RE: Cures 2.0 Discussion Draft

Dear Congresswoman DeGette and Congressman Upton:

Thank you for the opportunity to submit comments on the Cures 2.0 initiative. On behalf of a coalition representing patients, healthcare providers, and the nuclear medicine industry, we urge you to use this opportunity to expand Medicare beneficiary access to diagnostic radiopharmaceuticals. These highly targeted precision diagnostic drugs result in more accurate diagnoses and treatment of Parkinson’s disease, prostate cancer, Alzheimer’s disease, neuroendocrine tumors and other difficult to diagnose conditions. However, because Medicare does not appropriately reimburse all diagnostic radiopharmaceuticals in the hospital settings, it is challenging for beneficiaries to receive the right diagnostic scan at the right time.

Over 20 million Americans benefit from nuclear medicine procedures annually. Diagnostic radiopharmaceuticals are drugs necessary for all nuclear medicine imaging studies to diagnose and determine severity of disease and inform treatment. Nuclear medicine studies image an organ’s anatomy and determine organ function which optimizes a physician’s ability to evaluate and prescribe the most effective treatment pathway for patients suffering from Alzheimer’s disease, Parkinson’s disease, cardiovascular disease, some forms of cancer including prostate, breast and neuroendocrine, and other diseases.

The current reimbursement structure for radiopharmaceuticals in the Medicare hospital outpatient setting limits patient access to innovative diagnostics tools and stifles innovations. Diagnostic radiopharmaceuticals are statutorily considered drugs and must be approved by the Food and Drug Administration (FDA), but are arbitrarily treated differently by the Centers of Medicare and Medicaid Services (CMS), which has packaged them into procedural bundles, known as Ambulatory Payment Classifications (APCs), since 2008. Bundling lower volume, higher valued precision diagnostic radiopharmaceuticals fundamentally does not work. Many of these precision diagnostic radiopharmaceuticals are used one time on a specific subset of the patient population. The cost of these precision diagnostic radiopharmaceuticals significantly exceeds the cost of the procedural bundles.

CMS’s decision to package precision diagnostic radiopharmaceuticals creates a disincentive for hospitals to utilize the best diagnostic imaging products for patients. As a result, innovative diagnostic tools at readily accessible healthcare locations are not offered to Medicare beneficiaries. In certain cases, providers are prescribing lower cost alternatives that may result in inaccurate diagnosis and treatment...
plans, adding unnecessary cost to the system and delaying targeted treatments for patients. CMS’s payment policy has also severely disadvantaged the emerging, precision diagnostic imaging industry, and limited the ability of new, more effective diagnostic imaging technologies to penetrate the market.

We support the inclusion of bipartisan legislation that would help ensure that patients in need have access to clinically appropriate diagnostic radiopharmaceuticals at the right time. A bill soon to be introduced by Reps. Scott Peters (D-CA), Bobby Rush (D-IL), Dr. Neal Dunn (R-FL) and Dr. Greg Murphy (R-NC) the “Facilitating Innovative Nuclear Diagnostics (FIND) Act”, would direct CMS to pay separately in the outpatient hospital setting diagnostic radiopharmaceuticals with a mean cost per day that exceeds $500 and which were approved by the FDA after 2007. This legislation will safeguard access to the most appropriate imaging using diagnostic radiopharmaceuticals and encourage innovation and development of additional diagnostic radiopharmaceuticals that will be used in the future to improve patient care.

We appreciate the opportunity to submit comments on the Cures 2.0 initiative. Please contact Stacie Aman at (202) 731-1489 or saman@captolcounsel.com should you have questions or comments. We look forward to working with you and your colleagues in Congress to help ensure beneficiary access to diagnostic radiopharmaceuticals.