



DATA LICENSE AGREEMENT

America's Poison Centers and Centers for Disease Control and Prevention

This Data License Agreement (hereinafter referred to as “the Agreement” or “this Agreement”) is entered into and made effective as of **October 4, 2022** (“Effective Date”), by and between America’s Poison Centers, a nonprofit corporation with a principal place of business at 4601 North Fairfax Drive, Suite 630, Arlington, VA 22203 (hereinafter referred to as “the Association”) and Centers for Disease Control and Prevention, Division of Environmental Health Science and Practice (DEHSP), a federal agency hereinafter referred to as “CDC” with a principal place of business at 4770 Buford Highway, Chamblee GA 30341 (each hereinafter referred to individually as a “Party” and collectively as the “Parties”) and as of the date hereof supersedes the License Agreement entered into by and between the Association and CDC dated as of March 29, 2011. The term “CDC” used throughout applies only to the specific divisions identified in this document.

WHEREAS, the Association is a nationwide organization that maintains data and information related to poison exposures and which represents the poison centers (PCs) of the United States and the interests of poison prevention and treatment of poisoning. These PCs as well as other poison-related organizations are members of the Association. the Association’s mission is to advance PCs in their public health mission.

WHEREAS, CDC is a federal agency that develops and applies disease prevention and control, environmental health, and promotes the reduction of morbidity and mortality through public and professional education, hazard surveillance, and scientific research activities designed to improve the health of the people of the United States;

WHEREAS, the Association owns and operates the National Poison Data System (hereinafter referred to as “NPDS®”) as a poisoning surveillance database containing toxicological information on poison exposures reported to U.S. PCs that serve all U.S. states and territories;

WHEREAS, CDC wishes to license from the Association the data contained in NPDS® (hereinafter referred to as the “Data”);

WHEREAS, CDC wishes to use the Data to improve surveillance for intentional and unintentional chemical and poison exposures. CDC will use NPDS® to 1) improve public health surveillance for chemical and poison exposures; 2) identify early markers of hazardous incidents with the objective of providing rapid and appropriate public health response; and 3) find potential cases and enhance situational awareness during a known incident.

WHEREAS, the Parties wish to memorialize the terms and conditions of the rights in the Data granted to the CDC by the Association, with such license to be effective *nunc pro tunc* for a term commencing the date of signature of this License Agreement.

NOW THEREFORE, in consideration of the mutual promises contained herein, and other good and valuable consideration, the sufficiency and receipt of which is hereby acknowledged, the Parties agree as follows:

1. DATA LICENSE

To assist **CDC**, and further the Association's Section 501(c)(3) tax-exempt purpose, the Association grants CDC, and CDC accepts from the Association pursuant to the terms and conditions of this Agreement, a revocable, royalty-free, non-exclusive, non-transferable license and right to use, to reproduce, and to prepare derivative works of, the Data provided under this Agreement, subject to the terms and solely for the purposes stated herein.

CDC is not permitted to transmit, access, receive, share, and/or use any part of the Data except as specified herein. Notwithstanding anything to the contrary herein, the Data (in whole or part) shall be used solely by CDC and is limited to usage for the purpose(s) described herein. Once the Agreement terminates or expires, CDC will certify in writing to the Association the termination of usage of the Data. The Association may additionally request from CDC certification of termination of usage and appropriate maintenance or destruction of the Data. CDC agrees to respond to any such request with written certification of termination of usage and appropriate maintenance or destruction of the Data.

"The Parties agree that the Covered Data provided under this Agreement is Licensed. To the extent that it is subject to any laws applicable to the Recipient, Recipient agrees to notify the Association of such laws as they become applicable and will maintain, store, protect, archive and/or dispose of Covered Data in accordance with any applicable law.

Obligations under law to archive Covered Data will survive termination of this Agreement. If required by law for this licensed data, provider agrees that an archival copy of the Covered Data may be retained by Recipient to comply with relevant records retention requirements and/or for the purposes of research integrity and verification. As a federal agency, the disposition of certain records in CDC custody and control is governed by the Federal Records Act and may only be accomplished in accordance with schedules for destruction as provided under law."

For the avoidance of doubt, notwithstanding the license of NPDS® Data as described herein, ownership of all such Data as between the Association (on behalf of itself and its members) and CDC is retained by the Association. CDC is not permitted to transmit any such Data to any other entity, sub-agency, or otherwise outside the scope of this Agreement without the Association's written permission in each instance.

2. SCOPE OF GRANT OF LICENSE

The CDC and the Association are committed to compliance, as may be applicable, with the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder, as amended ("HIPAA Rules"), including the HIPAA Privacy Rule, as amended ("the Privacy Rule") and this Agreement is intended to satisfy, where applicable, obligations of CDC and the Association under the HIPAA rules and to ensure the integrity and confidentiality of certain licensed information Disclosed or made available to CDC and certain information that CDC uses, discloses, receives, transmits, maintains, or creates, from the Association. As applicable to the Data and the Association, CDC, as licensee, is a "public health authority" as defined at 45 C.F.R. 164.501 and as used in 45 C.F.R. 164.512(b), Standards for Privacy of Individually Identifiable Health Information, promulgated under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). CDC, as a public health authority, is authorized by 45 CFR 164.512(b) to receive Protected Health Information ("PHI").

(a) CDC may exercise the rights granted hereunder for the purpose of CDC's national chemical exposure surveillance needs, including development of aberration and outlier detection, situational awareness capabilities, and GIS functionality in NPDS.

(b) CDC may exercise the rights granted hereunder 1) to conduct statistical analyses of the Data to identify statistical methods that can be applied to NPDS® data to reveal hazards and outbreaks, 2) to apply these statistical methods to the Data to analyze reports to identify patterns, deviations from patterns, outbreaks, and public health incidents, and 3) to provide access to analyzed data to federal, state, and local public health authorities during an incident of public health significance according to the Association/CDC Standard Operating Procedures for Use and Release of NPDS® Data ("Standard Operating Procedures"), attached, and as allowed herein.

(c) CDC may exercise the rights granted hereunder to prepare summary reports including, but not limited to, summaries of poison exposure experiences with specific types of poisonings, hazards, or outbreaks, and summaries of statistical methods and their application to NPDS® data (hereinafter referred to as "Summary Reports"). CDC may not disclose any Summary Report publicly that contains geographic identifiers (*e.g.*, state, county, zip code, area code/exchange), poison center identifiers, hospital identifiers, patient identifiers, or product tradename/brand identifiers unless CDC obtains the prior, written consent of the Association, provided, however, that CDC may release such information pursuant to the Standard Operating Procedures. Notwithstanding anything to the contrary in this Agreement, DEHSP may (a) only access NPDS® data (generic and product codes) within NPDS® that the parties mutually and reasonably agree applies to the work of CDC/DEHSP and (b) not share any NPDS® data or access thereto with any other CDC Center or government office other than Summary Reports (which are limited to NPDS® data/results in aggregate form).

(d) Applicable federal and/or state laws that govern the collection, use, disclosure, and maintenance of the Data may be cited as standard authorities related to the Data, which includes project-specific authorities and regulations. Parties acknowledge that CDC, as a federal agency, is not subject to the application of state or local laws or regulations or the internal policies and/or procedures of the other party, except where consistent with federal law. However, nothing in applicable federal law shall be deemed to give CDC any additional rights regarding the use or disclosure of Data beyond what is provided for herein.

3. TERM AND TERMINATION

(a) This Agreement shall commence immediately upon the Effective Date and shall be effective for the duration of the current Cooperative Agreement (Grant N0. 1-NUE1EH001395-01) between the Parties. The Parties may mutually agree in writing to revise the terms of the Agreement. Either party may terminate the Agreement immediately in writing; approval of termination by the other party is not required. Nothing herein is intended to conflict with the terms of the Cooperative Agreement between the Parties. See ¶9.

(b) Upon termination of this Agreement, the license granted hereunder is immediately revoked. CDC shall immediately cease any further use of the Data, provided, however, that CDC may continue to make use of materials that incorporate the Data where such materials were created during the Term of the Agreement. Termination shall not relieve CDC of its obligations regarding maintaining the confidentiality of the Data or any obligations hereunder which survive termination, including but not limited to Confidentiality, Terms of Use, Ownership, and Warranty and Indemnification. CDC shall always give proper attribution to the Association for any permissible use, dissemination, reproduction, or disclosure of the Data or reports provided to CDC herein, as set forth herein or as otherwise agreed to in writing by the Parties.

4. RESTRICTIONS ON USE/TERMS OF USE/CONFIDENTIALITY

(a) CDC shall exercise the rights granted under this Agreement only for public health purposes. As used herein, “public health” shall refer to use which is confined to CDC’s centers, institutes and offices, and state and local health departments, and not, except as provided for herein, for the purposes or benefit of others, as outlined in the Standard Operating Procedures.

(b) CDC shall permit public health authorities to use the Data as outlined in the Standard Operating Procedures. Except as provided in the Standard Operating Procedures, CDC shall not permit any other party or parties to use or to access the Data in any fashion unless such use is in furtherance of the CDC’s business and CDC has secured the Association’s prior written consent to such third party access to, or use of, the Data in writing unless such access to, or use of, the Data is required by Federal law.

(c) If a public health emergency is determined, based in principle on the Data, by CDC, CDC will follow the Standard Operating Procedures attached hereto, to confirm the validity of the relevant portion of the Data with the Association prior to publication and to

notify the affected PCs and state health departments prior to the issuance of a public advisory. CDC expressly acknowledges that confirmation of data accuracy with the Association is of critical importance in the event that poisoning cases are used as the basis of an emergency health advisory or public health decision prior to completion of the Association's usual fatality verification process.

(d) CDC shall not re-sell, disclose, advertise, transfer, give, provide access to, distribute, or publish the Data or otherwise allow its distribution other than internally and as stated above or outlined in the Standard Operating Procedures without the prior written consent of the Association, which consent may be withheld or conditioned in the Association's sole discretion. Prior to any external publication of Data in medical or scientific journals or Morbidity and Mortality Weekly Report (MMWR), CDC staff will submit the manuscript to the Association for approval of the release of NPDS® data included in the manuscript and the CDC will confirm with the Association in writing whether any key individuals at the Association or at participating PCs need to be acknowledged or designated as co-authors. Where outbreaks or incidents are geographically isolated or detected by individual PCs or small numbers of PCs, and CDC is preparing any external publication in medical or scientific journals or MMWR which is based on NPDS® data or PC information, CDC will specifically offer the opportunity for appropriate co-authorship to all PCs with a significant involvement in the outbreak or cases. The designation of co-authors shall adhere to accepted guidelines for authorship. Nothing in this paragraph shall preclude the Association or PCs from independently publishing cases, description of outbreaks, or their own analyses of NPDS® data.

(e) CDC agrees that it shall not publish the Data in any manner that expresses or implies that the publication constitutes a comparison of the safety of trademarked products insofar as poison experience is concerned, without the written permission of the Association, which permission shall not be unreasonably withheld where the comparison data is in furtherance of the public health.

(f) CDC agrees that at any time subsequent to its receipt, it will not contact or attempt to contact any party to which the Data relates (including but not limited to, the individuals, hospitals, medical personnel, or direct or indirect providers of the Data).

(g) CDC will not take any actions that violate this Agreement or that would otherwise be in derogation of the Association's proprietary or intellectual property interests in and to the Data.

(h) Any summary report prepared on these Data which is provided to a regulatory agency must contain the following disclaimer: "The content of this report does not necessarily reflect the opinions or conclusions of America's Poison Centers."

(i) In the event of a Freedom of Information Act (FOIA) request for data licensed under this Agreement, the CDC, acknowledging that these Data are considered proprietary by the Association, will apply all appropriate exemptions to withhold from release Data or records containing data that are deemed federal records for purposes of FOIA. Records, including Data, not in CDC's possession and control are not federal records for purposes of

disclosure under the FOIA. CDC will notify the Association in writing if such a request is received and allow for the Association's timely response. If CDC receives a legal request for the data, CDC will maintain such data in accordance with 5 U.S.C. § 552(b)(4) and other relevant federal law and that CDC would consult with them Party as required by 45 C.F.R. § 5.4.

(j) Where Data provided pursuant to this Agreement are identifiable or potentially identifiable, CDC agrees to maintain the confidentiality of the Data to the fullest extent required by applicable law. CDC further agrees to not disclose such Data, including but not limited to names and other identifying information of persons who are the subject of such Data, either during the term of this Agreement or longer, except as consistent with this Agreement or as required by applicable law. CDC will protect the privacy and confidentiality of the Data consistent, where applicable, with the following federal laws: the Privacy Act of 1974; to the extent applicable, standards promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Freedom of Information Act (FOIA). Where other more specific federal laws apply to the Data, CDC will comply with those laws, as well. CDC will seek to assert relevant exemptions to disclosure available under federal law, most critically, where applicable, for personal and/or private information, the disclosure of which would constitute an invasion of privacy; trade secret and commercial or financial information that is private and confidential; or information exempted from release by federal statute. Except as may be provided for in this Agreement, CDC shall not use the information from Data to link to other data nor establish contact with the named person or his/her family without prior written approval from the Association. Where required by law and/or where practicable, CDC agrees to notify the Association before releasing Data to a third party pursuant to a judicial, governmental, or other requests under law, to allow the Association the opportunity to state any objection to the disclosure of the Data. CDC understands and agrees that where applicable law permits or allows a use or disclosure but this Agreement does not permit or allow such use or disclosure, CDC must abide by the terms of the Agreement.

(k) The following disclosure statement must be included in all publications referencing the Association Data:

America's Poison Centers (the Association) maintains the National Poison Data System (NPDS), which houses de-identified records of self-reported information from callers to the country's poison control centers (PCs). NPDS® data do not reflect the entire universe of U.S. exposures and incidences related to any substance(s). Exposures do not necessarily represent a poisoning or overdose and the Association is not able to completely verify the accuracy of every report. NPDS® data do not necessarily reflect the opinions of the Association.

5. OWNERSHIP

The Association represents that it is the owner or licensor of the Data, that it has the full right and authority to grant this license, and that neither this license nor the Association's performance under this Agreement conflicts with any other agreement or obligation to which the Association is a party or by which it is bound, and that as of the date

of this Agreement, to the best of the Association's knowledge, the Data does not infringe any valid patents, copyrights, trademarks, or other proprietary rights of any third parties.

Except where otherwise agreed in writing between the Parties, as between CDC and the Association, the Association will own all rights, title, and interest, including all proprietary rights, copyrights, patent, and other proprietary rights, database rights, and any other intellectual property rights in and to, or has authority to license, all Data provided to CDC hereunder, and any other analyses, reports, or other intellectual property used, developed, created, or disclosed by the Association under this Agreement. The Parties agree that the Data provided under this Agreement and in the custody and control of CDC is subject to the laws applicable to the CDC, but nothing in such laws shall give CDC any additional rights other than what has been granted herein.

6. LIMITATIONS OF DATA VALIDITY

(a) The Data should not be interpreted by CDC as constituting the entire poison experience that members of the public may have had with the products included.

(b) The Association makes no representation or warranty as to the accuracy or validity of the Data concerning the experience furnished other than that the data were reported by affiliated members who were given the Association data collection guidelines and field definitions.

7. SECURITY

(a) CDC will comply with all applicable data privacy laws and regulations, will implement and maintain appropriate technical and organizational measures and other protections for the Data. CDC agrees to maintain, store, protect, archive, and/or dispose of Data in accordance with applicable law. In addition, CDC will use all reasonable administrative, technical, and physical measures to safeguard Data and to protect Data from unauthorized access, disclosure, use, or modification. This includes setting permissions to access or edit data commensurate with the level of sensitivity of the data. Should there be a data breach and unauthorized disclosure of Data, consistent with applicable legal requirements, CDC will notify appropriate response teams and the Association of the incident. Obligations under the law to maintain and secure Data will survive termination of this Agreement. At a minimum, both parties to this DLA agree that an archival copy of the Data may be retained by CDC to comply with relevant records retention requirements and/or for the purposes of research integrity and verification, subject to this Agreement, including but not limited to the Restrictions on Use of Data herein. CDC will immediately report to the Association any breaches of protection of Data or any compromises thereof originating from CDC and pertaining to Data that has been or is to be transferred to CDC.

(b) CDC agrees to maintain in confidence the Data by using at least the same physical and other security measures as CDC uses for its own confidential information and documentation, but in any event, no less than a reasonable standard of care. CDC further agrees not to disclose the Data, or any aspect thereof, to anyone other than employees or

agents who have a need to know or obtain access to such information to support CDC's authorized use of the Data and are bound to protect such information against any other use or disclosure. These obligations shall not apply to any information generally available to the public; information independently developed or obtained without reliance on the Association's information or Data or information approved for release by the Association without restriction.

8. ASSIGNABILITY

CDC may not assign this Agreement or the license contained herein, except upon the prior, written approval of the Association (which approval may be conditioned or withheld in the Association's sole discretion) and only provided that the assignee agrees in writing to be bound by the terms of this Agreement, and CDC immediately ceases all further use of the Data and exercise of the license granted hereunder in the event of such an assignment. All covenants, promises, and other terms in this Agreement shall be binding upon and inure to the benefit of both parties and their respective successors in interest, assignees, and legal representatives.

9. CONFLICT

In the event that the terms and conditions of this Agreement conflict with another agreement, the terms, and conditions of this Agreement shall be controlling unless otherwise required by Federal law.

10. CLAIMS

(a) In the event of any claims that the Data infringes upon any United States copyright or patent, CDC agrees to notify the Association of any such claim promptly, in writing and to cooperate fully with the Association during such proceedings as appropriate.

(b) In the event of any claims based upon the CDC's use of the Data, the Association agrees to notify CDC of any such claim promptly, in writing and to cooperate fully with CDC during such proceedings as appropriate.

11. WARRANTIES/REPRESENTATIONS/LIMITATIONS OF LIABILITY

EXCEPT AS EXPLICITLY SET FORTH HEREIN, the Association DOES NOT MAKE ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, WITH RESPECT TO THE DATA OR DELIVERABLES UNDER THIS AGREEMENT. THE DATA AND DELIVERABLES UNDER THIS AGREEMENT ARE PROVIDED ON AN "AS IS" AND ON AN "AS AVAILABLE" BASIS. EXCEPT AS EXPLICITLY SET FORTH HEREIN, the Association HEREBY DISCLAIMS ALL REPRESENTATIONS OR WARRANTIES OF ANY NATURE, EXPRESS, IMPLIED OR OTHERWISE, OR ARISING FROM TRADE OR CUSTOM, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, QUALITY, TITLE, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY, COMPLETENESS OR ACCURACY.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAWS, THE ASSOCIATION SHALL NOT BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, INDIRECT OR CONSEQUENTIAL DAMAGES OR LOST INCOME OR PROFITS, RESULTING FROM OR ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, WHETHER ARISING IN TORT, CONTRACT, STATUTE, OR OTHERWISE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAWS, EXCEPT FOR FRAUD OR WILLFUL MISCONDUCT BY THE ASSOCIATION, IN THE EVENT THAT THE ASSOCIATION IS FOUND LIABLE TO CDC, CDC SHALL ONLY BE ENTITLED TO RECOVER ACTUAL AND DIRECT DAMAGES IN AN AGGREGATE AMOUNT NOT TO EXCEED THE FEE PAID TO the Association UNDER THIS AGREEMENT OR ONE HUNDRED DOLLARS, WHICHEVER IS GREATER.

The act of distribution shall not constitute any such warranty, and no responsibility is assumed for the CDC's application of the Data or related materials.

Each party represents and warrants that in entering into and performing the obligations under this Agreement it will not violate any third-party proprietary rights or any agreement with a third party. Each party agrees that it will be responsible for its own acts and omissions, as well as the acts or omissions of its officers, directors, agents, and employees, and the results thereof; and, shall not be responsible for the acts and omissions of the other party and the results thereof.

With respect to any claim against either Party as pertains to utilization of Data under the Agreement, the Party shall immediately notify the other party and the Parties shall cooperate fully in any defense.

12. COMPLETE AGREEMENT

The Parties agree that this Agreement and the attached Standard Operating Procedures are the complete and exclusive statement of the agreement between the Parties, which supersedes and merges all prior proposals, understandings and all other agreements, oral or written, between the parties relating to this Agreement. However, the Parties acknowledge that each Party has obligations under the Cooperative Agreement; nothing herein is intended to be read to conflict with the terms of such Cooperative Agreement. See ¶9.

13. AMENDMENT

This Agreement and the attached Standard Operating Procedures may not be modified, altered, or amended except by written instrument duly executed by both Parties.

14. WAIVER

The waiver or failure of either Party to exercise in any respect any right provided for in this Agreement shall not be deemed a waiver of any further right under this Agreement. Neither the waiver by any of the parties hereto of a breach of or a default under any of the

provisions of the Agreement, nor the failure of any of the parties, on one or more occasions, to enforce any of the provisions of the Agreement or to exercise any right or privilege hereunder shall thereafter be construed as a waiver of any subsequent breach or default of a similar nature, or as a waiver of any of such provisions, rights or privileges hereunder.

15. SEVERABILITY

If any part of any provision of the Agreement shall be invalid or unenforceable in any respect, as determined by a court of appropriate jurisdiction, such part shall be ineffective to the extent of such invalidity or unenforceability only, without in any way affecting the remaining parts of such provision or the remaining provisions of the Agreement.

16. GOVERNING LAW

This Agreement and performance hereunder shall be governed by Federal Law.

17. RELATIONSHIP OF THE PARTIES

For purposes of this Agreement, neither Party is an agent of the other and neither Party has express or implied authority to act on behalf of or make any representations whatsoever on behalf of the other. The relationship of the Association to CDC shall be at all times one of independent entities, and neither party shall be nor represent itself to be an employee, agent, partner, or joint venturer of the other. Nor shall either party have the right or authority to assume or create any obligation on behalf of or in the name of the other. Neither party shall be responsible for the procurement or payment of any taxes, insurance, or benefits for the other party, or its subcontractors, employees, or agents (if any).

18. MISCELLANEOUS

(a) To facilitate execution, this Agreement may be executed in as many counterparts as may be required. All counterparts shall collectively constitute a single Agreement. This Agreement may be executed through delivery of duly executed signature pages by facsimile or electronic transmission, with the same effect as original signatures.

(b) Each party to this Agreement represents to the other Party that, at all times during the term and at such other times as may be indicated, it shall comply with, and as applicable, shall require its directors, officers and employees to comply with its duties and obligations pursuant to applicable law and this Agreement, including but not limited to duties and obligations which survive the termination of this Agreement.

(c) All of the rights and remedies of the parties hereto shall be cumulative with and in addition to, any other rights, remedies, or causes of action allowed by law and shall not exclude any other rights or remedies available to either of the parties hereto.

19. NOTICES

All notices and demands of any kind or nature which any party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served by registered or certified United States mail, by facsimile transmission or by overnight courier (e.g., Federal Express) to the following addresses:

If to **CDC**:

Centers for Disease Control and Prevention
4770 Buford Highway, Chamblee GA 30341

770.488.3422
GHU5@cdc.gov
Attn: Amy Helene Schnall, DrPH

If to the Association:

America's Poison Centers
4601 North Fairfax Drive, Suite 630
Arlington, VA 22203
Tel: 703-894-1858
Fax: 703-683-2812
Attn: Richard J. Fogelson

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Without limiting the generality of the foregoing, if notice is given by facsimile transmission, such notice shall be deemed to be provided upon confirmation of the receipt of the transmission. Any party hereto may, from time to time, by notice in writing served upon the other party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

IN WITNESS WHEREOF, the parties have accepted, agreed, and executed this Agreement as reflected by the authorized signatures below.

Centers for Disease Control and Prevention

By:  Date: 9/30/2022
Erik Svendsen, PhD
Director, Division of Environmental Health Science and Practice (DEHSP)_

America's Poison Centers
Authorized Signatory

Richard Fogelson
Chief Executive Officer

Date: 10-4-22

Attachment 1

Standard Operating Procedures ("SOPs") for Use and Release of Data from the National Poison Data System® (NPDS®) between the America's Poison Centers (the Association) & Centers for Disease Control and Prevention (CDC)

Purpose

The purpose of these SOPs is to provide guidance for the use and release of national toxic exposure surveillance data from NPDS® to ensure its appropriate, prompt, and accurate use for routine public health practice and for public health emergencies.

Access and Use

The Health Studies Section (HSS) within the Emergency Management, Chemical, and Radiation Branch (EMRCB) of the National Center for Environmental Health (NCEH) currently has access to data from NPDS.

NCEH/HSS uses NPDS® data to 1) improve public health surveillance for chemicals and poisons exposures, 2) identify early markers of chemical events with the objective of providing rapid and appropriate public health response, and 3) find potential cases and enhance situational awareness during a known event. NCEH/HSS scientists use NPDS® daily to conduct national surveillance for hazardous exposures (see 'Procedures' section). Staff scientists examine reported NPDS® anomalies to identify cases and clusters of illness of public health importance and create case-based definitions during public health events to facilitate case finding. CDC works closely with the Association and provides both funding and guidance for system development, as well as epidemiologic and toxicologic expertise during public health events. An Association toxicologist is on call 24" to respond to CDC if an anomaly of potential public health importance is identified or for consultation during an event. Anomalies are identified by various automated surveillance mechanisms in NPDS® including call volume surveillance, clinical effect (signs and symptoms) surveillance, and case-based surveillance, although new automated surveillance mechanisms may be developed and implemented in the future. Currently, 11 case-based definitions for exposures deemed a high priority to CDC are defined (Table I). Case-based definitions for surveillance can be deleted, added, or modified as needed by the Association and CDC.

Standard Operating Procedures (SOPs) for NCEH to receive or access and use NPDS® data are included below. SOPs include a description of the routine use of NPDS® data by each program and the use of NPDS® data by each program in the event of a sudden or expected emergency incident.

Routine Public Health Surveillance

NCEH / Health Studies Section

- Data Collection
 - Specialists in Poison Information (SPIs) collect and code data from an individual who has contacted a PC to get information (an "information" case or to report exposure and to get help on treatment (an "exposure" case. Data are collected by the SPI using standard protocols and entered into the regional PC database.
 - A subset of data from each electronic case record is uploaded from the regional PCs' data to NPDS. Data are uploaded on average every 8 minutes. NCEH/HSS will have real-time access to the NPDS® system.
- Data analysis
 - Uploaded data are aggregated and analyzed using automated algorithms to detect anomalies in case volume, clinical (signs and symptoms), and case-based definitions established by the user.
 - Automated analysis of case volume data identifies hourly anomalies by comparing the hourly total case volume to each PC to a threshold on historical data. Hourly case volume is also assessed at the national level for total cases and human exposure cases.
 - NPDS also identifies clinical effect anomalies based on the frequencies of clinical effects reported over a 24-hour interval compared to historical baseline.
 - Case-based definitions identify cases about exposures to specific substances of interest (e.g., ricin) to detect sentinel cases and to track potential cases during a known event. Cases meeting a case-based definition are identified individually and reviewed daily (see Appendix for the current list of case-based definitions).
 - Changes in these automated mechanisms for surveillance can be implemented as needed by the Association and CDC.
- Data Review
 - Anomalies in clinical effects and case-based definitions are reported via automated email notification to CDC and are reviewed daily by HSS epidemiologists and toxicologists, as well as the Association toxicologists, to determine if any may indicate an exposure or incident of potential public health significance. The Association reviewer classifies and records the anomaly's public health significance, the reason for the incident (e.g., chemical accident, adverse drug reaction), and the number of cases associated with the reason for the incident.
 - Call volume anomalies are reviewed daily by the America's Poison Centers Toxicology Team members.
 - The Association Toxicology Team will contact PCs as needed to request additional detailed information about reported exposures within 48 hours upon receipt of an anomaly.

- As needed, HSS scientists will reach back to the Association Toxicology Team to clarify and request any needed additional information about reported anomalies.
- CDC may request that the Association contact an individual PC to obtain additional information.
- Determination of public health significance
 - For each type of surveillance anomaly (e.g., clinical effects), NCEH/HSS scientists and the Association determine the public health significance of an anomaly or identified case using the following general criteria:
 - Reported symptoms are associated with a reportable disease
 - Exposure is a toxin or chemical that can be used in terrorism
 - Exposure is related to a commercial product that is part of an ongoing public health investigation due to its potential adverse health effects
 - Anomaly includes multiple persons with evidence of a common exposure
 - Anomaly includes illness not normally associated with a particular substance

These criteria can be modified as needed by the Association and CDC and a current list can be found at <https://www.cdc.gov/nceh/hsb/chemicals/ncrs.htm>

- Notification of Impacted state(s) and PC(s) of Incident
 - If data from NPDS® are determined to indicate an incident of public health significance, CDC will notify the appropriate state health department and PC where the case originated, and the Association
- NCEH/HSS is the CDC organizational unit responsible for the interpretation and communication of information about an incident of public health importance detected by NPDS® via EpiX, HAN, internal Emergency Operations Centers (EOC) reports, or other existing communication mechanisms.

Surveillance During a Public Health Emergency

NCEH / Health Studies Section

- Incident Identification
 - A public health emergency can be identified through daily routine surveillance of anomaly reports generated by NPDS® (e.g., reports of persons exposed to selenium), identified by state or local public health agencies (e.g., outbreak of salmonella-associated peanut butter), or can be a publicly recognized incident (e.g., Deepwater Horizon oil spill).
- Data Use
 - During an emergency, CDC will use NPDS® for case-finding and/or for situational awareness
 - HSS epidemiologists in consultation with the Association toxicosurveillance team may examine the data regarding each potential case identified using this definition aid will determine whether or not the potential case is a missed positive or is a potential case.
 - If necessary, the toxicosurveillance team will conduct the PC reporting the exposure to obtain the detailed report about the initial call.
 - HSS scientists compile a line list of NPDS® data based on their or the toxicosurveillance team query of PC data or who may have been exposed in a given incident.
- Sharing Information
 - Health Departments and Other Federal Agencies
 - CDC will notify the Association when it has been asked to coordinate surveillance across jurisdictions (e.g., during a large, multi-jurisdictional incident).
 - CDC may share information about potential cases (e.g., type of exposure, source of exposure, the extent of exposure to date, signs, and symptoms) to the appropriate state, tribal, local, or territorial public health departments, and to federal agencies.
 - The Association will follow its policy and guidelines for emergent surveillance data release related to known or suspected public health threats.
 - Personally identifiable information about the potential case, such as name, address, and phone number, is not shared through NPDS® with CDC. Identifying information is only available at the regional PC, which could share it with state and local health officials as necessary for public health follow-up.
- General Public
 - HSS and the Association may develop informational materials for the public (e.g., press releases) advising people on what actions to take (e.g., to contact their local HD or regional PC) if they think they may have been exposed or if they need information regarding the exposure and its potential health effects. These efforts increase the capacity for potential case finding using NPDS®.

- Medical Community
 - HSS and the Association will develop communications for the medical community to place clinicians on alert for patients displaying symptoms consistent with the exposure, as well as to remind them that the PCs are an excellent resource for information regarding the management of exposed patients.

Table 1. Description of current case-based definitions NCEH/HSS uses to identify persons/animals with potentially high priority exposures in NPDS® -- July 2022

<u>Def ID</u>	<u>Owner</u>	<u>Description</u>	<u>Status</u>	<u>Created</u>	<u>National</u>	<u>Internal Subscriber</u>	<u>Boolean Expression</u>
426	America's Poison Centers	the Association-Paralytic Shellfish Poisoning Surveillance	Active	1/26/2008 2:43:28 PM	Yes	CDC ToxTeam	<GC Paralytic shellfish 0252000> AND <CT Exposure 0> AND <ET Ingestion 70>
427	America's Poison Centers	the Association-Ciguatera National Surveillance	Active	1/26/2008 2:45:26 PM	Yes	CDC ToxTeam	<GC Ciguatera 0256000> AND <CT Exposure 0> AND <PS Human 1>
428	America's Poison Centers	the Association Puffer Fish National Surveillance	Active	1/26/2008 3:04:05 PM	Yes	CDC ToxTeam	<GC Tetrodotoxin 0261000> AND <CT Exposure 0> AND <PS Human 1> AND <ET Ingestion 70> AND NOT <ET Bite/sting 75> AND NOT <PC Salamanders 3685918>
892	America's Poison Centers	Ricin-Toxalbumins	Active	5/11/2009 2:45:32 PM	Yes	CDC ToxTeam	<CT Exposure 0> AND <PS Human 1> AND <GC Plants: Toxalbumins 0095000> AND NOT (<MO No effect 0> OR <MO Not followed, judged as nontoxic exposure (clinical effects not expected) 5> OR <MO Not followed, minimal clinical effects possible (no more than minor effect possible) 6> OR

							<MO Unrelated effect, the exposure was probably not responsible for the effect(s) 8>) AND NOT <PC Robinia pseudoacacia (Botanic name) 2278285>
971	America's Poison Centers	Botulism-Test Definition-October 2009	Active	10/21/2009 9:05:25 AM	Yes	CDC ToxTeam	<CT Exposure 0> AND <PS Human 1> AND NOT (<MO Confirmed nonexposure 9> OR <MO No effect 0> OR <MO Not followed, judged as nontoxic exposure (clinical effects not expected) 5> OR <MO Unrelated effect, the exposure was probably not responsible for the effect(s) 8>) AND (<PC Botulism (Biological warfare agent) 4357491> OR <PC BOTULISM 2279655> OR <GC Botulism 0127000>) AND ((<CE Blurred vision 371> OR <CE Photophobia 507> OR <CE Visual defect 381> AND NOT <CE Ocular - Irritation/pain 374>) OR (<CE Dysphagia 328> OR <CE Muscle weakness 361> OR <CE Paralysis 362>)))
1018	America's Poison Centers	Arsenic Syndromic Report (Revised)	Active	1/1/2010 5:30:54 PM	Yes	CDC ToxTeam	<CT Exposure 0> AND <PS Human 1> AND (((<GC Arsenic Pesticides 0004562> OR <GC Arsenic (Excluding Pesticides) 0004000>)) OR ((<CE Muscle weakness 361> OR <CE Hypotension 306>) AND <CE Abdominal Pain 323> AND <CE Diarrhea 327> AND (<CE Nausea 334> OR <CE Vomiting 338>))))

							AND NOT (<ET Dermal 74> OR <ER Other - Malicious 14> OR <ER Unknown reason 18> OR <MO No effect 0> OR <MO Not followed, judged as nontoxic exposure (clinical effects not expected) 5> OR <MO Not followed, minimal clinical effects possible (no more than minor effect possible) 6> OR <MO Unrelated effect, the exposure was probably not responsible for the effect(s) 8> OR <MO Minor effect 1> OR <PC Grant's Ant Control 2409609> OR <PC Grant's Ant Control 6779073> OR <PC Grant's Kills Ants - Ant Control Stakes 2409749>)
1193	America's Poison Centers	Cholinesterase Inhibitors - Modified	Active	2/14/2012 1:38:39 PM	Yes	CDC ToxTeam	(<CT Exposure 0> AND <PS Human 1> AND (<CE Dyspnea 393> OR <CE Diaphoresis 406> OR <CE Excess secretions 408> OR <CE Lacrimation 375>) AND (<CE Diarrhea 327> OR <CE Fecal incontinence 331>) AND NOT <GC Unknown Types of Suspected Food Poisoning 0148374>) AND (<PT Atropine 147> OR <PT 2-PAM 175>) AND NOT <ER Intentional - Suspected suicide 9> AND NOT <ER Unintentional - Misuse 5>
1268	America's Poison Centers	the Association Radiation Surveillance for CDC	Active	1/14/2014 3:04:17 PM	Yes	CDC ToxTeam	(<PS Human 1> AND <CT Exposure 0>) AND ((<GC Alpha Radiation 0200649> OR <GC Beta Radiation 0200650> OR

							<GC Gamma Radiation 0200651> OR <GC Neutron Radiation 0200652> OR <GC X-ray Radiation 0200648> OR <GC Specific Nonpharmaceutical Radionuclides 0200653> OR <GC Specific Pharmaceutical Radionuclides 0077591> OR <GC Ionizing Radiation: Type Unknown 0200656>) AND NOT (<GC Radon 0200654> OR <GC Non-ionizing Radiation: Type Unknown 0200655> OR <ER Unintentional - Bite / sting 6> OR <ER Adverse reaction - Drug 15> OR <PC Smoke detectors 2757685> OR <CT Caller Referred 12> OR <PC NONIONIZING RADIATION 5320546> OR <MO Confirmed nonexposure 9>))
1288	America's Poison Centers	WMD - Priority Agents Human Exposure Copy 1	Active	10/8/2014 8:55:05 PM	Yes	Al Bronstein, Alexandra Funk, Alfred Aleguas, Amy Schnall, Art Chang - CDC, CDC ToxTeam, Diane Calello, Douglas Borys, Hannah Hays, Henry Spiller,	(<CT Exposure 0> AND <PS Human 1>) AND (<GC Anthrax 0201059> OR <GC Nerve Gases 0201061> OR <GC Other Biological Weapons 0201060> OR <GC Other Chemical Weapons 0201062> OR <GC Other Nuclear Weapons 0200640> OR <GC Other Radiological Weapons 0200639> OR <GC Other Suspicious Substances (Non-Powder) 0201134>) AND NOT (<MO No effect 0> OR <MO Unrelated effect, the exposure was probably not responsible for the

						Jeanna Marraffa, Maria Mercurio-Zappala	effect(s) 8> OR <MO Not followed, minimal clinical effects possible (no more than minor effect possible) 6> OR <MO Unable to follow, judged as a potentially toxic exposure 7> OR <PC Unknown Substance (Non-Powder) 7354733>) AND NOT (<ER Unintentional - Occupational 3> OR <PC Ebola Virus 6963684> OR <PC FILOVIRUS INFECTIONS 5731686>)
1368	America's Poison Centers	ZIKA VIRUS INFECTION - NATIONAL	Active	8/17/2016 11:26:17 AM	Yes	CDC ToxTeam	(<CT Exposure 0> AND <PS Human 1>) AND <PC Zika Virus Infection 7323019>
2027	America's Poison Centers	the Association Cyanide Syndromic with new CEs	Active	1/1/2019 12:34:57 AM	Yes	CDC ToxTeam	<CT Exposure 0> AND <PS Human 1> AND (<CE Agitated/irritable 348> OR <CE CNS Depression (Major) 630> OR <CE CNS Depression (Mild) 631> OR <CE CNS Depression (Moderate) 632> OR <CE Confusion 351>) AND <CE Acidosis 400> AND NOT <ER Suspected suicide 9> AND (<PT Amyl nitrite 141> OR <PT Hydroxocobalamin 166> OR <PT Sodium nitrite 180> OR <PT Sodium thiosulfate 181>)