Resolutions

Resolution: 820
(I-17)

Introduced by: American Society of Clinical Oncology
College of American Pathologists

Subject: Elimination of the Laboratory 14-Day Rule under Medicare

Referred to: Reference Committee J
(Peter C. Amadio, MD, Chair)

Whereas, The Medicare Date of Service (DOS) policy for Clinical and Laboratory Pathology Specimens was adopted by the Centers for Medicare & Medicaid Services (CMS) in 2007, creating the Laboratory 14-Day Rule;

Whereas, The 14-Day Rule specifies that billing for “complex diagnostic laboratory services” performed on pathologic specimens collected in the hospital setting be bundled into the inpatient diagnosis-related group (DRG) or outpatient (OPPS) payments made to the hospital if ordered within 14 days of discharge;

Whereas, Payment bundling of pathologic tests, including molecular and genomic testing of cancer specimens, creates a strong disincentive to hospitals to perform or send out specialized pathologic tests during the 14-day window after discharge, leading to delays in diagnosis and therapy;

Whereas, Since the adoption of the 14-day rule in 2007 there have been a growing number of therapies that are targeted to specific somatic (tumoral) mutations and delays in molecular testing can result in delays in initiation of these effective treatments; and

Whereas, Amidst complaints from stakeholders, CMS is currently considering changes to the Medicare Outpatient Prospective Payment System (OPPS) including whether to limit or eliminate the 14-Day Rule, therefore be it

1. 42 CFR § 414.510


“Affordable Care Act (Pub. L. 111-148), Section 3113(a)(2) defines the term “complex diagnostic laboratory test” to mean a diagnostic laboratory test—(A) that is an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay; (B) that is determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics; (C) which is billed using a Healthcare Common Procedure Coding System (HCPCS) code other than a not otherwise classified (NOC) code under such Coding System; (D) which is approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act; and (E) is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)).”


RESOLVED, That our American Medical Association actively lobby the federal government to change laboratory Date of Service rules under Medicare such that complex diagnostic laboratory services performed on pathologic specimens collected from a hospital procedure be paid separately from inpatient and outpatient bundled payments. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/12/17

RELEVANT AMA POLICY

Laboratory Services Contracted by a Physician H-260.998

Our AMA believes that: (1) laboratories should bill and collect from patients or third party payers for laboratory services; (2) attending physicians are entitled to fair compensation for professional services rendered; and (3) bills for laboratory services performed by attending physicians should show the location where services were rendered and a description of such services.