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2021 Omnibus Includes Nuclear Medicine Patient Safety, Transparency Provisions

Nuclear Regulatory Commission (NRC) is Re-Evaluating 40 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 2021 Omnibus Appropriations Act includes critical language to protect the safety of nuclear medicine patients and enhance transparency within the American healthcare system.

The Omnibus maintains language contained in the House Energy & Water Development Appropriations report regarding NRC's evaluation of its policy on nuclear medicine extravasations, which occur when a radio-pharmaceutical injection partially misses the vein. Current NRC policy includes a loophole from reporting requirements allowing these events to remain hidden from NRC, patients, and treating physicians. Significant extravasations can negatively affect disease diagnosis and treatment in the short-term and can lead to adverse tissue reactions from the radiation in the long-term.

Ron Lattanze, CEO of Lucerno Dynamics, said, "Patients undergoing nuclear medicine procedures deserve to know their procedures were performed safely and effectively. If a patient receives an unintentional dose of radiation to the tissue exceeding NRC reporting limits, that should be reported and the problem should be addressed. For two years, we have called on NRC to close this loophole that is unjustified by the science and puts patients at risk. We are pleased Congress agrees, and we thank the bipartisan group of lawmakers in the House and Senate for including 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 received extremely high doses. In creating this loophole 40 years ago, NRC's belief was that extravasations are inconsequential, occur frequently, and are "virtually impossible to avoid."

For two years, Lucerno Dynamics has presented scientific and clinical evidence to NRC and its Advisory Committee on Medical use of Isotopes (ACMUI) that providers can drastically reduce the occurrence of extravasations with dedicated monitoring and feedback to the injection technologists. This evidence

included positive results from the largest quality improvement project ever conducted for nuclear medicine injections and 36 case studies of recent extravasations where the 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 the Organization of Agreement States (OAS), lawmakers, physicians, medical physicists, experts, patients, and patient advocates.

As OAS (NRC's regulatory partner in 39 states) says, in 1980 when the current rule was created, "*there was a smaller scope of radioisotopes in use, practice and techniques were still in early development, the consequences were not fully understood, and medical practitioners told the NRC that extravasations were nearly impossible to avoid. Four decades later, it is clear that the rationale for this exemption is no longer appropriate. Overnight, the NRC could make a policy decision to drastically improve the health, safety and clinical outcomes for hundreds of thousands of patients a year.*"

NRC

The Energy & Water Development division includes the following provision focused on the NRC:

> *Re-Evaluation of Nuclear Medicine Event Reporting*.—The Committee is pleased the Commission is independently evaluating extravasation medical event reporting and is engaging outside stakeholders and the Organization of Agreement States. Extravasations that exceed medical event reporting limits provided in 10 C.F.R. Part 35 Subpart M can harm patients through unintended radiation exposure, compromised imaging that negatively affects care, additional interventional procedures, and repeated imaging procedures. The Committee is concerned that the recommendations from the NRC Advisory Committee on Medical Use of Isotopes regarding the medical event reporting of extravasations are not focused on patient safety. The Committee encourages the Commission to keep patient safety at the forefront and to complete its evaluation of the inconsistent approach to medical event reporting expeditiously. Consistent application of medical event reporting criteria will reveal potential problems, both local or generic issues, with a facility's medical use of radioactive material and ensure that affected patients and their physicians will know about extravasations that exceed reporting limits. The Committee encourages the Commission to clarify when extravasations should not be excluded from the medical event reporting criteria and directs the Commission to provide a briefing on this topic not later than 30 days after enactment of this Act.

CMS

The Labor, HHS, Education division includes the following provision focused on CMS:

> *Extravasations*.— The Committee is aware of evidence demonstrating the prevalence of extravasations in nuclear medicine procedures. Extravasations of diagnostic radiopharmaceuticals negatively affect the sensitivity and quantification of nuclear medicine scans and can affect disease staging and treatment assessment, result in unnecessary invasive procedures and additional radiation exposure, and lead to higher costs for patients and payers. The Committee is pleased CMS is engaging with outside stakeholders to consider using a variety of levers to encourage providers to engage in nuclear medicine injection quality control and assurance. The Committee requests an update on this issue in the fiscal year 2022 Congressional Budget Justification.

VA

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

Nuclear Medicine Quality Improvements.—The Committee is aware of evidence demonstrating the prevalence of extravasations in nuclear medicine procedures. Extravasations of diagnostic radiopharmaceuticals negatively affect the sensitivity and quantification of nuclear medicine scans. Extravasations can affect disease staging and treatment assessment, result in unnecessary invasive procedures and additional radiation exposure, and lead to higher costs for patients and payers. Additionally, extravasations of diagnostic and therapeutic radiopharmaceuticals can expose patient's tissue to radiation doses that far exceed dose thresholds that are known to lead to side effects. As America's largest integrated healthcare system, VHA should lead by example in acting to reduce medical errors and medical waste. The Committee encourages VHA to monitor injection quality, image extravasations when they occur, perform dosimetry, notify patients and their physicians when doses exceed reportable limits, and implement programs to reduce extravasations in the future. The Committee requests an update on this issue in the fiscal year 2022 Congressional Budget Justification.

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