



August 1, 2022

Attention: Christi A. Grimm and Ruth Ann Dorrill and Julie K. Taitsman

Dear Ms. Grimm, Ms. Dorrill and Ms. Taitsman,

I represent Patients Rising Now: a nonprofit organization that provides education, resources, and advocacy for people living with rare and chronic illnesses. Formed in 2015, Patients Rising Now has developed a significant following of over 110,000 patients and caregivers and has guided them on their journeys to advocate for themselves and their loved ones to get the care and treatments they need to live a fulfilling life. As a patient advocacy organization, we support reforms and legislation aimed at advancing patient access to affordable, quality healthcare. For this reason, we became a member of the Patients for Safer Nuclear Medicine Coalition (PSNM).

PSNM comprises 29 patient advocacy organizations representing several hundreds of thousands of patients and their family members. The goal of the coalition is to develop federal policies that support safe, transparent, and effective nuclear medicine care on behalf of all patients in the US. We read in your STAT News [article](#) that 27% of Medicare beneficiaries experienced harm during hospital stays. I write you today on behalf of PSNM to make you aware of the harm to Medicare beneficiaries due to radiopharmaceutical extravasations.

Radiopharmaceutical extravasations are the misadministration of isotopes injected into skin tissue instead of a vein which can negatively affect any patient undergoing one of the over 19 million nuclear medicine procedures performed each year in the United States. Large radiopharmaceutical extravasations can lead to potentially severe adverse tissue reactions in the area around the injection site as well as contributing to compromised, potentially inaccurate diagnostic images used to determine a course of treatment. It is estimated that these large extravasations occur **every minute** in the U.S.

Shockingly, providers are not required to report radiopharmaceutical extravasations to hospital administration, patients, their physicians, or to organizations like CMS that pay for these nuclear medicine procedures. These preventable errors not only compromise diagnostic images, but they can also result in adverse tissue reactions. Tissue reactions that can take *up to three years* to manifest. The patient has a right to know that they have been extravasated.

That is why Patients Rising Now, along with PSNM, supports a petition for rulemaking (Docket NRC-2020-0141) the Nuclear Regulatory Commission (NRC) is currently reviewing. The petition calls for the elimination of an outdated reporting exemption for radiopharmaceutical extravasations that meet existing medical event reporting criteria. You can find more information on why the reporting exemption is wrong [here](#).

What you may find interesting is that medical societies are advocating to keep these medical errors hidden from patients and even from their own hospital administrators. In fact, the NRC Office of Inspector has opened an investigation into whether the NRC medical staff are being unduly influenced

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by those they regulate. PSNM believes they are. Why is it that Chief Medical Officers at hospitals are notified of extravasations of chemo, contrast CT, and large extravasations on the general floors, but not informed of any radiopharmaceutical extravasations?

Congress agrees that nuclear medicine should be safer and supports CMS engagement with outside stakeholders on the issue of extravasations. Language in the FY22 Omnibus Appropriations Act stated: *“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.”*

The NRC is charged with protecting patients during procedures involving the use of isotopes, but it is virtually impossible to directly address extravasations when information is incomplete or unavailable in the first place. The petition before the NRC will ensure the current reporting exemption will be removed so that patients are notified and the NRC is also made aware of significant extravasations. A reporting requirement would also help arm your organization and patients with information about which nuclear medicine centers have the best records of proper medical isotope administration.

PSNM approaches this issue as advocates on behalf of cardiology, neurology, and oncology patients throughout the U.S. Our intent is not to burden nuclear medicine with reporting; our lives depend on high quality nuclear medicine procedures. We believe providing advanced notice of the elimination of the reporting exemption will allow practitioners time to dramatically reduce future extravasations. This will minimize extravasations and reporting and in no way limit access to nuclear medicine.

Please urge the NRC to support the recommendations included in the petition in Docket: NRC-2020-0141. Requiring reporting of significant extravasations will benefit all parties involved. It will protect patients, reduce costs, and provide better training to our healthcare professionals. On behalf of the patients we serve, we ask you to get involved and take a position on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Wilcox".

Terry Wilcox
Executive Director