American College of Radiology

June 23, 2025

The Honorable Brett Guthrie, Chairman
U.S. House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Ranking Member
U.S. House Energy and Commerce Committee
2107 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Guthrie and Ranking Member Pallone:

The American College of Radiology (ACR)—a professional medical specialty society representing over 40,000 physicians and medical physicists with radiation safety expertise—would like to express **strong opposition to H.R. 2541, *The Nuclear Medicine Clarification Act***. If implemented, this bill would place potentially debilitating financial burdens on physicians and health care facilities and lead to disruptions in care, including to patients being treated for cancer. Further, H.R. 2541 would overturn ongoing Nuclear Regulatory Commission (NRC) rulemaking that aims to achieve similar goals to H.R. 2541, **but would cost roughly $6.4 billion less.**

Extravasation and Nuclear Medicine

Extravasation occurs when traces of drugs or other fluids injected intravenously partially leak into surrounding tissue. Extravasation can occur with any intravenously administered substance. In rare cases totally unrelated to nuclear medicine, extravasation can lead to significant complications, depending on the nature, toxicity, and/or fluid volume of the leaked substance. In the context of diagnostic or therapeutic nuclear medicine, however, only a very small amount (often less than 1ml) of a radiotracer or therapeutic isotope is injected to image or treat cancer and other diseases. Extravasations in nuclear medicine are typically reabsorbed by the body within a short period of time (often minutes) without any safety issue or need for medical intervention.

H.R. 2541 would require the NRC to amend its regulations to require diagnostic nuclear medicine and cancer care physicians and facilities to proactively measure and quantify asymptomatic extravasations and report any case meeting an arbitrary and non-actionable threshold as a "Medical Event." Unlike all current NRC Medical Events, this would not be limited to errors or cases with harm. Moreover, NRC is on-record as not wanting to collect the questionable and inactionable data that H.R. 2541 would mandate.

Cost Implications of H.R. 2541

Approximately 20 million diagnostic and therapeutic nuclear medicine procedures are performed in the United States annually. To comply with the changes proposed in H.R. 2541, all U.S. healthcare facilities that offer nuclear medicine procedures would have to acquire new technology to monitor all related imaging and cancer or other therapy procedures for potential extravasation. **The NRC estimates the method implicated by H.R. 2541 would cost patients, physicians, healthcare**

facilities, and the Federal government over $6.4 billion.[1] These costs would be prohibitive for many small or rural facilities, imaging centers, and critical access hospitals, which would be forced to discontinue or drastically reduce nuclear medicine services. This would lead to patient access issues, particularly in rural areas, and would delay critical cancer care for many patients.

Further, physicians would not be able to bill Medicare or Medicaid for the additional costs of purchasing the proprietary technology needed to comply with this bill as this equipment would not be considered a necessary component of clinical service. As a result, patients would face additional out-of-pocket costs that may prevent them from accessing life-saving care.

Current Rulemaking Efforts

The NRC is currently in rulemaking to require reporting of extravasations to the agency based on real-world outcomes rather than a proprietary dose estimation process. This NRC rulemaking was the result of a multi-year exploration, with several public comment opportunities, and followed by a bipartisan, unanimous (5-0) NRC Commissioners' decision. If passed, H.R. 2541 would disrupt this evidence-based, risk-informed rulemaking process in favor of an extremely costly policy with no known patient safety improvements or clinical benefits.

The ACR is committed to ensuring the protection of patients during nuclear medicine procedures. However, H.R. 2541 would lead to significant logistical and financial burdens for physicians, their practices, patients, and government agencies and would not yield any improvements in patient safety or transparency. Further, the bill would reduce access to critical care for patients across the country, as many imaging centers and community hospitals would be unable to absorb the costs necessary for compliance with the bill. Please see the accompanying FAQ that provides additional details about this important issue. If you have any questions, please contact Michael Peters, ACR Senior Director, Government Affairs, at mpeters@acr.org.

Sincerely,

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Dana H. Smetherman, MD, MPH, MBA, FACR
Chief Executive Officer
American College of Radiology

[1] U.S. Nuclear Regulatory Commission, *Regulatory Analysis for the Proposed Rule: Reporting Nuclear Medicine Injection Extravasation as Medical Events.* Available at: https://www.nrc.gov/docs/ML2401/ML24016A293.pdf