



***AN OVERVIEW OF THE INFORMATION
SHARING PROCESS
BETWEEN THE FDA AND STATE &
LOCAL OFFICIALS***

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March 20, 2014*

COMMUNICATIONS WITH THE STATES

FDA may share nonpublic information with State and local government officials as part of cooperative law enforcement or regulatory activities, with two groups:

- 1. Commissioned Officials**
- 2. Non-Commissioned Officials Covered by State Agency's 20.88 Commitment**

COMMISSIONING VS. §20.88

Commissioning

- Employee is commissioned as an FDA official to help conduct examinations and investigations
- CCI, PPI, and pre-decisional information may be shared
- Trade secrets may be disclosed
- Confers Federal authority to conduct inspections, investigations, etc.
- Generally requires background checks and requires some time to complete

§20.88

- The state agency certifies that it has authority to protect nonpublic information received from FDA, and commits that it will do so
- CCI, PPI, and pre-decisional information may be shared
- Trade secrets may not be disclosed without permission of their owner
- No Federal inspectional authority is conferred
- Background checks are not required, and the process is quicker to complete than commissioning.

COMMISSIONING OVERVIEW

FDA may either issue pocket credentials or a certificate to commissioned state and local officials.

- Pocket Credentials
 - Typically issued to state and local officials who are routinely involved in facility inspections and involve a Level 5 public trust background investigation.
- Certificates
 - Typically issued to executive and senior-level state agency officials and background checks are discretionary.

A commissioned state or local official is authorized to receive nonpublic information only for the purposes of their work with the FDA. Nonpublic information received from FDA cannot be further shared with non-commissioned officials except as permitted by 20.88

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.

WHAT CAN OR CANNOT BE SHARED?

Trade Secret

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

Confidential Commercial

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

§20.88 PROCESS

- State Agencies identify non-commissioned employees who may receive nonpublic information from FDA pursuant to §20.88
 - Each of these employees sign a confidentiality commitment with FDA
 - The employee's name and signed agreement is forwarded to FDA's Office of Policy and Risk Management (OPRM)
 - A non-commissioned employee who has not signed a confidentiality commitment is **not** authorized to have access to non-public information from FDA

STATE'S RESPONSIBILITIES UNDER 20.88

- By signing a confidentiality commitment, the state or local official understands that:
 - Persons responsible for unauthorized disclosure of non-public information could face criminal, civil, or other sanctions
 - Future cooperative efforts with FDA could be jeopardized

ADDITIONAL STATE RESPONSIBILITIES UNDER 20.88

- State and local agencies commit that:
 - They have the authority to protect nonpublic information received from FDA
 - They will not disclose nonpublic information without written consent from FDA or the sponsor, subject to certain notice provisions
 - They will promptly inform FDA of attempts to obtain nonpublic information through subpoena, court order, or other compulsory process, such as State FOI laws
- State and local agencies should inform FDA of any changes to State law or regulations that would impact their ability to honor these commitments

FDA'S RESPONSIBILITIES

- FDA is not permitted to share certain kinds of NPI with state employees except pursuant to 20.88 or commission, and FDA does not share NPI with states and local officials as a matter of routine
- FDA's decisions about whether to share NPI will continue to depend on the facts of each case

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