

# CMS Open Payments Mock Audit Workshop

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Informa Transparency, Aggregate Spend,  
& HCP Engagement Conference

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# Introductions



## Brian Bohnenkamp

Partner  
King & Spalding

- 17 years at King & Spalding
- Established subject matter expert on a variety of compliance topics, including life sciences transparency laws and regulations
- Frequent speaker and moderator at industry conferences
- Provides counsel to the Ad Hoc Sunshine and State Law Compliance Group



## Jim Accumanno

Chief Compliance Officer  
Karyopharm Therapeutics

- 14 years of in-house legal and compliance experience
- Karyopharm's Chief Compliance Officer and VP, Legal since October 2022
- Leads commercial legal team and all state, federal, and international transparency reporting efforts



## Jon Wilkenfeld

President  
Potomac River Partners

- Founded Potomac in March 2006 and has advised more than 100 life science firms
- Established subject matter expert on a variety of compliance issues
- Frequent speaker and moderator at industry conferences



## Graham Rich

Sr. Manager  
Potomac River Partners

- Initially joined Potomac in 2013
- Heads Potomac's Transparency & Aggregate Spend Service Line
- Advised 30+ clients on transparency assessments, implementation, and reporting, including personally submitting reports on behalf of 20 entities for 2023 data

# Navilla Therapeutics, Inc. (Overview)



## Corporate Structure

- US Subsidiary of EU parent
- EU parent has minimal reporting requirements under Navilla Therapeutics SPA

## Approved Products (2)

### **CYSTIZIA (Nephrology - rare disease)**

- Approved August 1, 2018
- First-line treatment of nephropathic cystinosis in adults with CTNS mutation
- Did not report 2018 data to Open Payments (6-month grace period)

### **ZAX (Oncology)**

- Injectable - Approved October 2021
- First-line treatment for adults newly diagnosed with stage 3/4 PDAC (Pancreatic ductal adenocarcinoma) that are ineligible for surgery as combo chemo treatment
- Ongoing trials in other solid tumor types (e.g., esophageal, prostate)

**NOTE:** Navilla Therapeutics is a fictional company.

All information provided is fictional and for educational purposes only.

# Navilla's Transparency Journey

## Current Resourcing:

- Director of Transparency:
  - Open Payments
  - States
  - Assistance with Global reporting
- Reports to Compliance Officer

## 1 2018: Outside Assessment

- **Resourcing:** Compliance Manager
- Conducted an Open Payments planning project with outside consultant
- Provided with roadmap of actions to complete regarding documentation, process, and source system enhancements

## 3 2022: ZAX Approval + Turnover

- **Resourcing:** Hired Dir. of Transparency in Jan.; Compliance Mgr. left after submitting 2021 data
- Transitioned to SAAS-based approach

## 2

## 2019-2021: Consultant Support

- **Resourcing:** Compliance Manager with support of different outside consultants (using Excel)
- Consultant responsible for “submitting” 2019 data to OP

## 4

## 2023-2024: Director-Led

- **Resourcing:** Dir. Of Global Transparency led submissions of 2021-2023 data

# Navilla CMS Open Payments Spend

**Search**  
Locate specific profiles to view payment data for healthcare providers, teaching hospitals, or companies

**Search by Type**

- Individual Provider
- Teaching Hospital
- Company

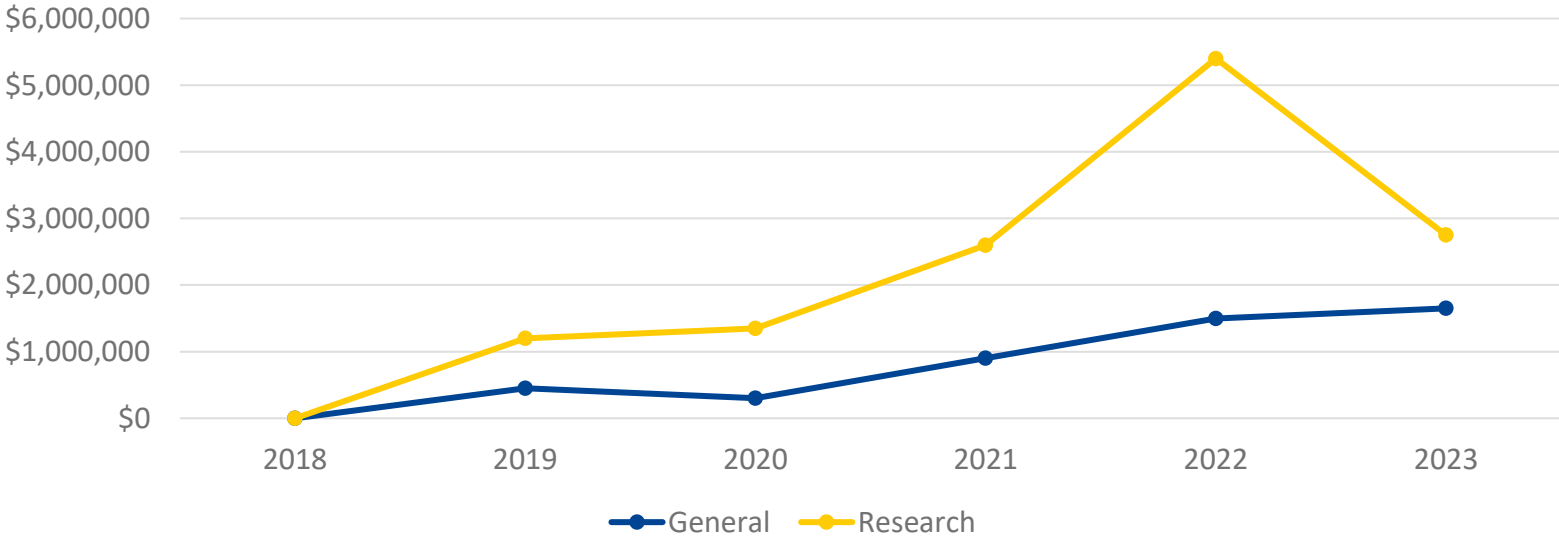
**Find a company profile**

Navilla **Search the Data** →

[Advanced Search](#)

Data displayed on this search tool is from January 2017 through December 2023. Beginning with Program Year 2021, data on [Non-Physician Practitioners](#) is available.

Payments Across All Years



# 1. Notice of Inquiry

**Fact Pattern:** The Company receives a letter from CMS on February 11, 2025

- Notifies that “Navilla Therapeutics Inc.” has been selected for an Open Payments audit
- Identifies the auditor and informs that the auditor will be reaching out shortly to schedule a kickoff call
- The letter does not identify why Navilla was selected for audit



## Legal Counsel

- What role should counsel play in early notification period?
- Is there the ability to move the audit until after reporting is complete?



## Compliance Team

- What are your immediate first steps?
- Who is on your response team?



## Transparency Team

- How will this impact current year reporting?

## 2. Initial Kick-off Meeting with Auditor

**Fact Pattern:** The Auditor reaches out to schedule a kickoff call; call set for February 20, 2025

- Auditor explains audit scope, objectives, criteria, and process; auditor informs that periods audited will include 2021, 2022, and 2023
- Auditor asks the Company to provide an overview of the types of payments and transfers of value provided to covered recipients, as well as the systems used to track and report payments
- On February 21, 2025 the Company receives questionnaires and initial requests for documents



### Legal Counsel

- Can you get an NDA in place with auditors?



### Compliance Team

- What are the key outcomes from the meeting that you want to accomplish?



### Transparency Team

- What are the steps that can be completed between notification and arrival?

# 3. Receipt of Questionnaires and Document Requests

**Fact Pattern:** Company receives 3 questionnaires from the Auditor to complete by March 14, 2025

- 1) internal controls, 2) Open Payments program processes, and 3) fraud risks
- Accompanied by document requests, including requests for Open Payments submissions, Code of Conduct, Board meeting minutes, written policies and procedures, chart of accounts, and general ledger, among others
- In reviewing the questionnaires, the team identified the following about their documents:
  - Data Capture SOP had not been updated since the SAAS system went live; outdated
  - Data Reporting SOP; created with an initial effective date of August 31, 2021; nothing formal before
  - Assumptions Document last updated in 2019; did not cover expansion of NP/PAs; Title still says “Draft”
  - No all-employee Policy. “Commercial” manuals cover reqs. Code says “follow laws and regulations”



## Legal Counsel

- Do you reserve documents for follow-up? What do you provide proactively vs. reactively?



## Compliance Team

- What level of detail should be provided in the responses?



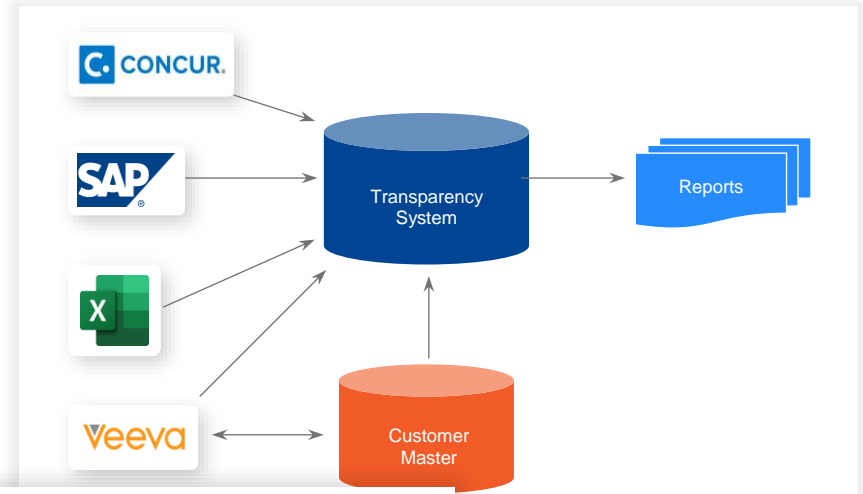
## Transparency Team

- Can you explain what the team identified in more detail?



# What Navilla Provided

- System Map
- Transparency Policy (from Commercial Manual)
- Data Capture SOP, Data Reporting SOP
- Internal Assumptions Document (from 2019)
- Communication About NP/PA expansion



**Transparency Reporting Requirements**

PharmaCo tracks and reports transfers of value to HCPs in accordance with the federal Sunshine Act, applicable state and local requirements, and PharmaCo policies.

**Transparency Quick Checklist for the Field**

- Inform HCPs that PharmaCo discloses HCP spend data in accordance with applicable transparency requirements
- Use approved sign-in sheet templates
- Review and ensure HCP profile information on sign-in sheet is complete before existing program (e.g., includes state license numbers and/or NPI for Speaker Programs)
- Enter spend data into the appropriate tracking system (Concur for Lunch and Learns or Veeva CRM for reprints) with supporting documentation (sign-in sheet and receipts)
- Search for HCPs in Concur and email [TEQuestions@pharmaco.com](mailto:TEQuestions@pharmaco.com) for assistance if you're unable to find the profile
- Confirm the correct Covered Recipient and type (e.g., office staff vs. medical professional) when entering information into Veeva CRM and Concur
- Submit all HCP transfers of value on a timely basis

**COVERED RECIPIENTS OF VALUE**

PharmaCo reports transfers of value to HCPs, including:

- Doctors of Medicine
- Doctors of Osteopathic Medicine
- Physician Assistants (PA)
- Nurse Practitioners (APRN, NP)
- Clinical Nurse Specialists (CNS)
- Certified Registered Nurse Anesthetists (CRNA, AA)
- Certified Nurse Midwives (CNM)
- Pharmacists (RPh/PharmD)

**Other HCP recipients as required by applicable federal, state, or local laws**

**COVERED TRANSFERS OF VALUE**

The federal Sunshine Act requires manufacturers to report all transfers of value to HCPs and HCEs to the federal government. Spend data also require additional reporting to certain state or local laws. Some examples of HCP spend include:

- Providing a meal to an HCP staying on an official call
- Distributing an educational report to an HCP
- Providing an educational grant to a healthcare entity
- Compensating an HCP for serving as a freelance advisor
- Providing an honorarium to an HCP for speaking at an event
- Reimbursing an HCP for a flight or ground transportation to an advisory board

**STATE AND LOCAL REPORTING REQUIREMENTS**

**HCP-Related Spend and Your Role**

**Who counts as an HCP?**

"Healthcare Professional (HCP)" refers to a provider of medical or health services that provides, purchases, reorders, reconstitutes, uses or influences or arranges for the purchase, reimbursement, prescription or use of medical products in the U.S.

**Examples of who includes (does not include):**

- Physicians (MD, DO)
- Physicians (D.O., DPM)
- Nurse Practitioners
- Physicians and public agents
- Business (APRN)
- Consultants (PHC, CM)
- Research team
- Pharmacists
- Members of Pharmacy & Therapeutics or Drug Utilization Review committees
- Wholesalers
- Distributors

**What is my role when it comes to HCP spend?**

You only pay to submit complete, accurate documentation of HCP spend (Sign-in sheets, receipts, etc.) Make appropriate documentation links available to current information to the Medical or Sales professional.

**Key HCP recipients when entering data in Veeva/Concur. Please submit OOB to IT if addresses are not established in Veeva.**

Information that should be captured on your sign-in sheet and in Concur data entry includes:

- State license number
- Date
- Number of attendees
- Location or Title
- Recipient name
- Phone address
- State
- Meal cost of business meal provided
- Meal vendor (vendor address should reflect actual meal location)

When entering spend data in Concur, capture all HCP recipients as "Healthcare Professional" in the system.

**Additional Resources**

- SOP - US Transparency Data Capture
- PHC - Healthcare Professionals on Conferences and Speakers Policy
- OSL - Guidance on State Requirements for HCP Interactions

Contact [USPHCDataCapture@navilla.com](mailto:USPHCDataCapture@navilla.com) for transparency questions.

Business Rules Document – v.1 DRAFT <DATE>  
 PRIVILEGED & CONFIDENTIAL – FOR AUTHORIZED COMPANY USE ONLY – NOT FOR DISSEMINATION

**18. Date of Payment**  
 Sunshine Act Approach:

<Company Name> will utilize a consistent approach for date for each reportable nature based on the table below:

| Nature   | Date  |
|--|---|
| Compensation for services other than consulting including serving as faculty or as a speaker at an event other than a continuing education program | Event date  |
| Consulting Fees  | Meetings: Event date<br>All other: Check posting date or Electronic Fund Transfer (EFT) date  |
| Education  | Distribution date (or order date if distribution date is not available)   |
| Food and beverage (in-kind)  | Date of Consumption   |
| Food and beverage (Reimbursed)   | Date of Consumption (if Meeting Management vendor utilized)<br>Check posting or EFT date (if no Meeting Management vendor utilized) |
| Travel and lodging (in-kind)   | Travel: Travel initiation date<br>Lodging: Date of Check-in<br>Travel: Travel initiation date<br>Lodging: Date of Check-in          |
|  | Check posting date or EFT date  |
|  | Shipping date   |
|  | Check posting date or EFT date  |

issued checks with the original check posting date.

a check or EFT date, the check posting date will be listed to tie with travel paid for by third parties will be based on the travel date (lodging).

meals incurred from multiple events/programs or over multiple days, when possible. If separation is not possible, the first day of the event will be used for the check posting date approach for state law reporting as they do for District of Columbia, Miami-Dade, Nevada and Vermont). There is no

# 4a. Field Work – Sample Transactions

**Fact Pattern:** Company is asked to provide transactions and supporting documentation for 25 Research and 25 General Payments from each year of 2021-2023

- Upon analysis, Research transactions came from 4 different CROs, two of whom Navilla has not worked with since ZAX approval in 2022
- General included sample across natures, including ERP, Concur, Veeva, and vendor data



## Legal Counsel

- How do you handle requests that appear out-of-scope (e.g., data <6 months post-launch; >5 years from reporting)?



## Compliance Team

- Are you prepared to educate auditor about data reqs (e.g., non-prescriber spend, de minimis transactions, “no-shows”)?



## Transparency Team

- What steps do you need to take to capture all of the documentation and data requested?

# 4b. Field Work – Search for Missing Transactions

**Fact Pattern:** Auditor asked for Navilla’s entire “General Ledger” (GL)

- Navilla is concerned about sensitive information in the GL that is wholly unrelated to Open Payments or payments to HCPs, and asks the auditor if the Company could instead provide:
  - Details of all Organization Tax IDs in the Vendor Master; Once matched, requested additional details
  - Certain details for payments in 2 GL categories: HCP Consulting; Research
- Auditor’s sampling transactions to determine if any transactions were NOT reported to Open Payments



## Legal Counsel

- How do you handle requests that go beyond reasonable scope of an audit?



## Compliance Team

- Any confidentiality concerns with audit (e.g., providing Tax IDs)?



## Transparency Team

- How do you explain simply to an auditor with minimal transparency experience how ERP data is reported to CMS?

# 5a. CMS Auditor Preliminary Findings

**Fact Pattern:** Auditor provides draft of initial findings to Navilla; findings include:

1. CRO payments lacked documents validating reported amount (e.g., no invoices from Site to CRO)
2. Identified prescribers (esp. NP/PA) classified as “Business Guests” within sample requested and were not reported to Open Payments for one of the Concur meals
3. One Teaching Hospital payment for Exhibit Fee was not reported in 2022; identified by Teaching Hospital Tax ID search
4. ZAX research payments were never reported until commercial approval
5. Payments to third parties at request of HCPs were not reported consistently



## Legal Counsel

- What can you do in response to draft findings with which you do not agree?



## Compliance Team

- How do you communicate to the auditors that errors can occur?



## Transparency Team

- Can you explain these findings to the audience?

# 5b. CMS Auditor Preliminary Findings

**Fact Pattern:** Auditor provides draft of initial findings to Navilla; findings include:

1. Contracted amount for one Speaker was not consistent with amount paid and reported
2. Sample payment for “Consulting Fees” includes both Meals and Travel; inconsistent with internal assumption
3. Advisory Board payments were reported as “Honoraria” in 2021 then reported as “Consulting Fees” in 2022-23; no documented rationale for change in interpretation in Assumptions Document
4. Source Concur data does not match the record reported to CMS; data was changed in Transparency System



## Legal Counsel

- What can you do in response to draft findings with which you do not agree?



## Compliance Team

- What are some ways to respond to auditors, especially when you feel findings are unjustified?



## Transparency Team

- Can you explain these findings to the audience?

# 6. Management Representation Letter

**Fact Pattern:** Navilla and Auditor resolve issues regarding draft findings, and the audit nears close-out. The Auditor sends the company a draft Management Representation Letter. The letter includes various representations that Navilla must make to the Auditor, including, among others:

- (1) The Company has complied with the Open Payments requirements
- (2) The Company has disclosed all known instances of non-compliance with the Open Payments requirements that occurred during the audited period
- (3) The Company has provided all information requested by the Auditor



## Legal Counsel

- What potential concerns are there with management signing the letter?



## Compliance Team

- What communication do you need to provide so management feels ready to sign?

# 7. Post-Audit Company Updates

**Fact Pattern:** The audit concludes and the Company understands that the Auditor sent the audit report to CMS. The Company is now assessing next steps and ways to mitigate any potential risk that CMS might assess civil money penalties.



## Legal Counsel

- What is the likelihood that CMS re-audits? What would be the next steps if CMS wants to enact Civil Money Penalties?



## Compliance Team

- What do you do to prevent the audit findings and other potential findings from occurring in the future?



## Transparency Team

- Based on the findings, what corrective actions should the transparency team take?

# Key Takeaways



Limited time between notification from CMS and start of the audit



Preparing yourself or someone on your team to run point on the audit



Consider whether a pre-assessment is better preparation than a mock audit



Work backwards to identify ways CMS might find missing transactions and implement those as completeness checks (e.g., TIN lookup)



Apply document best practices to your transparency resources



CMS audits should be treated with the same sensitivity as a government investigation



# Contact Information



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