§414.510 Laboratory date of service for clinical laboratory and pathology specimens.

The date of service for either a clinical laboratory test or the technical component of physician pathology service is as follows:

(a) Except as provided under paragraph (b) of this section, the date of service of the test must be the date the specimen was collected.

(b)(1) If a specimen was collected over a period that spans 2 calendar days, then the date of service must be the date the collection ended.

(2) In the case of a test performed on a stored specimen, if a specimen was stored for—

(i) Less than or equal to 30 calendar days from the date it was collected, the date of service of the test must be the date the test was performed only if—

(A) The test is ordered by the patient’s physician at least 14 days following the date of the patient’s discharge from the hospital;

(B) The specimen was collected while the patient was undergoing a hospital surgical procedure;

(C) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;

(D) The results of the test do not guide treatment provided during the hospital stay; and

(E) The test was reasonable and medically necessary for the treatment of an illness.

(ii) More than 30 calendar days before testing, the specimen is considered to have been archived and the date of service of the test must be the date the specimen was obtained from storage.

(3) In the case of a chemotherapy sensitivity test performed on live tissue, the date of service of the test must be the date the test was performed only if—
(i) The decision regarding the specific chemotherapeutic agents to test is made at least 14 days after discharge;
(ii) The specimen was collected while the patient was undergoing a hospital surgical procedure;
(iii) It would be medically inappropriate to have collected the sample other than during the hospital procedure for which the patient was admitted;
(iv) The results of the test do not guide treatment provided during the hospital stay; and,
(v) The test was reasonable and medically necessary for the treatment of an illness.

(4) For purposes of this section, “chemotherapy sensitivity test” means a test identified by the Secretary as a test that requires a fresh tissue sample to test the sensitivity of tumor cells to various chemotherapeutic agents. The Secretary identifies such tests through program instructions.

§ 414.511 Adjustments to the Clinical Laboratory Fee Schedule based on Technological Changes.

(a) CMS may make adjustments to the fee schedules as CMS determines are justified by technological changes.
(b) Technological changes are changes to the tools, machines, supplies, labor, instruments, skills, techniques, and devices by which laboratory tests are produced and used.
(c) CMS will propose and finalize any adjustments to the fee schedules as CMS determines are justified by technological changes in the Federal Register.

[78 FR 74820, Dec. 10, 2013]

Subpart H—Fee Schedule for Ambulance Services

Source: 67 FR 9132, Feb. 27, 2002, unless otherwise noted.

§ 414.601 Purpose.

This subpart implements section 1834(1) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(1) of the Act requires that, except for services furnished by certain critical access hospitals (see §413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule.

§ 414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as “ground”) ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient’s reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, required to be furnished by ALS personnel.

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS procedure:

(1) Manual defibrillation/cardioversion.
(2) Endotracheal intubation.
(3) Central venous line.
(4) Cardiac pacing.
(5) Chest decompression.
(6) Surgical airway.