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2022 Omnibus Includes Nuclear Medicine Patient Safety, Transparency Provisions

Nuclear Regulatory Commission (NRC) is Re-Evaluating
42-Year-Old Loophole in Nuclear Medicine Safety Requirements

Omnibus Directs NRC, CMS, Veterans Health Administration to Prioritize Patient Safety

CARY, NC – Lucerno Dynamics, a North Carolina-based medical technology company, today announced that the Fiscal Year 2022 Omnibus Appropriations Act preserves critical language to protect the safety of nuclear medicine patients and enhance transparency within the American healthcare system.

The Omnibus preserves language contained in the House and Senate Energy & Water Development Appropriations reports regarding NRC's evaluation of its policy on nuclear medicine extravasations, which occur when a radio-pharmaceutical is mistakenly injected into the soft tissue rather than the vein as intended. Current NRC policy includes a loophole from reporting requirements allowing these events to remain hidden from NRC, patients, and treating physicians. Significant extravasations can invalidate imaging studies, cause mistaken diagnosis, injure arm tissue, and increase the chance the patient develops cancer.

Ron Lattanze, CEO of Lucerno Dynamics, said, "Patients undergoing treatment for cancer and many other diseases deserve to know if their tissue was unintentionally irradiated at high – potentially dangerous – doses. If a patient receives significant unintentional radiation to the tissue, it should be reported, and the problem should be addressed. NRC has had evidence for several years that shows their exemption policy is incorrect and now they need to close this scientifically unjustifiable loophole that puts patients at risk. We are pleased Congress agrees, and we thank Democrats and Republicans in the House and Senate for agreeing to this important language."

Background:
NRC requires nuclear medicine providers to report medical events that result in unintended irradiation of patient's tissue of a dose equivalent greater than 0.5 Sievert. However, since 1980, a loophole in this rule has exempted extravasations from these reporting requirements, even when patients receive extremely high doses. In creating this loophole 42 years ago, NRC's belief was that extravasations are "virtually impossible to avoid."

For three years, Lucerno Dynamics has presented scientific and clinical evidence to NRC that the occurrence of extravasations can be drastically reduced with dedicated monitoring. This evidence included positive results from the largest quality improvement project ever conducted for nuclear medicine injections and dozens of case studies of recent extravasations where patient tissue was unintentionally irradiated with doses far in excess of NRC's 0.5 Sievert limit. A petition for rulemaking

filed by Lucerno Dynamics and accepted for docketing by NRC has garnered letters of support from lawmakers, physicians, medical physicists, experts, patients, and patient advocates.

NRC

The Energy & Water Development division of the Omnibus preserves a provision from the House and Senate Energy & Water Development reports focused on the NRC:

Re-Evaluation of Nuclear Medicine Event Reporting. —Evidence shows that certain nuclear medicine extravasations may exceed medical event reporting provided in 10 C.F.R. Part 35 Subpart M. These events may harm patients through unintended radiation exposure, compromised imaging that negatively affects care, additional interventional procedures, and repeated imaging procedures. The Committee continues to encourage the Commission to consider the inclusion of significant extravasations in medical event reporting to improve safety, quality, and transparency for patients, treating physicians, and the Commission itself.

CMS

The Labor, HHS, Education division preserves a House provision focused on CMS:

Nuclear Medicine Quality Improvement. —The Committee is aware of evidence demonstrating the occurrence and consequence of extravasations in nuclear medicine procedures. These events can harm patients through compromised imaging that negatively affects care, repeated or additional procedures, increased costs, and unintended irradiation to patient tissue. The Committee supports CMS engagement with outside stakeholders on the issue and encourages CMS to explore the development of a MIPS quality improvement activity related to nuclear medicine injection quality as well as the feasibility of a MIPS quality measure to allow for the meaningful evaluation and improvement of nuclear medicine injection quality.

VA

The Military Construction & Veterans Affairs division preserves a provision focused on the Veterans Health Administration (VHA):

Nuclear Medicine Quality Improvements. —The Committee understands that the Nuclear Regulatory Commission and Centers for Medicare and Medicaid Services are considering regulatory actions to improve nuclear medicine injection quality. The Committee continues to encourage VA to monitor injection quality, as well as image extravasations and perform dosimetry and notify patients when they occur and urges the Department to adopt any new regulatory requirements.

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