



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

January 9, 2023

Directive Dir. No. 2022-002

**TO: EVOLVING AND EMERGING THREATS COMMITTEE MEMBERS,
COMPONENT HEADS AND ONDCP STAFF**

FROM: RAHUL GUPTA, DIRECTOR

**SUBJECT: CRITERIA FOR DESIGNATING EVOLVING AND EMERGING DRUG
THREATS**

- 1. Purpose.** This directive establishes the criteria and procedures that ONDCP will use in designating and terminating the designations of emerging and continuing drug threats. The directive fulfills ONDCP's statutory duty to promulgate and publicize standards for making and terminating emerging drug threat designations.
- 2. Authority.** *The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018, 21 U.S.C. § 1708.*
- 3. Rescission.** This directive cancels all prior ONDCP directives, standard operating procedures, and written instructions for designating emerging and continuing drug threats.
- 4. Responsibilities.** The Emerging and Continuing Threats Coordinator, the Evolving and Emerging Threats Committee and the Office of Translational Research are primarily responsible for carrying out work related to the evolving and emerging threats portfolio. The ONDCP Director is ultimately responsible for making emerging and continuing drug threat designations and terminating such designations after consultation with relevant parties such as the Emerging Threats Committee, the Emerging Threats Coordinator, the Assistant Director for the Office of Translational Research, other ONDCP staff and the heads of relevant national drug control program agencies.
- 5. Legislative Intent.** Through enacting 21 U.S.C. § 1708 Congress codified its intention for the Federal government to closely monitor evolving and emerging drug threats and to act early in the development of a national trend to prevent such threats from reaching levels seen during the opioid crisis. In particular, the SUPPORT Act required ONDCP to promulgate standards for designating an evolving or emerging drug threat and terminating such a designation. 21 U.S.C. § 1708(c). The SUPPORT Act required ONDCP to establish the Evolving and Emerging Threats Committee (Emerging Threats Committee) consisting of representatives from National Drug Control Program Agencies and other agencies, representatives from State, local and Tribal governments, and representatives from other entities designated by the ONDCP Director. 21 U.S.C. § 1708(b). The Committee is responsible for supporting ONDCP's efforts to designate and terminate the designation of evolving and emerging drug threats. *See* 21 U.S.C. § 1708(b)(6).

The Emerging Threats Committee was formed on May 21, 2019 with a goal of preventing future drug related public health emergencies. The Committee met on multiple occasions throughout 2019 and 2020 to discuss potential criteria for identifying and designating emerging drug threats. The Committee considered a variety of factors related to morbidity and mortality, public health and law enforcement data points and other indicators that may signal emerging drug threats. On May 15, 2020, ONDCP issued an advance notice of proposed rulemaking (ANPRM) that contained 11 potential criteria that the Committee developed to monitor and identify evolving and emerging drug threats. *See* 85 Fed. Reg. 29366 (May 15, 2020). ONDCP requested comments on whether the initially proposed criteria were appropriate and asked whether additional criteria should be used by the Agency in determining whether to designate a drug as an emerging threat. In the ANPRM, ONDCP also requested ideas on standards for terminating emerging threat designations after they are issued. Through the mechanism of the ANPRM, ONDCP sought public comments on numerical or statistical benchmarks that should be used in relation to the 11 criteria.

Although the criteria were not required to be promulgated through notice-and-comment rulemaking because they are merely procedural in nature, ONDCP sought public comment in an effort to enhance the quality and scientific basis of the criteria. ONDCP modified the proposed criteria for designating emerging drug threats based on the public comments received in response to the ANPRM. ONDCP welcomes public input on the standards promulgated here for consideration in future updates.

ONDCP reviewed the proposed criteria, as well as all the public comments submitted in response to the ANPRM, and validated the earlier work by adopting ten of the 11 proposed criteria. The criteria established in this directive will enable ONDCP and the Evolving and Emerging Threats Committee to be proactive in monitoring and identifying emerging drug threats in the United States. The overarching goal of the criteria is to help prevent another large-scale drug misuse crisis and to enhance our ability to respond to the evolving nature of the illicit drug landscape in the United States.

- 6. Explanatory Statement on Application of the Criteria.** It should be noted that although the criteria will be used to guide ONDCP in making designations of evolving and emerging threats under the SUPPORT Act, the designations are not automatic. Instead, a substance – or a change in a pattern of drug use – is identified by the criteria described below for further review and final determination by the ONDCP Director. The Director maintains the final decision-making authority on what substance or pattern of consumption to designate as an evolving or emerging threat and when to make a designation. Further, the Director may decide that a substance does not rise to the level of an evolving or emerging threat, but does merit further monitoring and/or data collection as part of routine or enhanced surveillance activities. In addition, if a substance does not meet the national criteria to be labelled as an evolving or emerging threat, that does not mean that a locality, State or regional coalition is prohibited from other methods to treat the substance as an emerging threat in that specific locale.

Metrics for the individual criteria. ONDCP will use standard metrics, to determine what might be considered by the ONDCP Director as an evolving or emerging threat, that references

increased or decreased rates of public health measures (listed below). ONDCP believes both the rate of increase, and the broad geographical distribution of an increase are both important considerations. Therefore, ONDCP will review for designation any substance or patterns of use that *increases* by at least 15 percent in at least three of the four census regions. Although variation from year to year is to be expected, an increase at the 15 percent level, in at least three census regions, is a significant signal sufficient to trigger further review.

Conversely, a decrease of at least 15 percent with respect to the criteria in at least three of the four census regions would trigger agency review of whether a previously issued emerging or evolving drug threat designation should be terminated. Such determinations would be made when the ONDCP Director decides that an emerging drug threat is no longer a threat to public health. Note that data sets vary in their timeliness; ONDCP will rely on the most up to date 12-month data available, compared to the previous 12 months.

Meeting these criteria would put a substance or pattern of use on an “eligible list” for further monitoring and for consideration for designation by the ONDCP Director. Other potential factors that ONDCP will take into consideration when making the determination include: the magnitude of an increase or decrease, weighing the cost of developing plans against the potential benefits, the threat’s potential for spreading quickly, and the drug’s potential for harm. All of these considerations, together with a qualitative and quantitative assessment of the criteria, will be considered by the Committee, the Emerging Threats Coordinator and ultimately the Director prior to making an evolving or emerging threat designation.

The data available to identify and measure evolving and emerging substances are of varying quality and availability. Ideally data for identifying emerging threats would be representative, generalizable, and available in near real-time, but these are not always the sorts of data available for evolving and emerging threat surveillance. For example, by its very nature, a new emerging drug threat will not necessarily have a clear baseline domestic presence. Quantitative determinations about increases in multiple census will be informed both by existing public data sets, special tabulations of federal data (requested as necessary from ONDCP), and analysis by subject-matter experts at the national and state level.

7. Criteria to Inform Designating Emerging and Evolving Drug Threats

Criteria 1: *An increase in morbidity or mortality due to drug overdose occurring in at least three census regions among the general population.*

Criteria 2: *An increase in polysubstance use and substance use disorders involving multiple substances occurring in at least three census regions among the general population.*

Criteria 3: *An increase in individuals or cohorts (e.g., a particular age group, ethnicity, gender, sexual orientation, etc.) diagnosed with substance use disorder, or an increase in drug-related overdose rates in a specific cohort occurring in at least three census regions.*

Criteria 4: *An increase in emergency department visits, hospitalizations, or treatment admissions related to the use of a new or evolving drug, class of drugs, or other substance occurring in at least three census regions.*

Criteria 5: *Increased reporting by health care providers or laboratories of new or novel clinical illnesses by patients with suspected or known exposure to a drug, class of drugs, or other substance occurring in at least three census regions.*

8. Criteria to Inform Terminating Emerging and Evolving Drug Threat Designations

Criteria 1: *A decrease (or other improvement) in morbidity or mortality due to drug overdose occurring in at least three census regions among the general population involving a previously designated substance.*

Criteria 2: *A decrease (or other improvement) in polysubstance use and substance use disorders involving multiple substances occurring in at least three census regions among the general population including a previously designated substance.*

Criteria 3: *A decrease (or other improvement) in individuals or cohorts (e.g., a particular age group, ethnicity, gender, sexual orientation, etc.) diagnosed with substance use disorder, or a decrease in drug-related overdose rates in a specific cohort occurring in at least three census regions involving a previously designated substance.*

Criteria 4: *A decrease (or other improvement) in emergency department visits, hospitalizations, or treatment admissions related to the use of a new or evolving drug, class of drugs, or other substance occurring in at least three census regions involving a previously designated substance.*

Criteria 5: *Decreased (or otherwise improving) reporting by health care providers or laboratories of new or novel clinical illnesses by patients with suspected or known exposure to a previously designated drug, class of drugs, or other substance occurring in at least three census regions.*

9. Public Statement

ONDCP must upload a public statement on ONDCP's website explaining the designation of an emerging drug threat or the termination of such designation and must notify the appropriate congressional committees of the availability of such statement when a designation or termination of the designation has been made.

10. Emerging Threat Response Plan

Upon making an emerging threat designation under 21 U.S.C. § 1708(c), ONDCP must publish and make publicly available an Emerging Threat Response Plan in accordance with the requirements of 21 U.S.C. § 1708(d).

11. Evaluation of media campaign

Upon designation of an emerging threat under 21 U.S.C. § 1708(c), the ONDCP Director must evaluate whether a media campaign would be feasible and appropriate to address the threat. If the Director determines that a media campaign is appropriate, the Director will conduct a

national anti-drug media campaign in accordance with the requirements of 21 U.S.C. § 1708(f), if funding is made available for this purpose.

12. The ONDCP point of contact for all matters referenced in this directive

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