May 15, 2020

Re: EPA-HQ-OA-2018-0259

The Association of Public Health Laboratories (APHL) appreciates the opportunity to comment on EPA's supplemental notice of proposed rulemaking (SNPRM) that makes clarifications, modifications and additions to *Strengthening Transparency in Regulatory Science.* These changes however, only accentuate the concerns APHL expressed in our comments to the original proposed rule, copied below, and we once again strongly urge EPA to withdraw the proposed rule.

While APHL commends the thoughtful explanations EPA provides in the SNPRM, and the proposed changes to the definition of "models" and "model assumptions," these do not change the flawed basis of the original proposed rule. APHL does not believe that public availability and independent validation are necessary for research to be "influential scientific information" or to be the basis for "significant regulatory decisions." These qualities are not sufficient to mean research should be weighted more heavily than research where data must remain confidential. Also, allowing the Administrator to autonomously decide which exceptions can be made is antithetical to transparency. Independent validation and public availability are valuable general principles to strive for, however, and the tiered access system proposed in the SNPR may be a worthwhile pursuit independent of this rule.

Excluding important research from EPA decisions regarding laboratory science will reduce our ability to protect the public's health. Important public health research performed by our environmental health laboratory members will likely also suffer adverse effects as, for example, when people decline to participate due to privacy concerns.

Please contact Sarah Wright, environmental laboratories manager (sarah.wright@aphl.org), with any questions.

Sincerely,

Scott Becker
Chief Executive Officer

Kathryn Wangsness
Chair, Environmental Laboratory Science Committee

APHL works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

Copy of 2018 Comment

Association of Public Health Laboratories (APHL) Comments on EPA 40 CFR Part 30

Docket ID No. EPA-HQ-OA-2018-0259

Proposed Rule - Strengthening Transparency in Regulatory Science

The Association of Public Health Laboratories strongly urges the US Environmental Protection Agency (US EPA) to withdraw the proposed rule EPA-HQ-OA-2018-0259 - Strengthening Transparency in Regulatory Science for the following reasons:

1. It will unnecessarily add another layer of federal oversight to the vast collection of existing federal regulations. US EPA already has a myriad of existing promulgated federal regulations to draw from to ensure privacy, confidentiality, safety, and security protections prior to using health, epidemiological, or other scientific study data to make impactful decisions on final regulations, guidance, and advisories. These include "The Common Rule" Code of Federal Regulations (CFR) 45 Part 46, "Informed Consent" 21 CFR, National Institute of Health (NIH) Certificates of Confidentiality, Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and NIH Institutional Review Board (IRB). These existing regulations have been written for the same purpose as the proposed rule: to maintain strong transparency in both regulatory and non-regulatory science.

2. US EPA's goal to strengthen regulatory science transparency is attainable without adding this regulation to the federal collection. Simply put, US EPA must require enforcement of the existing federal rules that strengthen this kind of transparency. For example, the IRB process and the HIPAA Privacy Rule requirements exist to protect privacy, confidentiality, safety and security when conducting scientific studies and reporting scientific results. The US EPA and other federal agencies already spend a significant amount of taxpayer dollars to enforce these federally-required processes. Promulgating this proposed rule is therefore unnecessary.

3. The proposed rule attempts to establish a higher degree of transparency by requiring source disclosure in science regulations, but it effectively reduces transparency by questioning and even disallowing the use of available scientific study results that are fully protected under current federal rules and guidelines. Transparency is defined as "the essential condition for free and open exchange whereby the rules and reasons behind the regulatory measures are fair and clear to all participants."[1] The proposed rule's elimination of transparency in this way jeopardizes fully-balanced collaboration, cooperation and collective decision-making that regulatory science is highly dependent on.

[1] http://www.businessdictionary.com/definition/transparency.html

4. The rule as it is currently written leaves many questions unanswered. As stated in US EPA's mission, "EPA works to ensure that national efforts to reduce environmental risks are based on the best available scientific information."[2] APHL supports US EPA regulations that improve public health protection and are based upon the best available science. Developing these regulations often requires the use of health and epidemiological studies, which may require the use of confidential data. These studies, when following any of the applicable aforementioned research privacy regulations (e.g., "The Common Rule" CFR 45 Part 46"), are producing science that potentially represent the "best available science" needed by US EPA when developing regulations. Yet this proposed rule may deem these studies invalid. Questions arise as a result of this change that are not currently addressed in the proposed rule as it is written:

    - **How many current health and epidemiological studies (that could represent the best available science) will be deemed invalid by this new rule?**

    - The proposed rule states that "other federal agencies have developed tools and methods to de-identify private information for a variety of disciplines. The National Academies have noted that simple data masking, coding and de-identification techniques have been developed over the last half century and that 'Nothing in the past suggests that increasing access to research data without damage to privacy and confidentiality rights is beyond scientific reach'" (p. 4). **These statements suggest that any studies could potentially be made valid by using these tools and methods. What are the necessary time and financial resources to make this a reality?**

    - Some of the strategies identified in the proposed rule include "requiring access to data for the purposes of replication, validation and sensitivity evaluation; establishing physical controls on data storage; online training for researchers and nondisclosure agreements" (p. 4). **How would these new allowances affect the aforementioned research privacy regulations (e.g., "The Common Rule" CFR 45 Part 46") and change the ability for health and epidemiological research studies to gather a representative study sample?**

5. The proposed rule would clearly eliminate transparency in regulatory science by allowing an individual such as the Administrator to autonomously make exemptions and grant waivers (p. 7). This would unsystematically allow for some non-disclosure data and information to be used in decision-making processes that result in science-based regulations.

[2] https://www.epa.gov/aboutepa/our-mission-and-what-we-do

For the reasons above, the Association of Public Health Laboratories strongly urges US EPA to withdraw the proposed rule EPA-HQ-OA-2018-0259 - Proposed Rule - Strengthening Transparency in Regulatory Science.

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