



**NUMBER:** Directive 1801

**SUBJECT:** Epidemiologic Data Sharing Under the CPSA

**DIRECTIVE OWNER:** Directorate for Epidemiology (EP)

**EFFECTIVE DATE:** January 23, 2023

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1. **PURPOSE.** This Directive gives direction for providing Identified Epidemiological Data to certain outside parties under specified terms and conditions.

2. **AUTHORITIES:**

- a. Consumer Product Safety Act (CPSA), 15 U.S.C. § 2051 *et seq.*
- b. Consumer Product Safety Improvement Act of 2008, Pub. Law No. 110-314
- c. The Privacy Act of 1974, 5 U.S.C. § 552a.
- d. The Freedom of Information Act, 5 U.S.C. § 552, as amended.

3. **SCOPE.** This directive is intended for all CPSC staff who access or handle Identified Epidemiological Data, either directly or indirectly, and who may be asked to share Identified Epidemiological Data with Outside Parties.

4. **DEFINITIONS.**

- a. *Outside Party* – Any person except: an officer or employee of CPSC; an agent or representative of CPSC, including a contractor; and anyone acting in an official capacity as a consultant to the CPSC (e.g., advisory committee member).
- b. *Identified Epidemiological Data* – Summaries or epidemiological incident reports (death certificates, In-Depth Investigations (IDIs), reports from consumers, reports from medical examiners/coroners, news clips, and reports from manufactures or retailers). This does not include aggregated estimates or counts derived from the data, including National Electronic Injury Surveillance System (NEISS) estimates, counts of fatalities, or counts of incidents.
- c. *Clearinghouse Request* – A request by an Outside Party to CPSC’s Injury Information Clearinghouse for data in summary form.
- d. *Standards Development Organization Request* – A request by a member of a standards development organization (SDO) for data to be shared with an SDO to inform their work.



The response to such a request should only include redacted summary data or redacted IDIs.

- e. *Congressional Oversight Request* – A request by the Chairman or ranking minority member of a committee or subcommittee of Congress, acting pursuant to committee business, and having jurisdiction over the matter that is the subject of the information request. This may include summary data or epidemiological incident reports (death certificates, IDIs, reports from consumers, reports from medical examiners/coroners, news clips, and reports from manufactures or retailers).
- f. *Transmission to Other Federal Agencies pursuant to Contractual Agreements* – Certain epidemiological data may be shared with other federal agencies to comply with certain interagency contractual agreements, for example, injury data collected by CPSC as part of NEISS for the Centers for Disease Control and Prevention.
- g. *Exchanging Information with Data Submitters* – Data may be shared with the person or party who provided it. For example, when a consumer is contacted for clarification or additional information, the consumer’s report may be shared with the consumer.

**5. RESPONSIBILITIES.** CPSC staff may be asked to share epidemiological data with outside parties for a variety of reasons or purposes, including:

- a. To meet the statutory requirement (per the Consumer Product Safety Act) to maintain an Injury Information Clearinghouse to collect, investigate, analyze, and disseminate injury data, and information related to the causes and prevention of death, injury, and illness associated with consumer products.
- b. To provide data to standards development organizations to inform their consideration of options for making safer products.
- c. To make jurisdictional or agency-to-agency referrals involving products, hazards, or other complaints of relevance to other federal agencies.
- d. To deliver data per contractual agreements (e.g., National Electronic Injury Surveillance System All-Injury).
- e. To provide data in response to Congressional oversight requests.
- f. To a manufacturer to view incident information regarding their products.
- g. To exchange information with the submitter of the data regarding the data submitted.
- h. Other data requests not specified above.



Staff providing data to outside parties must do so in accordance with the relevant requirements, including section 6 and other provisions of the Consumer Product Safety Act, as amended, and the Privacy Act. Before release, such data shall also be reviewed by a supervisor or the supervisor's designated reviewer, to ensure compliance.

## **6. PROCEDURES.**

- a. **Clearinghouse Requests.** Staff will prepare epidemiological data in summary form (*i.e.*, not inclusive of underlying reports) complying with all relevant statutes (*e.g.*, Consumer Product Safety Act, Privacy Act), as determined by CPSC's Office of the General Counsel (OGC), and excluding manufacturer identifying and personally identifiable information. Staff will prepare the Clearinghouse data in accordance with Standard Operating Procedure 1801.1. Once prepared, these data will be published annually to CPSC's Clearinghouse and/or NEISS Online.
- b. **SDO Requests.** Staff will prepare data in a manner that complies with all relevant statutes (*e.g.*, Consumer Product Safety Act, Privacy Act), as determined by CPSC's OGC, and will exclude manufacturer identifying and personally identifiable information. Staff will follow Standard Operating Procedure 1801.2 to ensure that essential control procedures are followed before transmission of the summary epidemiological data. Staff will redact IDs in accordance with Standard Operating Procedure 1801.3 for release to SDOs.
- c. **Transmission to Other Federal Agencies/Contractual Agreements.** Staff will prepare data in a manner that complies with all relevant statutes (*e.g.*, Consumer Product Safety Act, Privacy Act), as determined by CPSC's OGC. Before transmission of the epidemiological data, staff will follow Order No. 0760.2, *Protection of Personally Identifiable Information for CPSC Information Systems* (April 4, 2009) or any successor directive, to ensure that essential control procedures are followed. This applies to the delivery of data per contractual agreements (*e.g.*, NEISS All-Injury), which can extend to data transfers involving parties collecting the data.
- d. **Congressional Oversight and Requests.** Staff will prepare data in a manner that complies with all relevant statutes (*e.g.*, Consumer Product Safety Act, Privacy Act), as determined by, and in coordination with, CPSC's OGC. Staff will transmit the data first to CPSC's Office of Legislative Affairs, which will coordinate with the OGC to determine the method for providing data in response to the congressional request.
- e. **Data for Manufacturers.** Staff will redact incident reports for manufacturer notification, in accordance with Standard Operating Procedure 1801.4. Staff will exclude personally identifiable information (except where permission has been granted to pass the information on to the manufacturer by the party to whom the identifying information



pertains), and information on other manufacturers. The prepared data will not be transferred until after a redundant review.

- f. **Exchanging Information with Data Submitters.** Staff will prepare the data in a manner that complies with all relevant statutes (e.g., Consumer Product Safety Act, Privacy Act), as determined by the CPSC’s OGC. Staff will follow Order No. 0760.2, (April 4, 2009) or any successor directive, to ensure that essential control procedures are followed before transmitting the epidemiological data.
- g. **Other Data Requests.** Requesters of epidemiological data that do not fit any of the prior categories should request the data through OGC’s Division of Information Access via a Freedom of Information Act (FOIA) request. Staff will transmit the data request to the FOIA office, which will transmit any permissible and responsive information to the requester.

**7. CANCELLATION.** This Delegation supersedes and cancels Directive D1304, *Epidemiological Data Sharing under the CPSA (Excluding FOIA)* (Oct. 5, 2021) and IP1304, *Data Delivery outside CPSC (Excluding FOIA)* (Jan. 25, 2022).

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Jason K. Levine  
Executive Director

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Date