

ASSOCIATION OF COMMUNITY CANCER CENTERS

THE FUTURE OF PRECISION MEDICINE AND CLINICAL DIAGNOSTICS IN ONCOLOGY



Association of Community Cancer Centers

Great strides have been made in identifying the genetic mutations and related factors that can potentially drive cancer. We are in an era of rapid innovation in medical therapies that are designed to treat not just a specific type of cancer but that treat that cancer in a way that is specific to each patient's genes, prognosis, disease progression, and comorbidities. This is the era of precision medicine.

Precision medicine is defined by the National Cancer Institute (NCI) as “[a] form of medicine that uses information about a person’s genes, proteins, and environment to prevent, diagnose, and treat disease. In cancer, precision medicine uses specific information about a person’s tumor to help diagnose, plan treatment, find out how well treatment is working, or make a prognosis.”¹ Complexities resulting from these advancements are difficult to keep pace with. However, the future of cancer screening, diagnosis and treatment lies with advances in precision medicine. **The Association of Community Cancer Centers is dedicated to the education of all key stakeholders and ensuring that innovation is not unintentionally stifled by existing policy or disregarded during the creation of new policy.**

Precision medicine relies on advances in clinical diagnostics to more clearly describe the patient’s cancer, deliver the right therapies to patients, and monitor the progression of the disease and treatment. For example, advances in Next Generation Sequencing (NGS), which have made it possible to sequence an entire human genome in a day, have made it possible to more accurately diagnose cancer by identifying specific cancer mutations and, in turn, match patients to personalized cancer treatments.²

Every minute counts when it comes to halting the progression of cancer, and, therefore, patients need to access the diagnostic testing that powers precision medicine and connects patients to appropriate medical therapies as quickly as possible. To that end, it is imperative that Medicare’s rules governing clinical diagnostic laboratory testing be designed to facilitate quick access to these tests.

Unfortunately, the date of service (DOS) rules for billing for clinical diagnostic laboratory services, and in particular the 14-day rule, often have the opposite effect. Under the 14-day rule, the DOS for a laboratory test performed on a specimen stored for up to 30 days generally is the date the specimen was collected in a hospital, unless the test was ordered at least 14 days following the patient’s discharge from the hospital as either an outpatient or inpatient. This means that hospitals may have to bill Medicare for these clinical diagnostic laboratory tests, even when the hospital did not order them, and clinical diagnostic laboratories may then have to bill the hospital for payment for a test instead of billing a Medicare Administrative Contractor (MAC) directly. This unnecessarily complicates the billing process and raises concerns for hospitals that may not wish to assume responsibility for the billing for a service they did not actually provide and which they may fear will not be covered by a MAC. Because many of the diagnostic tests used in precision medicine are offered only by certain specialized laboratories, only the MAC for the Medicare jurisdiction in which one of those laboratories resides may be familiar with a test and cover it. MACs that are not familiar with a particular test may inappropriately and unpredictably deny coverage, creating an administrative burden for the hospital that is required to bill for the test. In turn, providers may wait to order tests until they can be billed by the clinical laboratory to avoid the hassles associated with having the hospital bill for the test. These issues can create unnecessary barriers and delays for patients trying to access these diagnostic tests and related precision medicine therapies.

¹ NCI, Dictionary of Cancer Terms: Precision Medicine, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/precision-medicine> (last accessed Jul. 2, 2018).

² Sam Behjati and Patrick S. Tarpey, What is Next Generation Sequencing? 98 Arch. Dis. Child Educ. Pract Ed. 236 (Dec. 2013).

To address the unintended consequences of the DOS and 14-day rules, the Association of Community Cancer Centers (ACCC) has focused its advocacy efforts in recent years on trying to improve these rules to promote patient access to necessary diagnostics.

In practice, ACCC has already seen delays in cancer patients receiving the diagnosis they need to best treat their illness. For example, in 2014, 43,000 Medicare beneficiaries with diverse cancer types received molecular diagnostic testing for their cancer 14 to 30 days after their hospital outpatient encounter.³ 3,568 patients with lung cancer may have experienced a delay in the diagnosis of their tumor's epidermal growth factor receptor (EGFR) status,⁴ which could, in turn, delay these patients' receipt of drugs that target a mutation in EGFR.⁵ In addition, 2,604 patients with colorectal cancer may have experienced a delay in the diagnosis of a tumor's BRAF and KRAS status.⁶

ACCC advocacy efforts encouraging the Centers for Medicare & Medicaid Services (CMS) to adopt additional exceptions to the DOS rule to streamline and clarify coverage of diagnostic tests have met with some success.

On December 14, 2017, CMS finalized exceptions around hospital outpatient laboratory date of service (DOS) regulations. Under the new regulation, the DOS for Advanced Diagnostic Laboratory Tests (ADLTs) and molecular pathology tests excluded from the Medicare hospital outpatient prospective payment system (OPPS) packaging policy is the date the test was performed (instead of the date of specimen collection) if certain conditions are met. Since these exceptions only apply to outpatient testing, ACCC will continue its advocacy efforts on improving the DOS and 14-day rule for hospital inpatients. An in-depth discussion of the DOS rules and ACCC's current advocacy efforts on this issue follows.

DOS FOR CLINICAL LABORATORY TESTING DEFINED

Since 2001, CMS has defined the DOS for a "clinical laboratory test or the technical component of the physician pathology service" as "the date the specimen was collected."⁷ The DOS for an "archived" or stored specimen was defined as the date the specimen was pulled from storage.⁸ In response to requests for clarification, in 2005, CMS defined an "archived" specimen as one that has been in storage for more than 30 days.⁹ Tests on archived specimens could be billed by clinical laboratories. Tests on specimens stored for less than 30 days were billed based on the date the specimen was collected.¹⁰ As a result, the DOS often fell during a patient's hospital visit even though the test on the specimen itself was ordered days or weeks later. Under these circumstances, the diagnostic laboratory service was often bundled with the hospital service and billed by the hospital.

³ John Colleran et. al., Handout EO 12866 Meeting 0939-AT03 Regarding CY 2018 Hospital Outpatient Prospective Payment System (PPS) Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (May 9, 2017) (citing The Moran Company, 2014 Carrier 5% Standard Analytic File (SAF) and 2013-2914 Outpatient 5% SAF) available at <https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0938-AT03&meetingId=2741&acronym=0938-HHS/CMS>.

⁴ *Id.*

⁵ Elaine K. Howley, What Is EGFR and How Does It Relate To Cancer? U.S. News (Mar. 28, 2018).

⁶ John Colleran et. al., *supra* note 3.

⁷ 42 C.F.R. § 414.510(a). See also 66 Fed. Reg. 58,788, 58,791 (Nov. 23, 2001).

⁸ 66 Fed. Reg. at 58,792.

⁹ 70 Fed. Reg. 9,355, 9,357 (Feb. 25, 2005).

¹⁰ *Id.*

Today, the DOS is still defined as the date a specimen is collected; however, this definition is subject to certain exceptions¹¹ that have developed over time, in part to better draw the line between when a diagnostic laboratory service may be wholly distinct from a hospital visit and when it should be properly bundled with a hospital service. The current list of exceptions includes:

- Tests on **specimens collected over a period of two days**: the DOS is the date the collection ended.¹² This exception, with the DOS as the date the collection ended, became effective March 28, 2005.¹³ Under the policy in effect from November 25, 2002, until March 28, 2005, the DOS was the date the collection began.¹⁴
- Tests on **stored specimens, for which the specimen is collected less than 30 days before the test is performed**: the DOS is the date the test was performed if the 14-day rule applies, as described further below.¹⁵ This exception became effective March 28, 2005.¹⁶ As approved in the November 23, 2001, clinical diagnostic laboratory final rule, and effective until March 28, 2005, CMS stated that laboratory tests based on samples pulled from archived storage should use a DOS of the date the sample was obtained from the archives.¹⁷ CMS allowed Medicare Administrative Contractors (MACs) to define “archived” in the absence of a rule clarifying this issue.¹⁸
- Tests on **stored specimens, for which the specimen is collected more than 30 days before the test is performed**, in which case the DOS is the date the test is pulled from storage.¹⁹ This exception also became effective March 28, 2005 and subject to the same interpretive rules and timeframe as outlined in the previous bullet.²⁰
- **Chemotherapy sensitivity tests**, in which case a variation of the 14-day rule applies, as described further below.²¹ A chemotherapy sensitivity test is defined as one “that requires a fresh tissue sample to test the Sensitivity of tumor cells to various chemotherapeutic agents.”²² This exception became effective January 1, 2007.²³
- **Molecular pathology tests and certain advanced diagnostic laboratory tests (ADLTs)**, performed following a hospital outpatient’s discharge from the hospital outpatient department for which the DOS is the date the test is performed, so long as certain requirements are met, as described further below.²⁴ ADLTs are defined

¹¹ See generally 42 C.F.R. § 414.510.

¹² *Id.* § 414.510(b)(1).

¹³ 70 Fed. Reg. at 9,355, 9,357.

¹⁴ *Id.* See also 66 Fed. Reg. at 58,791-92.

¹⁵ 42 C.F.R. § 414.510(b)(2)(i).

¹⁶ 70 Fed. Reg. at 9,355, 9,357. CMS adopted this exception and the one in the next bullet as part of a Federal Register notice with no C.F.R. provisions. These rules were codified along with the chemotherapy sensitivity test exception effective January 1, 2007. 71 Fed. Reg. 69,624, 69,706 (Dec. 1, 2006).

¹⁷ 70 Fed. Reg. at 9,355, 9,357; 66 Fed. Reg. at 58,788, 58,791, 58,806.

¹⁸ 70 Fed. Reg. at 9,355, 9,357

¹⁹ 42 C.F.R. § 414.510(b)(2)(ii).

²⁰ 70 Fed. Reg. at 9,355, 9,357.

²¹ 42 C.F.R. § 414.510(b)(3).

²² *Id.* § 414.510(b)(4).

²³ 71 Fed. Reg. at 69,624, 69,706.

²⁴ 42 C.F.R. § 414.510(b)(5).

as “a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of that laboratory.”²⁵ To qualify for this exception, the test must “[be] an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins,” “[w]hen combined with an empirically derived algorithm, yield[] a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies),” “[p]rovide[] new clinical diagnostic information that cannot be obtained from any other test or combination of tests,” and “may include other assays.”²⁶ These new exceptions became effective on January 1, 2018.²⁷

The 14-day rule for stored specimens collected less than 30 days before the test is performed: As noted above, the 14-day rule applies to specimens collected less than 30 days before a test is performed. The 14-day rule applies as follows:

- 1) “The test is ordered by the patient's physician at least 14 days following the date of the patient's discharge from the hospital;”
- 2) “The specimen was collected while the patient was undergoing a hospital surgical procedure;”
- 3) “It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;”
- 4) “The results of the test do not guide treatment provided during the hospital stay;” and
- 5) “The test was reasonable and medically necessary for the treatment of an illness.”²⁸

A test that meets the criteria of this rule, and thus qualifies to be billed with a DOS as the date of the performance of the test, can be billed by the laboratory performing the service. A test that does not meet these criteria must be billed by a hospital, and therefore is treated as part of the billing for the diagnosis related group (DRG) or ambulatory payment classification (APC) for billing purposes. In finalizing regulations implementing this rule, CMS discussed patient discharges from both outpatient and inpatient stays as subject to the application of the 14-day rule.²⁹ Similarly, the regulation itself does not distinguish between outpatient and inpatient discharges and, therefore, the 14-day rule could come into play for purposes of determining the DOS of a laboratory test following both types of hospital visits.³⁰

The end result of this rule is that a hospital may end up billing for a service that it did not order or perform, and the laboratory would have to bill the hospital for its services. Because the test may have been ordered up to 14 days after the hospital service, the hospital may have to reopen the original claim to bill for the diagnostic test and may be concerned about a MAC denying coverage for a service once billed, as described previously. These challenges can create reluctance on the part of the hospital to bill for these services at all.

²⁵ *Id.* § 414.502.

²⁶ *Id.*

²⁷ 82 Fed. Reg. 59,216, 59,216, 59,400 (Dec. 14, 2017).

²⁸ 42 C.F.R. § 414.510(b)(2)(i).

²⁹ 71 Fed. Reg. at 69,706.

³⁰ 42 C.F.R. § 414.510(b)(2)(i).

In the alternative, a provider that wishes to order a given test for a patient may delay doing so to fall outside of the 14-day time frame and ensure that the test is unbundled from the hospital service. As noted above, both of these circumstances can create patient access issues either because a patient is delayed in getting a diagnostic service necessary to provide treatment with precision medicine or because billing challenges make it difficult for hospitals to offer the service at all.

The 14-day rule for chemotherapy sensitivity tests: CMS has adopted a modified version of the 14-day rule for an exception to the DOS requirement for chemotherapy sensitivity tests performed on live tissue. For these tests, the date of service is the date a test is performed if “[t]he decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge” and criteria (2) through (5) of the 14-day rule described above are met.³¹ CMS also treats both inpatient and outpatient discharges as subject to the application of this exception to the DOS rules.³² Again, tests that fall within this rule may be billed by clinical laboratories and tests that fall outside of this rule must be billed by hospitals. This too can lead to a result where hospitals end up billing for a test which they did not provide—or in the alternative—providers might delay deciding which chemotherapeutic agents to test to fall outside the 14-day window. This could create the same patient access issues described previously.

Criteria for molecular pathology tests and certain ADLTs: CMS more recently has adopted criteria for an exception to the DOS requirement for molecular pathology tests and certain ADLTs. Under this exception, the DOS for these tests is the date the test is performed if the following criteria are met:

- 1) “The test was performed following a hospital outpatient's discharge from the hospital outpatient department;”
- 2) “The specimen was collected from a hospital outpatient during an encounter . . . ;”
- 3) “It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;”
- 4) “The results of the test do not guide treatment provided during the hospital outpatient encounter;” and
- 5) “The test was reasonable and medically necessary for the treatment of an illness.”³³

An “encounter” is defined as “a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or [critical access hospital (CAH)] staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.”³⁴ An “outpatient” is defined as “a person who has not been admitted as an inpatient but who is registered on the hospital or CAH records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH.”³⁵ ACCC supported this rule as proposed and later finalized in its comments on the CY 2018 Outpatient Prospective Payment System (OPPS). CMS recently implemented this exception on July 2, 2018, and released a list of the laboratory codes that

³¹ *Id.* § 414.510(b)(3).

³² 71 Fed. Reg. at 69,706.

³³ 42 C.F.R. § 414.510(b)(5).

³⁴ *Id.* § 410.2.

³⁵ *Id.*

are subject to the exception.³⁶ CMS has indicated that it will “exercise enforcement discretion until January 2, 2019, for the laboratory [DOS] exception policy for [ADLTs] and molecular pathology tests excluded from the Medicare Hospital Outpatient Prospective Payment System packaging policy.”³⁷

Unlike with the other exception to the DOS rules described above, the molecular pathology test and ADLT exception is expressly limited to circumstances in which a patient has been discharged from a hospital *outpatient* stay. Therefore, this exception cannot apply for samples drawn from patients during an inpatient stay. Molecular pathology tests and ADLTs performed on samples drawn during an inpatient stay will have a DOS of the date the specimen was collected. Samples drawn during outpatient stays may fall into the molecular pathology and ADLT exception to the DOS rules.

ACCC ADVOCACY REGARDING THE DOS RULES

The continued evolution of the exceptions to the DOS rule is an effort to better define those laboratory services that appropriately fall within the scope of a patient’s hospital service and those that fall outside of this service. ACCC has been an active participant in this process. In addition to submitting comment letters to CMS regarding the implementation of the DOS rules, ACCC has also:

- Engaged with members and staff from the Senate and House committees with jurisdiction over this issue in 2016 and 2017,
- Met with representatives of the Office of Management and Budget in 2016 and 2017,
- Asked that CMS solicit public comment as part of the Outpatient Prospective Payment System proposed rule for fiscal year 2017 (which it did),
- Met with Marc Hartstein, then Director of the Hospital & Ambulatory Policy Group at CMS in 2016, and
- Met with Carol Blackford, the Director of the Hospital & Ambulatory Policy Group at CMS in 2017.

ACCC will continue with this advocacy going forward to encourage the administration and Congress to develop more effective DOS rules that permit laboratories and hospitals to bill for the services that they have actually ordered and provided and to ensure that the system includes appropriate incentives for patients to receive services as quickly as possible.

DISCUSSION QUESTIONS

- How have clinical diagnostic laboratory tests contributed to your ability to better treat your patients’ cancers by connecting them to the right medicine?
- Have you seen patients suffer from delays in accessing care because of the DOS rules?
- Are there additional exceptions to the DOS rules that CMS could adopt as alternatives to the 14-day rule to help carve out diagnostic tests related to cancer care from the 14-day rule?

³⁶ CMS, MLN Connects: Laboratory Date of Service Exception – Reminder https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2018-06-28-eNews.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending#_Toc517852425 (Jun. 28, 2018).

³⁷ CMS, MLN Connects: Laboratory Date of Service Exception https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2018-07-05-eNews.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending#_Toc518370289 (Jul. 5, 2018).



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