



September 11, 2017

The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Comment on CMS-2017-0091-0002 (“Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs”)

Dear Administrator Verma,

On behalf of the 30 million Americans with one of the approximately 7,000 known rare diseases, the National Organization for Rare Disorders (NORD) would like to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide comments on the proposed rule titled, “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs.”

NORD is a unique federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services.

The following comments refer only to the provisions within the proposed rule pertaining to the current Medicare DOS policy, also known as the “14-Day Rule”. We are concerned that the current 14-day reimbursement policy has adverse impacts on individuals with rare diseases by disincentivizing hospitals from providing timely diagnoses and care.

As stated in the proposed rule, the current policy governs whether laboratories bill clinical diagnostic laboratory tests directly to Medicare, or to the hospital following an inpatient or outpatient stay. If the test is ordered within 14-days of hospital discharge, the payment is bundled within the hospital reimbursement. Therefore, the lab must bill the hospital, and then the hospital must bill Medicare for reimbursement. If the test is ordered following the 14-day period, the lab may bill Medicare directly.

It is our understanding that this policy creates incentives for hospitals to delay ordering tests for patients until the 14-day period has passed, thereby avoiding involvement with the reimbursement for the test. We are concerned that this adverse incentive causes harm to our patients by encouraging hospitals to delay diagnoses and care.

Individuals with rare diseases rely on molecular pathology and advanced diagnostic laboratory tests for timely diagnoses. The diagnostic odyssey individuals with rare diseases too often undertake (the average time to diagnosis for an individual with a rare disease is seven years) should not be further exacerbated by CMS policy. We applaud the Administration for reevaluating this policy, and we encourage CMS to move forward with these reforms.

NORD thanks CMS for the opportunity to comment, and we look forward to working with CMS on ensuring that rare disease patients receive timely diagnoses and appropriate care. For questions regarding NORD or the above comments, please contact me at pmelmeyer@rarediseases.org or 202-545-3828.

Sincerely,

A handwritten signature in black ink, appearing to read 'Paul Melmeyer', with a long horizontal flourish extending to the right.

Paul Melmeyer
Director of Federal Policy