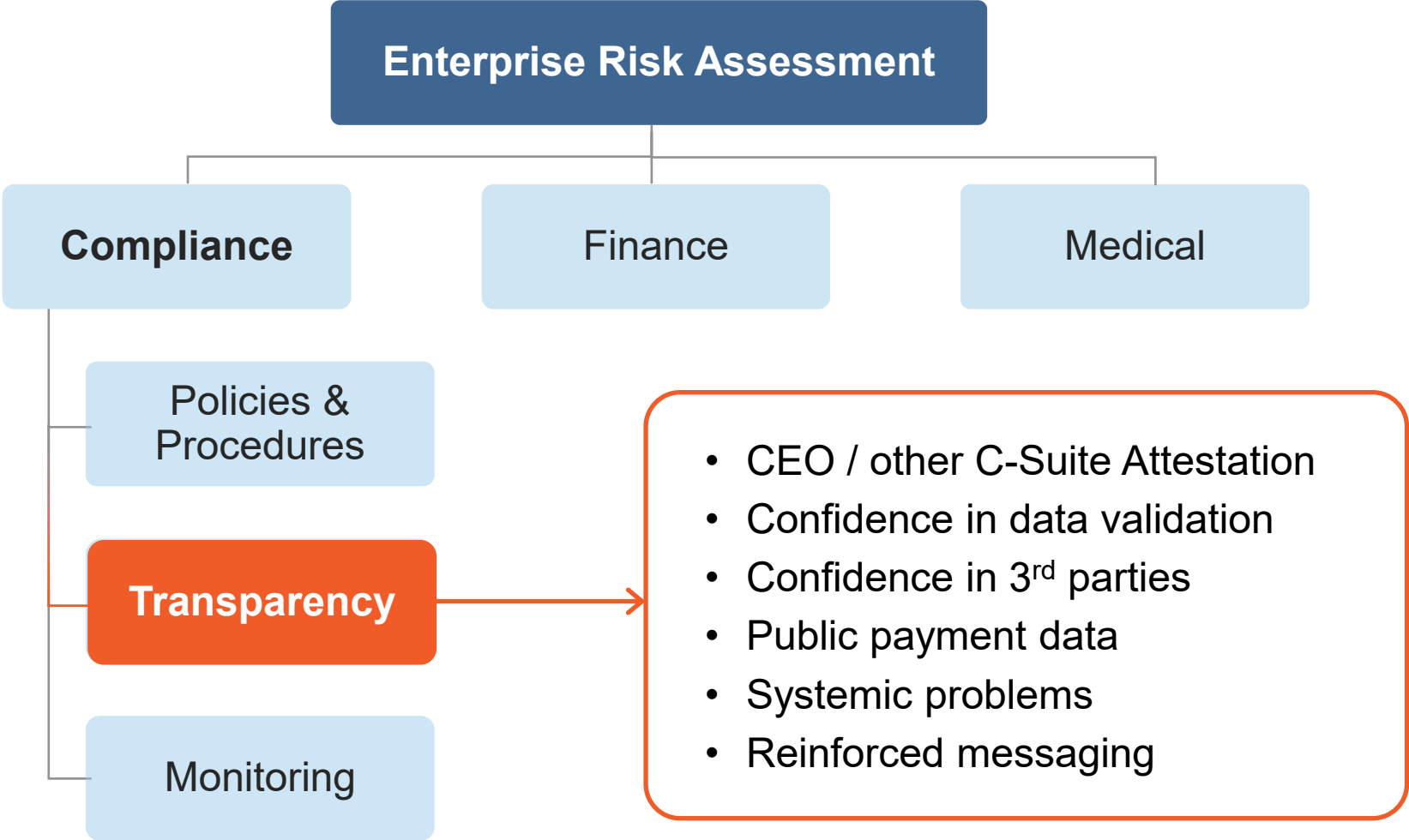
“All books, contracts, records, documents, and other evidence sufficient to enable the audit of compliance”



Preliminary Findings Followed by Management Representation Letter



Why Conduct an Assessment?





Mock audit vs. Audit readiness



Mock Audit vs. Audit Readiness



Audits are often viewed as adversarial

Team provides as little information as possible to the auditors

Out-of-scope path to see how company responds

Narrower scope, focus on individual aspects



We aim to be more collaborative

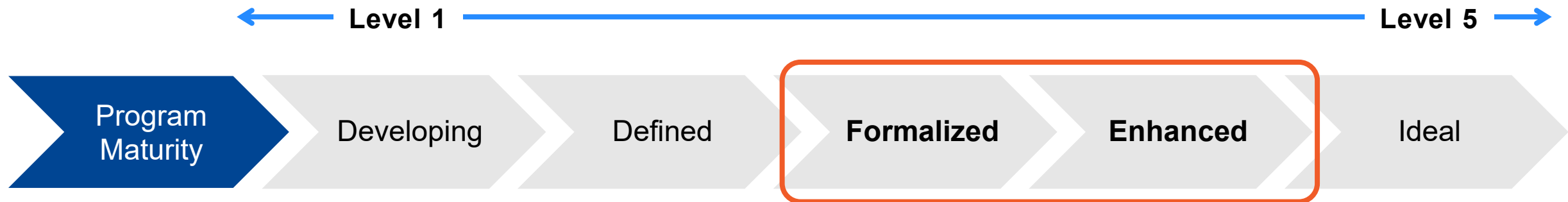
Actively encourage openness and transparency

Focus on real risks based on actual Open Payments requirements

Holistic review across the program

Program Maturity

- **How mature should my program be?**
- **Should maturity be measured in years?**
 - Consider program elements vs. age
- **Future expansions and scalability**
 - New launches/indications, global expansion



When Should I Conduct an Assessment?

- **Caution overburdening during reporting**
 - Support an audit **and** submit by March 31?
- **Keep other responsibilities in mind**
 - If Finance supports → end of year is busy



Federal Reporting

Ideal Time for Assessment

End of Year

JAN

FEB

MAR

APR

MAY

JUN

JUL

AUG

SEP

OCT

NOV

DEC

Cross-Functional Alignment

- How to approach the assessment with the cross-functional partners to be audited
- Alleviate fear
- Assure the function won't be seen as bad, lacking, etc.
- Assessment helps us grow and learn → continuous improvement

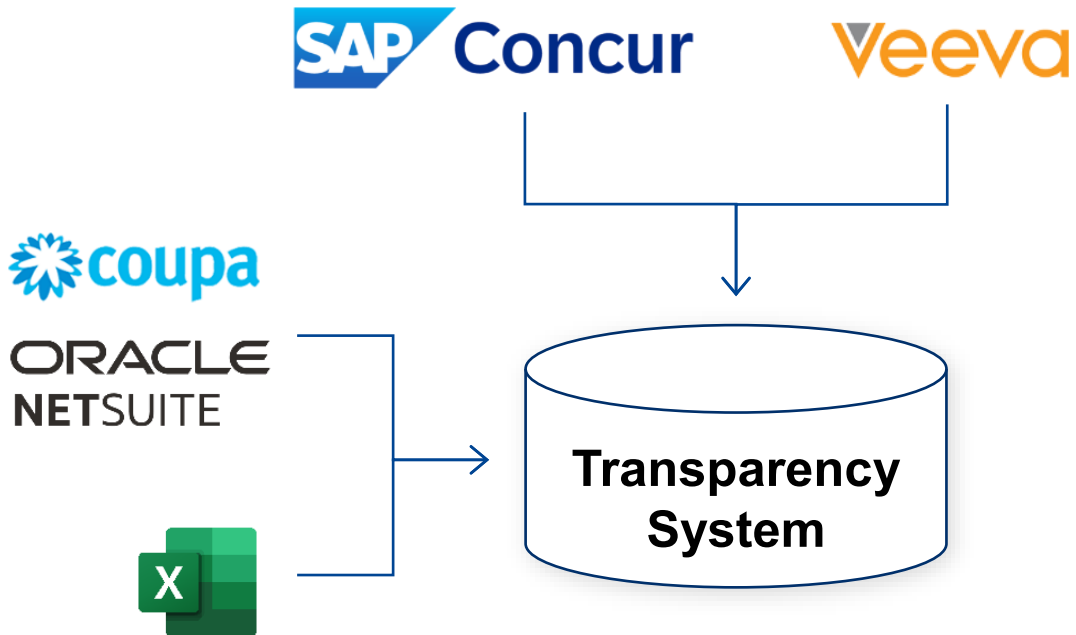


Potential Approach to Audit Readiness



What to Look For

Documentation & Processes



Training & Awareness



Stakeholder Interviews

Data Review

Source Systems



SAP Concur

Veeva

ORACLE
NETSUITE



Natures of Payment

- Consulting fees
- Food & beverage
- Travel & Lodging
- Gift



Statistical Analysis

- Highest value payment
- Most common payment value (mode)
- Other statistical outliers



Data Quality

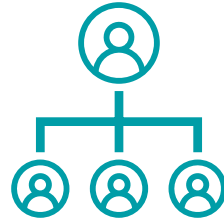
- Included and excluded
- Payments that failed validation
- Mismatched nature & recipients
- Missing time

Risk-based transactional review sample

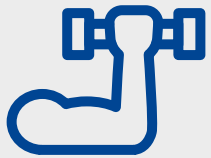
Auditee's Perspective

- Expectations before assessment started
- Documentation request fulfillment
- External vs. internal reviewers
- Overall Feelings
- Key takeaways
- *What might this look like for a larger organization?*





Impact for the Business



**Strengthens Oversight
& Governance**



**Demonstrates Program
Effectiveness**



**Protects the
Organization**



**Informs Strategic
Decision-Making**

Key Takeaway #1

Documentation & Processes

- Governance Documentation
- Policies
- Procedures
- Job aids
- Mapping Tables
- Assumptions Document
- CMS Submission History
- Transaction Decisions
- Supporting Documentation

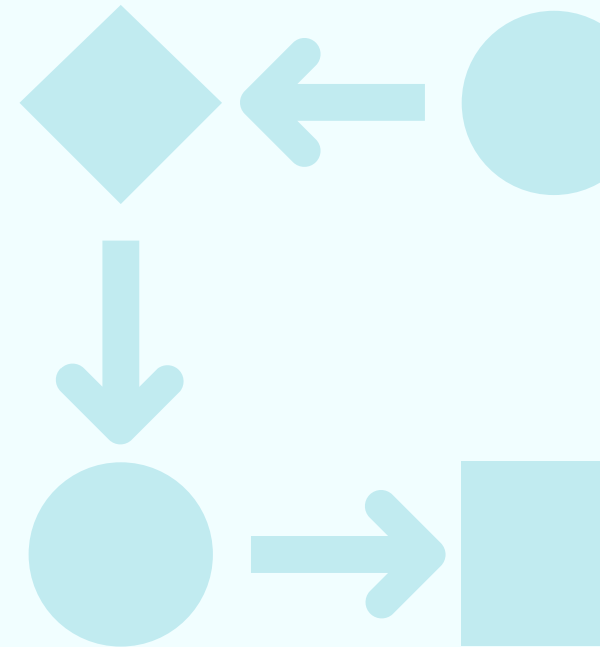
Training & Awareness

- Company-wide awareness
- Expense Entry (e.g., Concur)
- Third-party oversight
- Record management / retention



Key Takeaway #2 – Third Party Vendors

- **Contract language**
 - “Right to Audit”
 - Service level agreements
 - Timely response to requests
 - Record retention
- **Training records**
- **Supporting documentation for payments**



Key Takeaway #3

Data Review Checklist

Governance

- Clear roles and responsibilities?
- Structured data capture and data review processes?
- Do you have a quarterly close-out process?
- Sub-certification process?
- Record retention?

Common Data Gaps

- Missing HCP/O flags in ERP
- Incomplete Spend Capture (e.g., Study Product, In-Kind Items)
- Consulting Fees combined with other Natures (Travel, Meals)
- Mismatched type/specialty (wrong HCP)
- No documentation on rejected records, data/policy exceptions

Questions?