

April 16, 2018

Administrator Scott Pruitt  
Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

**Re: EPA-HQ-OPPT-2017-0652; Guidance: Expanded Access to TSCA Confidential Business Information**

Dear Administrator Pruitt:

On behalf of the American Academy of Pediatrics, American College of Obstetricians and Gynecologists, and the American Public Health Association, representing physicians and public health professionals dedicated to the advancement of the health and wellbeing of women, children, and families across our nation, we appreciate the opportunity to provide comments in response to the Environmental Protection Agency's (EPA) notice titled "Guidance: Expanded Access to TSCA Confidential Business Information" (EPA-HQ-OPPT-2017-0652-0003). Our comments will focus specifically on the draft guides for "*access to TSCA CBI for medical and environmental professionals in non-emergency situations*" (NEM guidance) and "*access to TSCA CBI in emergency situations*" (EM guidance). It is our hope that you will give our comments full consideration as you continue to implement the Toxic Substances Control Act as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA) to its fullest extent, with a careful eye toward preserving the public's health.

**Background**

As physicians and public health professionals, we are consistently seeking ways to advance the health of our patients and to improve health outcomes. Reducing exposure to toxic environmental agents is a critical area of intervention for ob-gyns, pediatricians, and public health professionals. An important outcome of pregnancy is no longer just a healthy newborn, but a human biologically predisposed to be healthy from birth to old age.<sup>1</sup> Harmful chemicals can cross the placenta in pregnancy, and in some cases can accumulate in the fetus, resulting in higher fetal than maternal exposure. Robust scientific evidence has emerged over the past several years demonstrating that prepregnancy and prenatal environmental exposures can have a profound and lasting impact on reproductive health across the life course. In addition, as infants and children grow and mature, their unique physiologic, developmental, and behavioral differences make them especially vulnerable to chemical exposures during critical windows of development.

TSCA Section 14(d) (15 USC 2613(d)) provides exceptions to protection from disclosure of confidential business information (CBI), and creates a pathway for health professionals to access CBI for the purposes of treating their patients with suspected exposure. The law provides for different processes for

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<sup>1</sup> Exposure to toxic environmental agents. Committee Opinion No. 575. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2013;122:931–5.

requests made in response to non-emergency (Section 14(d)(5)) and emergency situations (Section 14(d)(6)). It is of vital importance that both processes provide a pathway for health professionals to access CBI that is, as is required by TSCA Section 14(g)(3), “readily accessible and understandable, and allows for expedient and swift access to information.”

### **The Role of the Centers for Disease Control and Prevention**

TSCA Section 14(g)(3) requires EPA to consult with the Centers for Disease Control and Prevention (CDC) in the development of “a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d).” CDC is the nation’s premier health protection agency, with a [mission](#) to “[work] 24/7 to protect America from health, safety and security threats, both foreign and in the US.” Given CDC’s extensive work with the health professional community, and its mission that falls in line with the intent of TSCA as a mechanism to protect the public’s health from toxic chemical exposure, consultation and collaboration on a request and notification system will ensure a system that meets the needs of health professionals and their patients.

EPA does not provide an indication that CDC was consulted in the creation of the NEM guidance or EM guidance, as is required by Section 14(g)(3). Before finalizing both guidance documents, EPA should work with CDC to ensure that the NEM and EM documents, as well as the processes put in place to operationalize the request and notification system – including both the statement of need and confidentiality agreement – meet the letter and spirit of the law in establishing a system that is responsive to the needs of health professionals and their patients.

**Recommendation:** Consult with CDC before finalizing the NEM and EM guidance documents.

### **Definitions**

Both the NEM guidance and EM guidance include definitions that should be expanded to ensure that all relevant health professionals responsible for the treatment of patients or responding to public health emergencies are able to access CBI for the purposes of caring for those patients or responding to such emergencies. Specifically, we make the following recommendations:

*Agent of a poison control center (EM guidance only):* This definition is overly narrow and not reflective of statute. The EM guidance defines this term to only include persons employed “by a State, local, or tribal poison control center.” The proposed definition would potentially exclude a number of poison control centers, and should be broadened to be aligned with the statute by including those not run by a State government, local, government, or tribe.

*First Responder (EM guidance only):* This definition is overly narrow and not reflective of the statute. The EM guidance defines this term to only include persons “duly authorized by a Federal agency, State, political subdivision of a State, or tribal government”. The proposed definition would potentially exclude a number of first responders, including those employed or contracted by private entities, and should be broadened to include all first responders trained in urgent medical care or other emergency procedures.

*Health Professional:* This term is not used in the statutory provision. If included in the final NEM or EM guidance documents, it should not be limited to government-affiliated health professionals, and should be expanded to explicitly include physicians and nurses, as defined.

*Medical Emergency (EM guidance only):* This definition is overly narrow and should be expanded to include physicians and nurses. In addition, EPA should add a qualifier to encompass conditions that *could* result in *potentially* serious symptom(s) or that constitute a *potential*, not just actual, threat to health. This threshold is more consistent with medical practice, where health professionals respond to both suspected and confirmed emergencies. We therefore encourage EPA to update the definition to read:

Medical Emergency: any unforeseen condition which a health professional, including a nurse or physician, has a reasonable basis to suspect ~~would judge to~~ require urgent and unscheduled medical attention. Such a condition is one which could results in sudden and/or potentially serious symptom(s) constituting a potential threat to a person's physical or psychological well-being and which a health professional, including a nurse or physician, has a reasonable basis to suspect requires immediate medical attention to prevent possible deterioration, disability, or death.

*Nurse:* This definition is overly narrow and should be expanded to ensure that all relevant non-physician health professionals responsible for the treatment of patients are able to access CBI. Non-physician providers can be the first line of medical care, especially in rural and underserved areas. To ensure a broader definition that is consistent with how nurses are defined by other federal agencies and reflective of their role in the broader health care provider space, we encourage EPA to refer to Medicare statute ([42 USC 1395x](#)) and update the definition to read:

Nurse: a nurse (nurse practitioner, clinical nurse specialist, licensed practical nurse, certified-nurse midwife, or registered nurse who performs such services as such individual is legally authorized to perform in the State in which such services are performed) who furnishes a consultation or treats a person for a specific medical problem.

*Physician:* This could be expanded to include additional providers defined as "physician" in the Medicare statute ([42 USC 1395x](#)). This will ensure consistency across agencies and avoid confusion among providers who do not traditionally interact with EPA. The definition should be updated to read:

Physician: a physician (a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by the State in which s/he performs such function or action, a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which s/he performs such function or action) who furnishes a consultation or treats a person for a specific medical problem.

In addition, EPA should ensure that other health care professionals, such as physician assistants, who often provide primary care to patients and effectively act as treating or responding physicians or nurses can also access CBI.

*TSCA Confidential Business Information (TSCA CBI)*: EPA should specify in both NEM and EM guidance that health and safety information is *not* CBI. In Section III of both documents, EPA provides the example of “health and safety data for a particular substance or class of substances” that EPA must disclose. EPA is correct that EPA has mandatory obligation to release health and safety data. But EPA should clarify for the purposes of these guidance documents that health and safety information is *not* TSCA CBI and therefore not protected from disclosure. Further, it should be noted in Section III of both documents that, in the case that health and safety information is requested via this process, EPA should immediately provide the requested information to the requester without restriction.

**Recommendation:** Amend definitions of Agent of a poison control center (EM guidance only), First Responder (EM guidance only), Health Professional, Medical Emergency (EM guidance only), Nurse, Physician, and TSCA Confidential Business Information (TSCA CBI) to ensure they enable expedient and swift access to information needed to treat patients.

### **Timelines**

To avoid unreasonable delays in disclosing information, EPA should establish and strictly follow deadlines for each step of the process. The draft guidance documents do not include deadlines for EPA to take action on requests, notifications, and disclosures. To ensure health professionals gain expedient and swift access to CBI, as required by TSCA Section 14(g)(3), we recommend adoption of the following timelines:

*Processing requests*: EPA should commit in its guidance to promptly process all requests for information it receives pursuant to TSCA Sections 14(d)(5) and 14(d)(6). For TSCA Section 14(d)(5), EPA should commit to deciding on a request, and providing the required notification to claimants, within at most 5 business days of its receipt. For TSCA Section 14(d)(6), EPA should commit to processing the request within no more than 24 hours.

*Providing notification*: TSCA Section 14(d)(5) requires EPA to notify a confidentiality claimant of the intent to disclose information. To ensure a timely process, as soon as EPA makes a decision to disclose, EPA should submit a notice to the claimant immediately, in no case later than 5 business days after receiving the request.

*Disclosing the requested information*: TSCA Section 14(d)(5) requires EPA to provide the claimant with 15 days notification. To ensure a timely process, EPA should be fully prepared to disclose the information once the notification period expires, and should set a firm deadline to disclose the requested information not later than 1 business day after the 15-day notification period expires.

TSCA Section 14(d)(6) requires EPA to disclose the information *before* notifying the confidentiality claimant, though EPA shall notify the claimant “as soon as practicable *after* disclosure of the information” (TSCA Section 14(g)(2)(C)(ii)). Given that this information is to be shared before notifying

the claimant and arises in the context of an emergency, EPA should commit to disclosing information under this provision not more than 48 hours after receiving the request.

**Recommendation:** Establish and strictly follow clear timelines for:

- Processing requests (NEM guidance: 5 business days, EM guidance: 24 hours)
- Providing notification (NEM guidance: 5 business days), and
- Disclosing the requested information (NEM guidance: immediately following 15-day notification period, EM guidance: 48 hours).

### **Where to Request CBI**

TSCA Section 14(g)(3) requires EPA, in consultation with the CDC, to “develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d).” As part of that requirement, EPA should expedite development of an electronic request and notification system for both emergency and non-emergency requests, and provide a clear timeline for development of such system. TSCA Sections 14(d)(5), 14(d)(6), and 14(g)(3) do not differentiate channels used to submit requests for emergency versus non-emergency situations. Therefore, while EPA develops the electronic system, non-emergency requests should not, as is suggested in the NEM guidance, be limited to mail or delivery service, and should also be accepted via email, fax, phone, or messenger.

The NEM guidance states that “In some circumstances, it might be most efficient for EPA to simply provide the information orally, over the phone, and in other circumstances, the information may be provided in writing, and/or via electronic access.” EPA should amend the sentence to assert that, in the circumstances when information is provided orally, EPA will then share the information in writing with the requester. That should also be reflected in EM guidance.

The EM guidance states that “Telephonic or other requests made orally will be memorialized in writing by EPA.” EPA should amend the sentence to assert that, in these circumstances, EPA will then share the information in writing with the requester. That should also be reflected in NEM guidance.

### **Recommendations:**

- Expedite development of an electronic request and notification system for both emergency and non-emergency requests, and provide a clear timeline for development of such system.
- Consistent with EM guidance, allow for submission of non-emergency requests via email, fax, phone, or messenger.
- Ensure any information gathered or shared orally is provided to the requester in writing.

### **Verification of Eligibility**

Both the NEM and EM guidance include a requirement that requesters verify to EPA that they fall within one of the defined categories of requesters eligible for access to CBI under TSCA Sections 14(d)(5) or 14(d)(6). The list of information requested from EPA to verify eligibility includes “(4) a representation that the requester is certified to perform the services relevant to the requester’s position.” It is unclear what information EPA is requesting and what would satisfy a “representation.” Therefore, to ensure that the information requested is readily accessible and understandable, as required by TSCA Section 14(g)(3), we recommend striking (4) and replacing with “(4) attest that the requester is eligible to access TSCA CBI as defined in Section II of this document.” This can be achieved via a simple response of “yes” or “no.”

**Recommendation:** Simplify verification requirement (4) to an attestation that the requester is eligible to access TSCA CBI, allowing for a “yes” or “no” response.

### **Statement of Need**

TSCA Section 14(d)(6)(B) certifies that, in the event of an emergency, a statement of need is only required if requested by a claimant, and that a statement of need and confidentiality agreement are not required to be received before the information is disclosed. The EM guidance implies in several places that a requester would need to provide what amounts to a statement of need before being able to gain access to CBI, which is not consistent with the statute. EPA should clarify throughout the EM guidance that, even where requested, the statement of need is to be submitted “as soon as practicable, but not necessarily before the information is disclosed,” per TSCA Section 14(d)(6)(B)(iii). Further, EPA should clarify throughout the EM guidance that a statement of need is required only if requested by a claimant (TSCA Section 14(d)(6)(B)).

#### **Recommendations:**

- Clarify that, for requests made during emergency situations, a statement of need and confidentiality agreement are not required to be received before the information is disclosed.
- Clarify that, for requests made during emergency situations, a statement of need is required only if requested by a claimant.

### **Confidentiality Agreement**

Both NEM and EM guidance documents provide specific text of a confidentiality agreement and state or imply that a requester must sign that specific agreement. Having a model agreement can be helpful, and, subject to incorporation of the changes recommended below, we agree the amended confidentiality agreement could serve as a template. However, while EPA should indicate it will accept the model agreement as sufficient, EPA should also indicate that it is open to negotiating the terms of the agreement with the requester. It is important to note that the confidentiality agreement is between EPA and the requester, and therefore confidentiality claimants have no role in a negotiation of the terms of the agreement, nor the statement of need. Specifically, we make the following recommendations to improve the model agreements:

First, EPA should insert “or health care” between “medical” and “decisions” each time it appears, consistent with the statute (TSCA Section 14(h)(c)).

Second, EPA should not dictate health professional speech and should strike the sentence “When disclosing TSCA CBI to a patient or person authorized to make medical decisions on behalf of the patient, I will advise that person that the information has been claimed confidential by a business and should not be further disclosed except as authorized by that business or by TSCA section 14.” That requirement is not in the statute and including the sentence in an agreement constitutes an inappropriate interference in the patient-provider relationship. To minimize interference in the patient-provider relationship, the law exempts disclosing CBI to patients from criminal penalties otherwise applicable to willful disclosure of CBI.

Third, EPA should strike “I certify that the statements I have made in this agreement and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under 18 U.S.C. 1001.” This certification clause lacks a qualifying clause and is not required under TSCA. If EPA chooses to retain it, EPA should modify to read as follows: “I certify that, to the best of my knowledge, the statements I have made in this agreement and all attachments thereto are accurate.”

**Recommendations:**

- Clarify that the confidentiality agreement text included in both NEM and EM guidance documents is a model agreement, and EPA is open to negotiating the terms of the agreement with the requester.
- Certify that confidentiality claimants have no role in a negotiation of the terms of the agreement, nor the statement of need.
- Update the model agreement to read “medical or health care decisions” each time it appears.
- Minimize interference in the patient-provider relationship by striking the sentence dictating that a requester “will advise” their patient.
- Strike the certifying statement, or modify to shorten and include a qualifying clause.

**CBI Handling Instructions**

EPA should not impose CBI handling obligations not required under TSCA or other laws. Both NEM and EM guidance documents include statements that go beyond statutory requirements in calling on requesters to consider “destroying such written or electronic copies once the need for the information subsides (by, for example, shredding, burning, or degaussing).” This language is overly prescriptive, and if included, should clarify that they are merely recommendations and not statutorily required.

In addition, every time NEM and EM documents reference criminal penalties associated with wrongful disclosure, EPA should also reference the exception in TSCA Section 14(h)(c) clarifying that a fine and/or

imprisonment “shall not apply to any medical professional (including an emergency medical technician or other first responder) who discloses any information obtained under paragraph (5) or (6) of subsection (d) to a patient treated by the medical professional, or to a person authorized to make medical or health care decisions on behalf of such a patient, as needed for the diagnosis or treatment of the patient.”

**Recommendations:**

- Clarify that any handling instructions are merely recommendations and not statutorily required.
- Include reference to the exception from criminal penalties for medical professionals disclosing information to their patients obtained via non-emergency or emergency requests.

Thank you for the opportunity to comment on the draft NEM and EM guidance documents. As organizations representing physicians and public health professionals who will utilize the new request and notification system for the purposes of treating patients, we hope you will give our recommendations full consideration.

Sincerely,

American Academy of Pediatrics  
American College of Obstetricians and Gynecologists  
American Public Health Association