Information Sharing Between FDA & State Agencies

AFDO Annual Educational Conference

***Ryan Cates**, Office of Partnerships (FDA)*

June 21, 2015

Topics Covered

- FDA Disclosure Policy
- 20.88 Agreements
- Commissioning
- State Contracts
- Unauthorized Disclosure
- Teaching Tools/Charts

FDA Info Disclosure Policy

- If applicable legal requirements are met, FDA may share non-public information (NPI) on own initiative or upon request regarding:
  - Investigations
  - Application Reviews
  - Assignments/Strategies, etc.

- Confidential commercial (CCI)
- Trade secret (TSI) (with limitations)
- Pre-decisional, deliberative process (PDI)
- Personal Privacy Information
- Open investigatory law enforcement

Information Sharing Vehicles

Commissioned Officials

- Credentials or Certificates
- Discretionary sharing
- Qualified state regulatory official
- May receive PDI, CCI, and TSI

State Contracts

- Permitted to "receive and review official FDA documents" related to contract
- May receive PDI, CCI, and TSI

21 CFR § 20.88 Agreement

- Discretionary sharing of NPI
- With State government officials and associations
- Case-Specific and Long-Term Options
- Having counterpart functions to FDA
- May receive PDI and CCI*
- Primary information sharing tool

How Many?

20.88 Agreements

- 84 agreements
  - 5 with counties
  - 3 with associations

Commissioning & State Contracts

- 4,074 Commissioned Officials
- 110 contracts in FY14

Sharing under State Contracts

- Non-public information sharing can occur through contracts
- Form 3398, Commitment to Protect Non-Public Information
  - Section H of the contract ensures confidentiality
- Contact your state liaison or Contracting Officers' Representative for more information

21 CFR 20.88

- 21 CFR 20.88 is a **Federal regulation** that pertains to FDA's communications with its state and local government counterparts regarding ALL commodities (food, pharmacy compounding, drugs, devices, tissue, etc.)
- §20.88 allows FDA to disclose **non-public information (NPI)** to **state and local counterparts** as part of cooperative law enforcement or regulatory efforts, if certain conditions are met.

What Can or Cannot Be Shared

Trade Secret

The FDA cannot disclose Trade Secret Information (TSI) to the States under a §20.88 agreement without express written authorization from the owner or submitter.

Confidential Commercial

Confidential Commercial Information (CCI) can be disclosed under a 20.88 agreement without the owner's authorization, but it must be in the interests of public health to do so.

5 Year Single-Signature Long-Term Food Information Sharing Agreements (ISA)

Issues With Past Agreements

FDA required a signature on a 20.88 agreement from every State official who needed access to FDA's NPI, resulting in delays in executing agreements

Agreements were short term, and narrow in scope

States had to request information and then be offered an agreement to cover that request

FDA Response

Signatures will no longer be required for every State official under the Food Information 20.88 Agreements

Only one person, authorized to sign for the State agency, needs to sign

Agreements will cover a period of five (5) years, and were effective beginning July 1, 2014.

Pre-Disclosure Assurances

In signing the Single-Signature Food Long-Term Information Sharing Agreement for the agency, a State official:

Certifies that the agency has legal authority to protect NPI received from FDA from public disclosure

AND

Provides the agency's written commitment

not to disclose FDA's NPI

State's Responsibilities

The State agency will adopt safeguards to prevent unauthorized disclosures, including:

- Procedures and policies for handling NPI
- Providing training (drafted by the FDA) to employees

State Responsibilities

- All persons who receive NPI under the agreement are responsible for protecting it from unauthorized disclosure
- Unauthorized disclosure of NPI may carry adverse consequences
  - Potential administrative, civil or criminal penalties under applicable Federal laws
  - May jeopardize future cooperative relationships between FDA and the State agency

Additional State Responsibilities

- State government agencies commit to inform FDA if the following situations should arise:
  - Subpoena
  - Changes to information laws or statutes
  - Unauthorized disclosure

Agreement, Not a Contract!

- Parties cannot sue one another
- There are, however, *FDA penalties* for unauthorized disclosures

What is Commissioning?

The Food, Drug, and Cosmetic Act requires examinations and investigations be conducted by:

- Employees of Dept. of Health and Human Services (DHHS) or
- Commissioned state, local, or territorial officials are granted the authority to :
    1. Conduct inspections and investigations
    2. Collect samples
    3. Receive and review non-public FDA information
    4. Copy and verify records

Types of Commissions

Credential

- "Field Work"
  - Conduct inspections
  - Collect samples
  - Verify and copy records
  - Receive and review information

Certificate

- "Office Work"
  - Verify and copy records
  - Receive and review information

Commissioning Considerations

- Background investigations
- Ethics and conflict of interest
- Information disclosure
- Leaving the commissioning program

Background Investigations

- Credential
  - Minimum Level 5 Background
    - Credit check
    - Criminal check
    - Reference check
- Certificate
  - RFDD or FDA Center determination

Ethics and Conflicts of Interest

- Ethical requirement
- Conflict of interest
  - Outside employment
  - Stocks, bonds, etc.
  - Income from a family member in a regulated area

Information Disclosure

- Non-public information
  - Trade secrets
  - Commercial confidential
  - Deliberative or other non-public

- Commissions are not solely for information sharing purposes

Information Sharing

- If you need information, you can contact:
  - Your district representative or liaison
  - Your contract representative
  - The national commissioning lead
  - FDA's Office of Policy and Risk Management at InfoShare-ORA@fda.hhs.gov
  - FDA's Freedom of Information Act office at (301) 796-3900

Leaving the Commissioning Program

- **Notify** FDA – State Liaison
- **Return** your credential – nearest District Office
- **Lost/stolen/missing** credential or certificate?
  - Police Report Required
  - Contact District Office/State Liaison

Commissioning Resources

- 21 USC 20.61 through 20.91
- Regulatory Procedures Manual, Chapter 3, Chapter 10
- The FDA Commission Guide
- FDA – StateCommissioning@fda.hhs.gov

Unauthorized Disclosure

An **unauthorized disclosure** occurs when non-public information is disclosed by persons authorized under the agreement to persons or entities NOT authorized under the agreement.

Unauthorized Disclosure Examples

- Unauthorized Disclosure within the State
  - A food-born illness has been identified in your state. You, as an employee of the Dept. of Health , have always received NPI through the Long-Term ISA. You realize that the contaminated food is part of the local school lunch program and you share CCI concerning the food with the Department of Education.

Dept. of Health cannot share this information with the Dept. of Education.

Unauthorized Disclosure Examples

- Unauthorized Disclosure Outside of the State
  - FDA and State Commissioned officials are on a pre-call discussing an outbreak. On the call, pre-finalized results are revealed by FDA officials. At the public call, an hour later, a non-commissioned state employee asks about the results. A state commissioned officer reveals the non-finalized results on the public call.

Pre-finalized results are CCI and cannot be shared with the public.

Unauthorized Disclosure Penalties

FDA is currently revising Chapter 3 of the Regulatory Procedures Manual (RPM), which will include and update to the repercussions associated with unauthorized disclosures.

- Suspended commissions
- Inability to receive NPI via 20.88 agreements individually or as an agency

Assistance Identifying Information

- Inspection Information and Sharing Chart
- Info Sharing Tools Spreadsheet
- Outbreak Sharing Pyramid
- Ownership & Disclosure Chart
- Trade Secret Flow Chart

Permission to Further Disclose

Request can be an email or physical letter

AND

must be sent to either the local District Office or the FDA Office of Policy and Risk Management

Office of Policy and Risk Management

Office of Regulatory Affairs
Food and Drug Administration
12420 Parklawn Dr. (Element Bldg.)
Rockville, MD 20857

InfoShare-ORA@fda.hhs.gov

Office of Partnerships

Office of Regulatory Affairs
Food and Drug Administration
12420 Parklawn Dr. (Element Bldg.)
Rockville, MD 20857

StateCommissioning@fda.hhs.gov