

14 Day Rule Frequently Asked Questions

What is the 14 Day Rule?

The Date of Service Regulation 42 C.F.R. §414.510, also called “14 Day Rule,” is a regulation set by the Centers for Medicare & Medicaid Services (CMS) that requires laboratories, including Caris Life Sciences®, to bill a hospital or hospital-owned facility for certain clinical laboratory services and the technical component of pathology services provided to Medicare patients when services are ordered less than 14 days after an inpatient or outpatient discharge.

Who is affected by the 14 Day Rule?

Hospitals and hospital-owned facilities (place of service) that collected a specimen.

How does the 14 Day Rule impact the facility?

Laboratories are required by Medicare to bill the hospital or hospital-owned facility for testing ordered within 14 days of patient discharge. Effective January 1, 2018, however, laboratories may now bill certain tests directly to Medicare for patients in the outpatient setting.

What if the specimen is collected during the hospital stay or outpatient procedure, but Caris profiling is ordered 14 days or more after discharge?

Caris will bill Medicare directly for any tumor profiling order placed 14 days or more after the patient is discharged. The hospital or hospital-owned facility will not receive a bill for Caris testing.

The decision to submit an order for testing should be guided by the clinical judgement of the ordering physician and should not be based on the application of any billing rules.

14 Day Rule Calculation

The below information is based on the Centers for Medicare and Medicaid Services (CMS) regulation, laboratory date of service for clinical laboratory and pathology specimens (42 C.F.R. §414.510).

