

NOTICE OF PROPOSED RULEMAKING DOCKET NO. NSD-104
AG ORDER NO. 6067-2024; RIN 1124-AA01
89 FR 86116 (Oct. 29, 2024)

***DEPARTMENT OF JUSTICE: PROPOSED RULE ON PROVISIONS PERTAINING TO
PREVENTING ACCESS TO U.S. SENSITIVE PERSONAL DATA AND GOVERNMENT-
RELATED DATA BY COUNTRIES OF CONCERN OR COVERED PERSONS***

MEETING SUMMARY

RE: MEETING WITH COUNCIL ON GOVERNMENT RELATIONS (“COGR”) REGARDING THE DEPARTMENT OF JUSTICE’S PROPOSED RULE ON PROVISIONS PERTAINING TO PREVENTING ACCESS TO U.S. SENSITIVE PERSONAL DATA AND GOVERNMENT-RELATED DATA BY COUNTRIES OF CONCERN OR COVERED PERSONS

DATE/TIME OF MEETING: NOVEMBER 26, 2024 3:30 PM – 4:00 PM EST

PLACE OF MEETING: VIRTUAL

ATTENDEES:

FROM THE NATIONAL SECURITY DIVISION OF THE DEPARTMENT OF JUSTICE

Allison Harrington, Attorney
Cory Jacobs, Attorney
Jailene Acevedo, Paralegal
Jennifer Roan., Program Analyst
Kaveh Miremadi, Attorney
Lee Licata, Deputy Section Chief for National Data Risk
Mike Goudey, Attorney

FROM THE DEPARTMENT OF COMMERCE

Isabella Carlton, Policy Advisor, Global Data Policy and Privacy
Marvin Wiley, Policy Advisor, Global Data Policy and Privacy

FROM COUNCIL ON GOVERNMENT RELATIONS (COGR):

Kristin West, Director of the Research Ethics and Compliance
Matt Owens, President

SUMMARY OF MEETING:

On November 26, 2024, representatives from the Department of Justice (“DOJ”) and the Commerce Department (“Commerce”) engaged with representatives from the Council on

Government Relations (“COGR”) regarding COGR’s comments on DOJ’s October 29, 2024 Notice of Proposed Rulemaking (“NPRM”) entitled “Proposed Rule on Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons.” *See* 89 FR 86116. These notes are a summary of the engagement; they are not a transcript. The Department of Justice has not shared these notes with meeting participants to confirm their accuracy.

During the engagement, a representative from DOJ briefly discussed the NPRM’s proposed requirements, including exceptions to the proposed rule, changes from DOJ’s March 5, 2024 Advanced Notice of Proposed Rulemaking (“ANPRM”), and comments received on the ANPRM. *See* 89 FR 15780. DOJ also noted that the NPRM comment period is open until November 30, 2024, and encouraged participants to submit comments on the proposed rule. During the engagement, representatives from DOJ also invited meeting participants to ask questions about the NPRM from participants.

Commerce asked that COGR provide an overview of the companies they represent and to state any concerns they have with DOJ’s NPRM. COGR stated that they are an association of research entities. They added they do not sell data, but rather use database of sensitive health data to conduct research and in some instances determine the best course of treatment. The COGR representative argued that the rule is really focused on trying to limit the sale of data and that the small amount of privately funded research that isn’t already exempt by the federal funding exemption should be carved out of the rule.

COGR asked if an entity having the ability to access a database would have the necessary commercial consideration as to constitute a transaction consideration under the NPRM. DOJ asked COGR what percentage of the research their members perform is not federally funded. COGR replied that while the percentage is dependent on the institution, each one has at least \$15,000,000 in federal research funds competitively awarded.

DOJ asked how much of the research from the entities that COGR represents is carved out from the NPRM exemption for federal funded research or through other exemptions. COGR replied that there are major funders for public health, including the Gates Foundation and Kaiser. COGR also receives funding for disease research from the Heart Association and Cancer Association. The federal government is the largest source of funding for COGR members, but they noted that public health has additional sources of funding. Additionally, COGR stated that many entities compete for private funding as the federal government does not always provide all funding.

DOJ asked how many COGR members have research that involves countries of concern or covered persons. Additionally, DOJ asked how much of their research is regulated. COGR stated that the member institutions have not given exact numbers, but they are certain that there are covered persons. They explained that some members are involved in collaborations with and have researchers from China and Russia, though it’s unclear whether these collaborations are also federally funded and therefore not regulated.

Commerce asked that COGR provide additional examples where members do not qualify for exemptions or have lack of clarity.

COGR has questions regarding the NPRM's data brokerage prohibition and when that would impact informal research endeavors or collaborations. They noted that such informal exchanges can occur on a small scale, such as one researcher to another. COGR will ask this in their comment on the NPRM. In this regard, COGR seeks clarification on how the rule applies to research that isn't funded or commercial but is more academic and includes individuals sharing data and creating databases.

Additionally, COGR stated that there are competing government pressures the research community is facing. For example, a recent OSTP memorandum to make research public for repositories. That mandate and many scientific publications require researchers to put underlying data into a publicly available repository for future researchers. That goes against the NPRM, which states that such information should not be made public where it can be accessed by a country of concern or covered person. Thus, COGR asked for clarification on how continuing will be regulated under the proposed rule.

In response to DOJ, COGR confirmed that they are referencing data that has already been made public.

Commerce asked if COGR's member institutions have completed any financial impact analyses. COGR stated that while they have done analysis, which include cybersecurity surveys. For COGR, conducting analysis of which entities are more than 50% owned by a country of concern would be costly. They added that it is difficult for universities since they are decentralized institutions. Further, they stated that it is also difficult to quantify opportunity costs for things like research that isn't undertaken because of the rule.

Commerce asked that COGR present any other concerns, to which COGR responded that they do not understand the definitions of covered persons. This will be included in their comment on the NPRM. Additionally, regarding due diligence, COGR stated that many institutions don't do export control transactions, with no massive export control regulatory regime. They added that some due diligence is visual. They stated that a missing part of cost analysis is the fact that institutions have wide range of research collaborations, so they would need to put a great effort up front into the determination of a covered person.

With regard to impact, Commerce asked COGR about their immediate and long-term concerns, including with compliance. COGR believes that there will be immediate impacts because of the upfront need to identify relevant data flows and potential covered persons. They are concerned with the categorization of data flows. They explained that once the data flows are known, they must determine the entities involved, then determine what constitutes data brokerage. After initial analysis, COGR determined that there may not be much that changes, but figuring that out is a great task.

They added that personal health research will continue to be done, to an extent, by HIPAA compliant organizations, noting that not all research intuitions are subject to HIPAA.

Commerce asked COGR which, if any, rule modifications would aid with their compliance efforts. COGR stated that carving private research out of the regulations would do so. They noted that private research transactions are small compared to all that the NPRM is set to regulate. DOJ stated that federal research is already carved out, but that the Executive Order

has an alternative requirement that the Department of Health and Human Services (“HHS”) promulgate its own regulations to mitigate this national security risk.

COGR stated that HHS is also required to make research data publicly available. And so, HHS will still have to help research entities reconcile same tension with HHS. COGR reiterated the competing mandates, which they believe is burdensome and will make reconciling increasingly difficult.

Referencing a prior NPRM engagement that DOJ held, COGR stated that most research projects are partially funded from different sources, half public and half private. They raised some concern with how research entities would have to determine whether the portion of the rule had federal funding as to be subject to the official business exemption.

DOJ stated that under the official business exemption, those projects are carved out from the rule’s coverage. The research, though carved out, would be an agreement with the U.S. government, but it would remain subject to other mandates.

Following the above statement, COGR gave an example scenario in which they needed to create a database for a grant project. In the example, they received a grant of \$100,000 but needed an additional \$50,000. They received \$25,000 from the institution and the other \$25,000 from a private source. Given this, how would the research be regulated? They asked if they would be clear simply by complying with the federal agency that funded the project.

DOJ stated that that research would need to comply with the federal funding agency, but it would not be regulated further by the NPRM since the transaction being regulated by the NPRM is the publication of that data. COGR asked for further clarification on this topic in the final rule.

Regarding thresholds, COGR replied to Commerce that they were too low, and they had concerns relating to biospecimens and direct medical treatment. According to COGR, the inability to send plasma or cell cultures to countries of concern is problematic, especially for cases of humanitarian use.

Commerce asked COGR if their member institutions have recommended alternative values for the NPRM thresholds. COGR replied that their member institutions have not proposed alternative numeric values for the thresholds. COGR added that their members have a greater concern with the general exemption of privately funded research and are unclear on the justification for putting that in a different category than federally funded research that is required to be made public.

COGR had no further questions.