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# State of New Hampshire

**OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION**
**DIVISION OF ADMINISTRATION**
**7 Eagle Square**
**Concord, N.H. 03301**
**Telephone 603-271-2152 · Fax 603-271-0597**

LINDSEY B. COURTNEY
Executive Director

November 22, 2021

His Excellency, Governor Christopher T. Sununu
and the Honorable Council
State House
Concord, New Hampshire 03301

## REQUESTED ACTION

Authorize the Office of Professional Licensure and Certification (OPLC) to enter into a Memorandum of Understanding (MOU) with the United States Food and Drug Administration (FDA) to permit OPLC to receive non-public information regarding compounded drug products, human drug supply chain security information and related information. Effective upon Governor and Council approval through June 30, 2025.

## EXPLANATION

Under 21 CFR 20.88, the FDA may share certain non-public agency records on a discretionary basis with state officials who perform counterpart functions to FDA as part of regulatory efforts. FDA requires state agencies who wish to receive such information to affirm in a MOU that the non-public information provided by FDA will not be disclosed with anyone outside of the agency without written confirmation from FDA that such information may be released. There is no fiscal impact to the State by entering into this agreement. If the State did not enter into this MOU with the FDA, OPLC would not be able to receive information from the FDA to assist it and the Board of Pharmacy in protecting the public.

Respectfully submitted,

Lindsey B. Courtney
Executive Director
Office of Professional Licensure & Certification

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

12420 Parklawn Drive
Element Building Room 4029
Rockville, MD 20852-1740

# Memorandum

**To:** State Officials Involved in the Protection of Public Health

**From:** Steven Tave, Director, Office of Strategic Planning and Operational Policy

**Date:** 11/10/2021

**Subject:** Five Year, Single-Signature, Long-Term Drug Compounding and Drug Supply Chain Security Information Sharing Agreement (ISA)

1. The Food and Drug Administration (FDA) would like to offer your agency the opportunity to enter into a confidentiality agreement to facilitate the exchange of non-public information regarding compounded drug products (human and veterinary drugs), human drug supply chain security information and related information (referred to as non-public compounding and drug supply chain security information) for a five-year period that will begin on the date above until June 30, 2025.

   The Long-Term Drug Compounding and Drug Supply Chain Security Information Sharing Agreement (ISA) allows for the (division) head of the State, local, or U.S. territory government agency (hereby referred to as State agency) to affirm that the non-public information provided by FDA will not be disclosed with anyone outside of their agency without written confirmation from FDA that such information can be released to the public. Furthermore, this agreement does not require that each individual in the agency who has a need to know or official interest in the non-public information to sign the confidentiality agreement. These streamlined procedures are in contrast to past 20.88 confidentiality agreements that required each individual in the agency sign the agreement prior to viewing non-public information.

2. Although FDA only requires one signature from the(division) head of your agency to permit the legal exchange of non-public pharmacy compounding and/or drug supply chain security information under this confidentiality agreement, we recognize that other individuals in your agency may need to know about and disseminate the non-public information quickly in an emergency such as an out outbreak, recall, or a report of suspect or illegitimate product in the supply chain. To facilitate this, we ask that you provide us with the names and contact information for key individuals in your agency along with their title, specialty, or subject matter expertise. For example, the Executive Director of a State Board of Pharmacy may want to provide contact information for division directors or managers in charge of compounding or drug supply chain security.

3. Under this confidentiality agreement, you are certifying, on behalf of your agency, that the agency has the legal authority to protect all non-public compounding and supply chain security related information that FDA shares with individuals in your agency and committing not to disclose such information. The reference to "non-public information" covered by this agreement includes any information subject to limitations on public disclosure under federal law and regulations. For FDA documents shared under this agreement, this may include: confidential commercial information, personal privacy information, pre-decisional information,

deliberative information, and law enforcement records. Trade secrets must not be shared under this agreement. Any request to share non-public information outside of your agency must be approved in advance by FDA.

4. Attachment A provides background information about the streamlined information sharing procedures for utilizing the Long-Term Drug Compounding and Drug Supply Chain Security ISA. Attachment B describes the conditions for sharing of non-public Drug Compounding and Drug Supply Chain Security information with State government officials. Attachment C must be completed and signed in order to establish the Long-Term Drug Compounding and Drug Supply Chain ISA. Attachment D is optional, but highly recommended. Please include a copy of your agency/division organizational chart.

   Please send a copy of Attachment C, Attachment D and an organizational chart to the email address ORAInfoshare@fda.hhs.gov with the subject line: Attention: Lauren DiPaola/20.88 LT ISA.

   If you have any questions about this program, please contact Lauren DiPaola at 301-796-3910 or ORAInfoshare@fda.hhs.gov.

Director, Office of Strategic Planning and Operational Policy

ATTACHMENTS:

A. Background Information on FDA Sharing of Non-Public Information with State Government Officials using the Single-Signature Long-Term Drug Compounding and Drug Supply Chain Security Information Sharing Agreement

B. Conditions for FDA Sharing of Non-Public Information with State Government Officials

C. CERTIFICATION (CONFIDENTIALITY COMMITMENT) for State Agencies

D. Designation of Key Points of Contact in State Agencies

## ATTACHMENT A

### Background Information on FDA Sharing of Non-Public Compounding and Drug Supply Chain Security Information with State Government Officials Using the Single-Signature 20.88 Long-Term Compounding and Drug Supply Chain Information Sharing Agreement

Under 21 CFR 20.88 FDA may share certain non-public Agency records on a discretionary basis with State Government officials who perform counterpart functions to FDA as part of cooperative law enforcement or regulatory efforts, provided that certain conditions are met. Information sharing under this provision is never mandatory, and each State government request will be processed only after duly considering FDA's concerns for confidentiality, the requester's need for the information, and the benefit to the public health that may result from such sharing.

Under this agreement, FDA can rapidly share non-public information, including confidential commercial information and pre-decisional information, with State agencies and officials responsible for compounded drug products, compounding facilities, and drug supply chain security matters. The Procedures also allow the sharing of drug compounding and drug supply chain security product information, inspection reports (omitting trade secrets), enforcement actions, illness investigation data, traceback information, and warning letters with State agencies and officials responsible for regulating compounded drugs and the security of the drug supply chain.

Under these agreements, State government agencies must provide a written statement that they have the legal authority to protect any shared information from any public disclosure and a commitment not to disclose such information without the written confirmation from FDA that such information can be released to the public. FDA will be unable to share non-public drug compounding and drug supply chain information with your agency if it cannot certify that the agency has the ability to maintain the confidentiality of all non-public information received from FDA. If a State agency fails to maintain the confidentiality of non-public information, FDA may refuse to share such information with the State agency in the future. Moreover, unauthorized disclosure of confidential commercial information could result in a civil or criminal violation. The conditions for confidential sharing of non-public information are further described in Attachment B.

**If a State agency does not sign the Certification in Attachment C, it may be excluded from conference calls and meetings with FDA and will be required to request all confidential information according to the procedures set forth in 21 CFR § 20.88.**

The procedures for releasing non-public information to State government agencies are listed below.

1. Directors of State agencies sign the certification form.
2. To request non-public information pertaining to drug compounding, the State agency sends a written request to the FDA District Director or State Liaison who has jurisdiction over that State and copies **Lauren DiPaola** (ORA/Office of Strategic Planning and Operational Policy (OSPOP), Division of Information Disclosure Policy (DIDP)) at ORAInfoshare@fda.hhs.gov.
3. When necessary and without receiving a formal request, an FDA District Director has the discretion to provide selected non-public information specific to drug compounding or drug supply chain security information to the signatories listed on the certification or to a State official commissioned by FDA. This should be done only for special circumstances.

## ATTACHMENT B

### Conditions for FDA Sharing of Non-Public Information with State Government Officials

The United States Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services, is charged with protecting and promoting the health of the American people. It is responsible for assuring that foods are safe, wholesome, and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and products that emit radiation are safe.

In an effort to enhance regulatory and enforcement cooperation between FDA and State and local government officials who perform counterpart functions to FDA, FDA promulgated a regulation under 21 CFR § 20.88 governing the communication of non-public information with State government officials. 21 CFR § 20.88 permits FDA, on a discretionary basis, to release non-public pre-decisional, confidential commercial, and/or other non-public information regarding FDA-regulated products to State officials. As long as the requirements in 21 CFR § 20.88 have been met at the time of the release, FDA's release of non-public information to a State government is not a public disclosure and does not compel FDA, if requested, to release such information to the public. **Non-public information that FDA shares with the State agency belongs exclusively to FDA, loaned for the purpose for which it was requested or for other cooperative law enforcement efforts.** FDA may take steps to retrieve the information shared with a State government agency at any time and it may initiate judicial proceedings if necessary [see United States v. Napper, The City of Atlanta, et al., 887 F.2d 1528 (1989)].

Before FDA may share non-public pre-decisional, confidential commercial, and/or other non-public information with non-commissioned State officials, FDA must receive a written certification from the State agency that it understands the conditions under which FDA shares non-public information, and certifies that it: (1) has the authority to protect the information from public disclosure and (2) will not disclose such information without written confirmation from FDA that the information no longer has non-public status, or in cases involving confidential commercial information concerning a regulated product-without the consent of the owner of the information (e.g., drug sponsor). FDA will rely on the State government agency's certification regarding its authority to protect FDA non-public information from disclosure. If changes occur in the State agency's statutes, laws, policies, or procedures that may affect the agency's ability to protect FDA non-public information from disclosure, it: (1) will notify FDA immediately and (2) will not disclose the non-public information without the consent of the owner, submitter, individual, or FDA as described above.

In the event an agency receives a subpoena, court order, or other compulsory process including a request under a state public records act or Freedom of Information Act to release non-public information received from FDA, it will contact FDA within two business days of receipt of the notice and the agency will take appropriate legal measures to resist the release of such information. The State agency will not release the information until FDA has had the opportunity to take appropriate legal measures to resist the disclosure of such information, has determined whether it will take such measures, and has notified the State agency of its determination—which notification shall be made in a timely manner. The certification or confidentiality commitment is provided as Attachment C.

When FDA receives the written certification setting out the commitment on the part of the State agency, it may share the information only when the following determinations are made.

Requests for non-public pre-decisional information:

The requested information must be reasonably necessary to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements.

Requests for confidential commercial information:

FDA must determine if (1) the owner of the information or sponsor for the product application has provided written authorization for the exchange or (2) the disclosure of the information would be in the interest of public health by reason of the State government's possessing information concerning the safety, effectiveness, or quality of a product or information concerning an investigation, or by reason of the State government's ability to exercise its regulatory authority more expeditiously than FDA.

As a regulatory and law enforcement agency, it is important that FDA avoid unauthorized disclosure of non-public information, particularly disclosures that might provide any company with a competitive advantage, place a submitting company at a disadvantage relative to its competitors, or result in an unwarranted invasion of personal privacy of an individual. It is essential that State officials s engaged in information exchanges with FDA understand and respect the obligations to protect FDA non-public information from unauthorized disclosure and take adequate security measures to prevent the unauthorized release of shared FDA non-public information.

Once the agreement has been signed, send the signed copy to ORAInfoshare@fda.hhs.gov with the subject line: Attention: Lauren DiPaola/20.88 LT ISA.

ATTACHMENT C

CERTIFICATION (CONFIDENTIALITY COMMITMENT) for State Government Agencies

**Statement of legal authority and commitment not to disclose non-public information including, but not limited to, confidential commercial or non-public pre-decisional information shared by the U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

***Reference: Information regarding drug compounding entities and drug supply chain-related matters.***

FDA may share non-public information concerning the safety, effectiveness, or quality of a product or facility with

Office of Professional Licensure and Certification

*(State government agency)*

in accordance with 21 CFR 20.88. **This sharing is in the interest of public health and is for the limited purpose of conducting cooperative law enforcement or regulatory efforts as they relate to drug compounding entities and drug supply chain security matters.**

My agency understands that:

1. Some or all of the non-public information it receives from FDA is considered to be confidential commercial, personal privacy information, or non-public pre-decisional information exempt from disclosure under the laws and regulations of the United States and that FDA considers it extremely important that my agency maintain the confidentiality of the information.
2. The non-public information received from FDA belongs exclusively to FDA and does not belong to my state agency. FDA may take steps at any time and may initiate judicial proceedings to retrieve non-public information shared with my agency.
3. Disclosure of non-public information shared by FDA could seriously jeopardize any further cooperative information sharing between FDA and my agency. Moreover, unauthorized disclosure of confidential commercial information obtained from FDA could be a civil or criminal violation and may carry legal consequences for the disclosing official.
4. **FDA will not reveal to non-commissioned officials any method or process that is entitled to protection as trade secret under section 301(j) of the FD&C Act [21 U.S.C. 331(j)].**

Therefore, Office of Professional Licensure and Certification certifies that it:

*(State government agency)*

1. Has the legal authority to protect FDA non-public information from disclosure, including but not limited to confidential commercial information, personal privacy information, and pre-decisional information.
2. If requested, has attached copies of the relevant statutes, regulations, court decisions, or other documents that establish this authority or has provided a summary of its legal authority.
3. Subject to the notice provisions of this paragraph, will not disclose FDA non-public information without the written statement from FDA that the information no longer has non-public status or, in cases involving confidential commercial information concerning a regulated product, without the consent of the owner of the information (e.g., drug sponsor). My agency will inform FDA within two business days of any effort made to

obtain the information from it by subpoena, court order, or other compulsory process, including a request under any state public records act or Freedom of Information act, and will refrain from disclosing such information. Under such circumstances, my agency will refrain from disclosing the information until FDA has had the opportunity to take appropriate legal measures to resist the disclosure of such information, has determined whether it will take such measures, and has notified my agency of its determination. FDA will make this determination in a timely fashion. The agency may disclose the information to a court of competent jurisdiction if 1) the court orders such disclosure, 2) the agency has taken legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure, and 3) the agency has notified FDA but failed to receive a timely determination of FDA actions.

4. Will promptly inform FDA of any changes to its laws, policies, or procedures that would affect its ability to maintain the confidentiality of the information FDA shares.
5. Has safeguards, including the adoption of policies and procedures to ensure that the information shared under this agreement will not be further disclosed consistent with the rest of this agreement.
6. Access to the non-public information shared under this agreement shall be restricted to the employees, and officials of the Participants, who require access to such information to perform their official duties in accordance with the uses of the information as authorized in this agreement, unless otherwise authorized in writing by FDA. All such personnel shall be advised of (1) the confidential nature of the information; and the obligation to keep such information confidential; and (2) safeguards against unauthorized disclosure of confidential information.
7. Will notify FDA of any actual or suspected unauthorized disclosure of any information shared pursuant to this agreement.

Lindsey B. Courtney

*Name of certifying official*

11/10/2021

*Date*

Executive Director

*Title of certifying official*

Lindsey B Courtney Digitally signed by Lindsey B Courtney Date: 2021.11.10 09:17:30 -05'00'

*Signature of certifying official*

6032716985

*Phone Number of certifying official*

lindsey.b.courtney@oplc.nh.gov

*E-mail Address of certifying official*

## ATTACHMENT D

### Designation of Key Points of Contact in State Government Agencies

This Attachment is used by the State government agency to provide FDA with key points of contact. FDA may wish to contact these individuals as primary respondents in emergencies, recipients of certain regulatory action notices, or recipients of pre-decisional information. If more space is needed, please attach a separate page with the name, position, a telephone number, and an e-mail address for the individual(s).

**Please include an agency/division organizational chart.**

*** In the first section, please enter the name of at least one person from your agency who's responsible for release of information to the public (e.g., FOIA/Public Records/Open Records Officer).**

*This person is a: Other

Lindsey B. Courtney
*Name*
Executive Director
Position
NH OPLC
*Program Area*
6032716985
*Phone Number*
lindsey.b.courtney@oplc.nh.gov
*E-mail Address*

Jessica Kallipolites
*Name*
Director, Division of Enforcement
Position
NH OPLC
*Program Area*
6035457021
*Phone Number*
jessica.f.kallipolites@oplc.nh.gov
*E-mail Address*

Rahkiya Medley
*Name*
Chief, Compliance Bureau
Position
NH OPLC
*Program Area*
6032718397
*Phone Number*
rahkiya.e.medley@oplc.nh.gov
*E-mail Address*

James Queenan
*Name*
Pharmacy Investigator/Inspector
Position
NH OPLC
*Program Area*
6032717603
*Phone Number*
james.m.queenan@oplc.nh.gov
*E-mail Address*

Elsa Croteau
*Name*

Pharmacy Investigator/Inspector
Position

NH OPLC
*Program Area*

6032712426
*Phone Number*

elsa.c.croteau@oplc.nh.gov
*E-mail Address*

Kaitlyn Simoneau
*Name*

Pharmacy Investigator/Inspector
Position

NH OPLC
*Program Area*

6034060995
*Phone Number*

kaitlyn.e.simoneau@oplc.nh.gov
*E-mail Address*

*Name*

Position

*Program Area*

*Phone Number*

*E-mail Address*

*Name*

Position

*Program Area*

*Phone Number*

*E-mail Address*

*Name*

Position

*Program Area*

*Phone Number*

*E-mail Address*

*Name*

Position

*Program Area*

*Phone Number*

*E-mail Address*

**From:** Phillips, Sheri
**To:** Courtney, Lindsey; Haley, Michael
**Cc:** Kelley, Heather
**Subject:** RE: GandC submission
**Date:** Wednesday, November 10, 2021 12:23:38 PM

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Hi Lindsey,

I reviewed these documents and they look good to me. Let me know if there is anything else you need me to do.

Thanks,

Sheri L. Phillips
Assistant Attorney General
Client Counseling Unit
N.H. Department of Justice
33 Capitol Street
Concord, NH 03301-6397
(603) 271-6836
Sheri.Phillips@doj.nh.gov



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**From:** Courtney, Lindsey <Lindsey.B.Courtney@oplc.nh.gov>
**Sent:** Wednesday, November 10, 2021 9:55 AM
**To:** Haley, Michael <Michael.R.Haley@doj.nh.gov>; Phillips, Sheri <Sheri.L.Phillips@doj.nh.gov>
**Cc:** Kelley, Heather <Heather.A.Kelley@oplc.nh.gov>
**Subject:** FW: GandC submission

HI Mike and Sheri,

Would one of you mind looking at this when you have a moment?

Thank you!

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**From:** Courtney, Lindsey
**Sent:** Wednesday, November 10, 2021 9:30 AM
**Cc:** Kelley, Heather <Heather.A.Kelley@oplc.nh.gov>
**Subject:** GandC submission

Hi Heather

I have the attached MOU with the FDA that I believe needs to go to G&C. Does this also need to be reviewed by DOJ?

**Lindsey B. Courtney, J.D. | Executive Director**
NH Office of Professional Licensure and Certification
7 Eagle Square, Suite 200, Concord, New Hampshire 03301
603.271.6985 (Office) 603.406.4018 (Cell) | lindsey.courtney@oplc.nh.gov | www.oplc.nh.gov