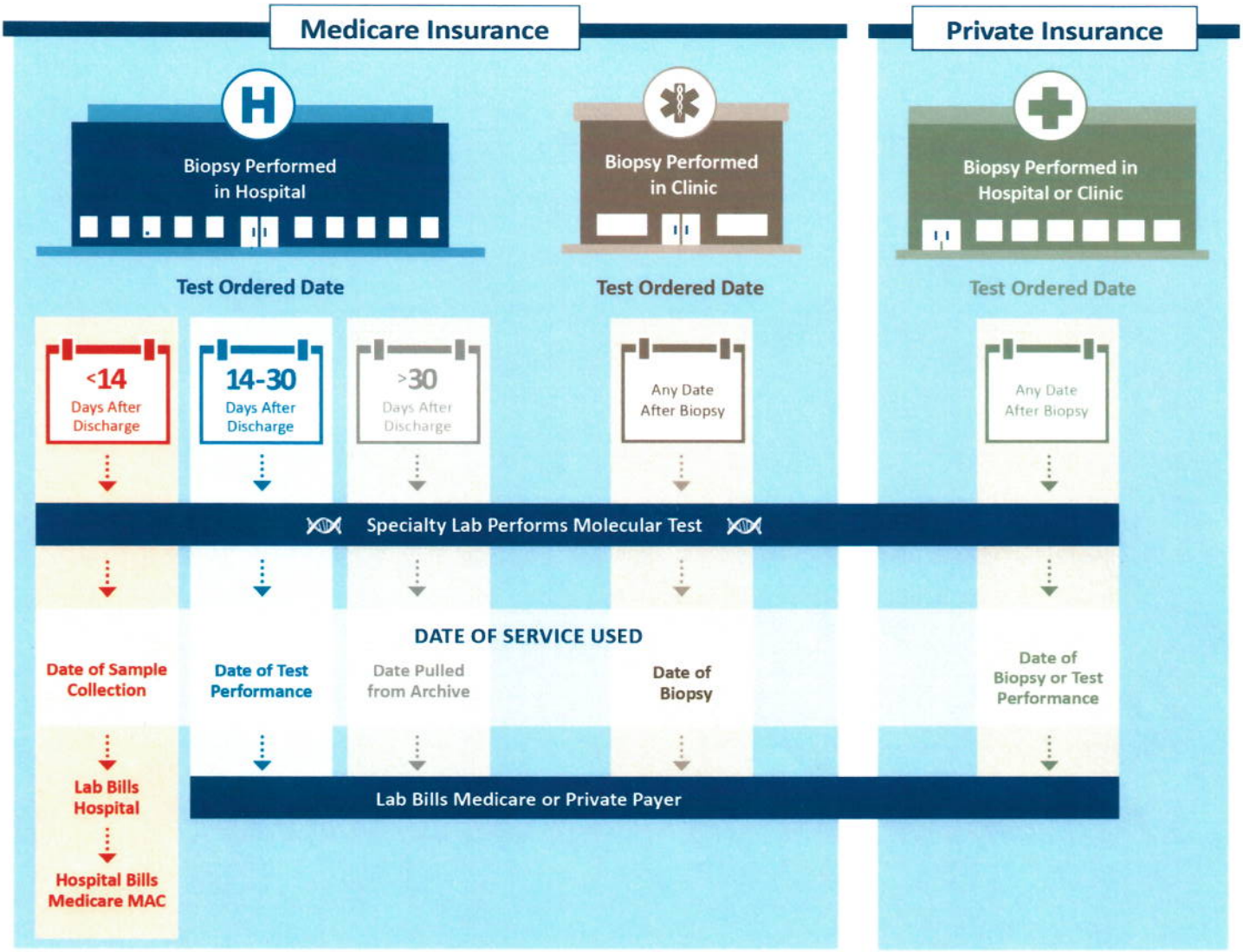
Medicare Date of Service Rule Creates Inconsistent Billing for Specialty Labs

(Example: Sample collected during biopsy)



Impact of Date of Service "14 Day" Rule on Diagnostics

May 2017
Biodesix
Boehringer-Ingelheim
Guardant Health
LUNGevity
Myriad Genetics
Veracyte

Overview

Background

- The Medicare Date of Service or "14 Day" rule sets **intricate laboratory billing requirements** for diagnostic tests based on when tests are ordered
- Rule was last modified in 2006
  - **Developed for the old world** of hospital and reference laboratories
- Now there are **advanced diagnostic laboratories** performing tests for biologically complex medical conditions that are the **only entity able to perform the test** and **help clinicians select which treatments will work best for individual patients**

Current Impact

- Depending on when a test is ordered, advanced diagnostic laboratories are required to bill the hospital - - not the performing laboratory's MAC - - and then the hospital bills the hospital's MAC
  - Hospitals may **limit access to testing** for fear of inability to receive payment from MACs
  - Resulting in **beneficiary access** issues
  - Resulting in **delayed diagnosis** that contribute to **reduced efficacy of treatments**
  - This practice is **inconsistent with standard Medicare billing policy**

Looking Ahead

- This issue will become more pronounced with further **advances in precision medicine and hospital consolidation**

Recommend that CMS solicit comments on Date of Service regulation in the CY 2018 Hospital Outpatient Prospective Payment (HOPPS) Proposed Rule

Date of Service Rule History

Year	Key Activities
Pre-2001	Medicare rules require the use of "**date of performance**" of the test
2001	Through rulemaking CMS changed the regulations for the date of service to be generally date when the "**specimen is collected**"
2006	Regulations amended to allow date of service as date of performance for certain tests ordered on "archived specimens" 14 days after patient discharge from the hospital
2010	**Congress recognized the issue and enacted legislation** requiring CMS to run a two year demonstration to examine the Date of Service rules
2012	CMS demo limited to tests with existing HCPCS codes or tests that applied for G-codes
2015	Limited participation in demo due to changes in CPT code set and **report to Congress did not make any recommendations**
2017	PAMA's new payment system requires lab performing the test to submit private payer rates

Introducing the Date of Service Rule

What is the 14 Day Rule?

- The Medicare regulation (42 C.F.R. § 414.510) determining the date of service for a test and therefore whether a laboratory can bill Medicare directly for a diagnostic test or whether the laboratory must bill a hospital

How does the 14 Day Rule Work?

- If laboratory tests are ordered within 14 days of a patient's discharge then date of service is the date of specimen collection, current regulation states that the tests should be considered part of the services rendered during the inpatient or outpatient stay and thus are part of the diagnosis related group (DRG) or Ambulatory Payment Classification (APC) payment
- If the tests are ordered more than 14 days after a patient's discharge, the laboratory bills Medicare separately

Does that mean hospitals are billing for a test they did not perform?

- Yes. Separate regulations require hospitals to bill Medicare directly for services furnished when the beneficiary was at the hospital even for tests unrelated to the stay that they did not perform (42 C.F.R. § § 411.15(m) and 410.42)

Is it logical for hospitals to bill for diagnostic tests performed within 14 days of a discharge?

- No. The diagnostic test is not performed at the hospital and is unrelated to the visit

Impact on Lung Cancer Outcomes

IN 2014

43,00

0

3,568

Patients with lung cancer potentially experienced a delay in diagnosis of tumor's EGFR status

[1] Medicare beneficiaries with various cancer types underwent molecular diagnostic testing 14-30 days following a hospital outpatient encounter.

- EGFR targeted therapy **doubles progression free survival** in patients with stage IIIB/IV metastatic lung cancer[2]
- EGFR testing is **recommended by NCCN** (category 1) to guide first-line therapy for NSCLC[3]
- A consensus group of experts convened by the Bonnie J. Addario foundation recommends patients begin **treatment within 2 weeks** of a lung cancer diagnosis in ideal circumstances[4]
- Delays in treatment for NSLC and starting on the wrong treatment can result in **worse patient outcomes.**[5,6]

1. The Moran Company: 2014 Carrier 5% Standard Analytic File (SAF) and 2013-2014 Outpatient 5% SAF; 2. Sequist LV, et al. J Clin Oncol, 2013; 3. NCCN Non-Small Cell Lung Cancer Guidelines V5.2017; 4. Dormady SP, et al. Navigating Lung Cancer, 3rd Edition. 2016 5. 5. Zhou C, et al. Annals of Oncology 2015. 6. Schuler M, et al. Annals of Oncology 2016.

Impact on Colorectal Cancer Outcomes

IN 2014

43,000[1]

Medicare beneficiaries with various cancer types underwent molecular diagnostic testing 14-30 days following a hospital outpatient encounter.

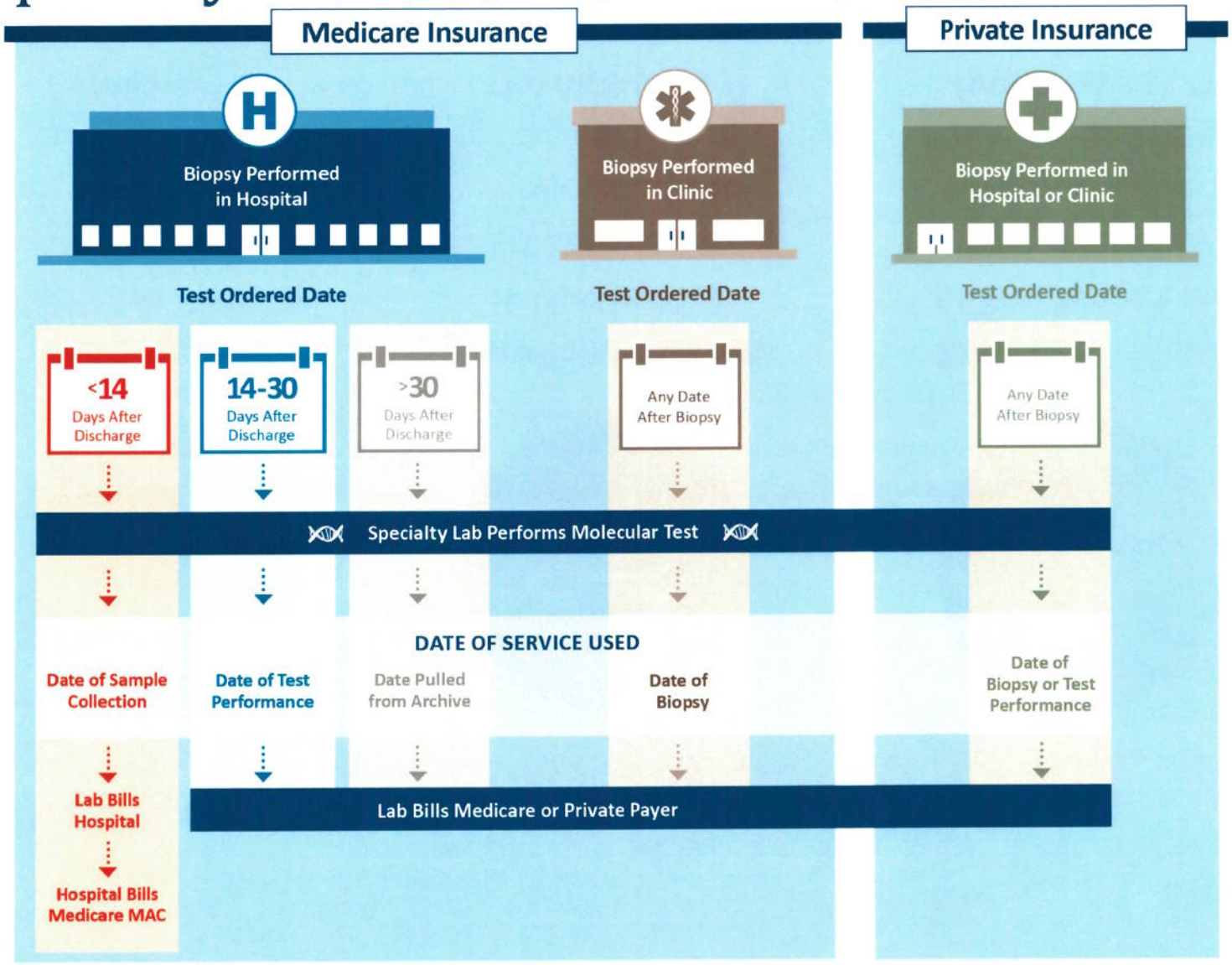
0 2,604

Patients with colorectal cancer potentially experienced a delay in diagnosis of tumor's BRAF and KRAS status

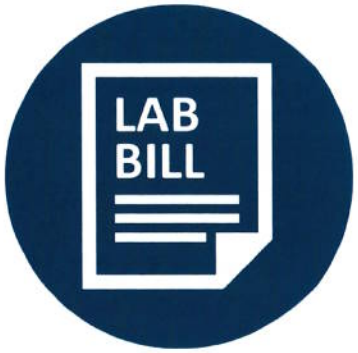
- A KRAS gene mutation is a predictor of response to first line treatment for metastatic colorectal cancer2
- BRAF and KRAS testing is recommended by NCCN (category 2A) to guide therapy selection in mCRC3

1. The Moran Company: 2014 Carrier 5% Standard Analytic File (SAF) and 2013-2014 Outpatient 5% SAF; 2. Soeda H, et al., Phase II trial of cetuximab plus irinotecan for oxaliplatin- and irinotecan-based chemotherapy-refractory patients with advanced and/or metastatic colorectal cancer, Oncology 2014; 3. NCCN Colon Cancer Guidelines V2.2017

DOS Rule Creates Inconsistent Billing for Specialty Labs (Example: Sample collected during biopsy)



Consequences of these Billing Policies



Inconsistent Medicare Policies force hospitals to bill Medicare for services not furnished in hospital and not related to hospital stay

Beneficiary Access is Limited for Medicare covered services due to billing complexity despite these services being separately payable

Reduced Efficacy of Treatment due to delaying or forgoing patient testing to avoid financial risk of not being paid by Medicare

Real World Examples

LUNGevity

- The largest national lung cancer-focused nonprofit, LUNGevity is dedicated to funding scientific research and empowering patients
- Chicago, IL

Biodesix

- Performs innovative blood-based genomic and proteomic tests that help guide treatment of patients with lung cancer
- Boulder, CO

Boehringer-Ingelheim

- One of the world's 20 leading research-driven pharmaceutical companies striving for value through innovation
- Germany & Ridgefield, CT

Guardant Health

- A pioneer in non-invasive cancer diagnostics and the first company to commercialize a comprehensive genomic liquid biopsy
- Redwood City, CA

Myriad Genetics

- Molecular diagnostic company focusing on six specialties: Oncology, Preventive Care, Urology, Dermatology, Autoimmune, Neuroscience
- Salt Lake City, Utah

Veracyte

- A genomic diagnostics company that is improving patient care for thyroid cancer, lung cancer and idiopathic pulmonary fibrosis.
- San Francisco, CA

Evaluating Date of Service Rule's Effects

Recent Evaluation Was Inconclusive

- Congress passed legislation in 2010 requiring CMS to run a two-year demonstration on the impact of the Date of Service Rule
- Demonstration ran from January 2012 to January 2014
- Report to Congress issued January 2016
- Does not contain any recommendations since low participation prohibited a thorough assessment of the effects of the Date of Service rule

Ask

Recommend that CMS solicit comments on Date of Service regulation in the CY 2018 Hospital Outpatient Prospective Payment (HOPPS) Proposed Rule

Additional Details

- Request public comment on excluding non-packaged lab services from the OPPS bundled billing requirements
- In rulemaking the agency can include appropriate limitations:
  - Only tests that are not packaged
  - Only for testing on specimens collected in the hospital outpatient setting

Rationale

- Patient access is limited under current policy
- Current policy is 10 years old and developed before advances in precision medicine
- Hospitals should not be required to bill for tests they do not perform
- Be consistent with Medicare policy for other providers of diagnostic services (e.g. imaging) for a beneficiaries after a hospital outpatient visit

Additional Outreach

Congressional Outreach

2016 & 2017

- Engaging Members and Staff from Committees of Jurisdiction

Administration Outreach

2017

- Met with representatives from the Office of Management and Budget
- Met with Carol Blackford – Director, Hospital & Ambulatory Policy Group

2016

- Met with Marc Hartstein – Director, Hospital & Ambulatory Policy Group
- Submitted a formal letter to CMS requesting that the FY 2017 Hospital Outpatient Prospective Payment Rule include a solicitation for public comment on the Date of Service rule
- Met with representatives from the Office of Management and Budget

Recommend that CMS solicit comments on Date of Service regulation in the CY 2018 Hospital Outpatient Prospective Payment (HOPPS) Proposed Rule

The Landscape of Precision Medicine Diagnostics

Precision medicine diagnostics are typically performed by specialized laboratories that have expertise in the platform and clinical area. Some have developed complex tests with **unique algorithms** that yield a patient-specific result, allowing patients and their doctors to make more informed decisions about treatment based on a **patient's unique molecular profile**

Typical Profile

- Lab is specialized in specific type of molecular testing or clinical indication
- Lab is unaffiliated with a hospital
- Some Advanced Diagnostic Laboratory Tests (ADLTs) are only performed by a single laboratory

Thank you