



Sharing Non-Public Information

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Agenda

- 20.88 Agreements and non-FOIA Sharing
- Overview of the FOIA
- Relevant FOIA Exemptions and Examples
- Information Sharing Chart



Information Sharing with State Agencies

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
 - Review Strategies, etc.
- Confidential commercial (CCI)
- Trade secret (TS) (with limitations)
- Pre-decisional, deliberative process
- Personal (Privacy Act if OK, “Other”)
- Open investigatory law enforcement

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 (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.

Sharing With State Agencies

21 CFR § 20.88 Agreement

- Discretionary sharing
- Of NPI, according to FDA’s law and procedures
- With State government officials
- Having counterpart functions to FDA:
 - Regulatory law enforcement (LE)
 - Health oversight
 - Public health function
- Case-Specific and Long-Term Options

Commissioned Officials

- Discretionary sharing
- Qualified state regulatory official
- Commissioned to “receive and review official FDA documents”
- May receive FDA’s NPI, including CCI and TSI

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 Drug Compounding 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 Drug Compounding Information Sharing 20.88 Agreements

Only one person, authorized to sign for the State agency, will need to sign

Agreements will cover a period of five (5) years, and are scheduled to go into effect later this year.

Long-Term Drug Compounding ISA

- The single signature Drug Compounding Information Sharing 20.88 Agreement covers the sharing of certain NPI-related to Drug Compounding
 - One official authorized to sign for the agency will sign
 - We expect this will usually be the highest official of the agency, e.g. Commissioner, Director
 - The agency may then provide NPI to its officials and employees who need the information to perform their official duties for the uses authorized in the agreement

Pre-Disclosure Assurances

In signing the Single-Signature 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

Some Additional State Responsibilities

- State government agencies commit to inform FDA if the following situations should arise:
 - An attempt is made to obtain FDA's NPI from the agency by subpoena, court order, or other compulsory process, including a request under any Freedom of Information type of law
 - There are any changes to the State's FOI statutes or regulations that may impact the Agency's ability to keep its commitment to protect non-public information under the agreement
 - There is actual or suspected unauthorized disclosure of any information shared pursuant to the agreement

Permission to Further Disclose

Any request to the FDA to further
disclose NPI must be in **WRITING**

Request can be an email or physical letter

AND

Must be sent to OPRM

Email: InfoShare-ORA@fda.hhs.gov

Address: Office of Policy and Risk Management
12420 Parklawn Drive
Room 4042
Rockville, MD 20857

Freedom of Information Act: 5 USC 552

- Provides for the sharing of agency records with the public
- FOIA is a disclosure statute, but has 9 exemptions for information that cannot be shared (non-public information)
 - FDA has regulations in 21 CFR Part 20 that mirror the exemptions
- Sharing with states, local governments, and other federal agencies occurs outside of the FOIA, but is governed by the same concepts applicable to non-public information

Exemption 4 of the FOIA

- Exemption 4 prohibits the release of confidential commercial and trade secret information to the public. This protects the financial interests of the information owner and prevents competitive harm

Confidential Commercial Information:

- Customer lists
- Suppliers
- Contractual relationships
- Lot size
- Units sold
- Future business plans
- SOP details

Trade Secret Information:

- Formulas
- Manufacturing process
- Sterilization methods

Exemption 5 of the FOIA

- Exemption 5 protects from disclosure:
 - Internal, pre-decisional deliberations
 - Records within the attorney/client privilege
 - Attorney work product (records prepared in anticipation of litigation)

Exemption 5 - Examples

- Internal discussion regarding potential violations
- Internal discussion regarding possible enforcement actions
- Communications with agency attorneys regarding violations, enforcement, etc.

Exemption 6 of the FOIA

- Exemption 6 prohibits the release of information that would constitute an unwarranted invasion of personal privacy
- Balance of the public's right to know against the individual's right to privacy

Exemption 6 - Examples

- Patient name, address, etc
- Medical staff name, location, etc
- Photographs of faces
- Names of complainants or confidential sources
- Names of non-management staff at firms

Exemption 7 of the FOIA

- Exemption 7 protects from disclosure certain types of law enforcement records, including:
 - Records that could reasonably be expected to interfere with enforcement proceedings
 - Records that could reasonably be expected to constitute an unwarranted invasion of personal privacy (similar to Exemption 6);
 - Records that could reasonably be expected to disclose the identity of a confidential source;
 - Records that would disclose techniques and procedures for law enforcement investigations

Exemption 7 - Examples

- Establishment Inspection Report if case is open (7A)
- Internal memo if case is open (7A)
- Records that would identify a confidential source (7D)
- Patient name, address, etc. (7C)
- Methods used for investigating or prosecuting cases (7E)

Information Sharing Chart

- The chart was provided with materials in advance of the meeting, and is posted on FDA's website
- Rows provide the types of FDA records likely to be created in the course of a compounding investigation
- Columns provide the types of nonpublic information likely to be contained within those records