

## 42 C.F.R. § 412.87

## Additional payment for new medical services and technologies: General provisions.

- (a) *Basis.* Sections 412.87 and 412.88 implement sections 1886(d)(5)(K) and 1886(d)(5)(L) of the Act, which authorize the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the hospital inpatient prospective payment system.
- (b) *Eligibility criteria*. For discharges occurring on or after October 1, 2001, CMS provides for additional payments (as specified in § 412.88) beyond the standard DRG payments and outlier payments to a hospital for discharges involving covered inpatient hospital services that are new medical services and technologies, if the following conditions are met:
- (1) A new medical service or technology represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- (i) The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- (ii) A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means one of the following:
- (A) The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- (B) The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient.
- (C) The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the outcomes described in paragraphs (b) (1)(ii)(C(1)) through (7) of this section.

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