Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1786-P
7500 Security Boulevard
Baltimore, MD 21244-1850

September 11, 2023

RE: Proposed Medicare OPPS and ASC Rule for CY 2024: Radiopharmaceuticals and Nuclear Medicine Provisions [CMS-1786-P]

Dear Ms. Brooks-LaSure:

On behalf of the undersigned organizations, we appreciate the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the Medicare hospital outpatient prospective payment system (OPPS) proposed rule for calendar year (CY) 2024. We represent the majority of the nuclear medicine community in the United States which includes developers, manufacturers, distributors, physicians, scientists, and technologists that produce and utilize diagnostic radiopharmaceuticals every day.

Diagnostic radiopharmaceuticals play an essential role, and an increasingly more sophisticated one, in understanding the disease state for many difficult-to-diagnose illnesses, including Alzheimer's disease, Parkinson's disease, initial and recurrent prostate cancer, and advanced breast cancer, cardiovascular disease, and rare indications such as neuroendocrine tumors. We welcome the opportunity to provide comments on how CMS should adequately reimburse for these essential diagnostic radiopharmaceuticals to ensure that patients have access to them, clinicians continue to study their practical applications, and innovators continue to invest in research and development to bring new diagnostic tools to the market.

Nuclear medicine imaging procedures are a safe and non-invasive way to image the body using specialized cameras and software applications in conjunction with diagnostic radiopharmaceutical drugs that are introduced into the body. Molecular imaging with diagnostic radiopharmaceuticals provides clinical advantages over many other conventional imaging tests such as X-rays and MRIs by illustrating function and anatomy of organs. Diagnostic radiopharmaceuticals are essential to this process and without them the scan would not yield any medically relevant information. Diagnostic radiopharmaceuticals have become increasingly specific allowing for much more detailed imaging that is vital to ensuring that patients receive the most effective and efficient treatments. Diagnostic radiopharmaceuticals are not interchangeable and substitutions with conventional imaging can impact patient care. CMS's decision to "policy package" diagnostic radiopharmaceuticals creates a disincentive for hospitals with outpatient imaging service lines to utilize the most innovative diagnostic radiopharmaceuticals because they are not adequately reimbursed through the OPPS which impacts patient care.

In the proposed OPPS CY 2024 rule, CMS has requested feedback on potential modifications to the current packaging policy for diagnostic radiopharmaceuticals. We believe that the current packaging policy for diagnostic radiopharmaceuticals under the OPPS has resulted in diminished patient access and discourages use of the most appropriate diagnostic tools which are instructive in determining the most appropriate course of treatment. To ensure that patients have access to the best diagnostic radiopharmaceuticals in readily accessible healthcare settings, we strongly urge

CMS to separately pay for diagnostic radiopharmaceuticals which exceed a specified threshold. This will ensure that patients have access to the most sophisticated diagnostic radiopharmaceuticals and receive the most medically appropriate treatment plan. We welcome the opportunity to work with CMS to ensure the seamless operationalization of this change in payment methodology.

Please note, each organization has submitted individual comments with additional background on our collective request for separate payment.

We appreciate CMS's willingness to reconsider the current reimbursement methodology for diagnostic radiopharmaceuticals.

Sincerely.

American College of Radiology
Council on Radionuclides and Radiopharmaceuticals
Medical Imaging & Technology Alliance
Society of Nuclear Medicine and Molecular Imaging