Health Law Webinar

Dispelling Widespread Misunderstandings of the Two-Midnight Rule

July 13, 2022

Fredrikson & BYRON, P.A.

Short Stays: Pre 10/1/13 Guidance

Medicare Benefit Policy Manual
(CMS Pub. 100-02)
§ 10 - Covered Inpatient Hospital Services Covered Under Part A

An **inpatient** is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. **Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight** and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.

Pre 10/1/13 Guidance

The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. **Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors…**

Pre 10/1/13 Guidance

…including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting.

Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient; and
- The medical predictability of something adverse happening to the patient.

What (Did) All the People Know?

- Large voluntary refunds for hospital stays of less than 24 hours.
- InterQual and Milliman were regularly applied.
- The Kyphoplasty national investigation.
- What was the standard pre-October 2013?

Regulatory Hierarchy: What's Binding

- Constitution (due process, contracts clause, enumerated powers).
- Statutes (U.S. Code/Social Security Act).
- Regulations/National Coverage Determinations.
  - Code of Federal Regulations.
  - State Regulations or Administrative Code.
  - NCD Manual. (A binding manual!).

Regulatory Hierarchy: What's NOT Binding

- Everything else is nonbinding.
  - Manuals.
  - Local coverage determinations.
  - Guidance from contractors.
  - Regulatory Preambles.
  - FAQs.

SSA 1871(a)(2)

“No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).”

Manuals/Guidance Can't Limit Coverage

- "Thus, if government manuals go counter to governing statutes and regulations of the highest or higher dignity, a person 'relies on them at his peril.'" Government Brief in Saint Mary's Hospital v. Leavitt.
- "[The Manual] embodies a policy that itself is not even binding in agency adjudications…Manual provisions concerning investigational devices also 'do not have the force and effect of law and are not accorded that weight in the adjudicatory process.'" Gov't brief in Cedars-Sinai Medical Center v. Shalala.

Two-Midnight Rule 42 CFR § 412.3

a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and § § 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital. ~~***This physician order must be present in the medical record***~~ **~~and~~** ~~*be supported by the physician admission and progress notes*~~~~, in order for the hospital to be paid for hospital inpatient services under Medicare Part A.~~ In addition to these physician orders, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622 of this chapter.

Written Order Requirement Removed 8/17/18

10. Effect of Revision of the Hospital Inpatient Admission Order Documentation Requirements

In section IV.M. of the preamble of this final rule, we discuss our policy to revise the admission order documentation requirements. Specifically, we are revising the inpatient admission order policy to no longer require the presence of a written inpatient admission order in the medical record as a specific condition of Medicare Part A payment. Our actuaries estimate that any increase in Medicare payments due to the change will be negligible, given the anticipated low volume of claims that will be payable under this policy that would not have been paid under the current policy.

- 83 FR 41144, 41761

Two-Midnight Rule 42 CFR § 412.3

a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner in accordance with this section and § § 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital. ~~***This physician order must be present in the medical record***~~ **~~and~~** ~~*be supported by the physician admission and progress notes*~~~~, in order for the hospital to be paid for hospital inpatient services under Medicare Part A.~~ In addition to these physician orders, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622 of this chapter.

Two-Midnight Rule 42 CFR § 412.3

b) The order must be furnished by a qualified and licensed practitioner who has admitting privileges at the hospital as permitted by State law, and who is knowledgeable about the patient's hospital course, medical plan of care, and current condition. The practitioner may not delegate the decision (order) to another individual who is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.

c) The physician order must be furnished at or before the time of the inpatient admission.

Two-Midnight Rule 42 CFR § 412.3

d) (1) Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.

(i) The **expectation** of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

Two-Midnight Rule 42 CFR § 412.3

d. (1) (ii) If an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and payment for an inpatient hospital stay may be made under Medicare Part A.

(D)(2) and (3) Expand Coverage a Bit

(2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Procedures no longer specified as inpatient only under § 419.22(n) of this chapter are appropriate for payment under Medicare Part A in accordance with paragraph (d)(1) or (3) of this section. Claims for services and procedures removed from the inpatient only list under § 419.22 of this chapter on or after January 1, 2020 are exempt from certain medical review activities.

(i) For those services and procedures removed on or after January 1, 2020, the exemption in this paragraph (d)(2) will last for 2 years from the date of such removal.

(ii) For those services and procedures removed on or after January 1, 2021, the exemption in this paragraph (d)(2) will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting.

Is “More Commonly” the Rosetta Stone?

- Is a 50% test the right way to consider status?
- What is a “reasonable expectation” of a 2-night stay? How sure should one be? Is it patient specific or condition specific?

What to Expect When You're Expecting

- Oxford: regard (something) as likely to happen.
- Merriman: to think that something probably will be or happen.
- The National Weather Service definition of likely: the equivalent of a 60 or 70 percent chance.
- Is it a "more probable than not?" test?

(D)(2) and (3) Expand Coverage A Bit

(3) Where the admitting physician expects a patient to require hospital care for only a limited period of time that does not cross 2 midnights, an inpatient admission may be appropriate for payment under Medicare Part A based on the clinical judgment of the admitting physician and medical record support for that determination. The physician's decision should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. In these cases, the factors that lead to the decision to admit the patient as an inpatient must be supported by the medical record in order to be granted consideration.

Bottom Line

- Physician expectation controls. Is a two-midnight stay anticipated? (Possible exception for intense care.)
- Government can assert that physician order and supporting documentation are required.


POLICE

Time Traveling Manual

10 - Covered Inpatient Hospital Services Covered Under Part A
(Rev. 234, Issued: 03-10-17, Effective: 01-01-16, Implementation: 06-12-17)

Patients covered under hospital insurance are entitled to have payment made on their behalf for inpatient hospital services. (Inpatient hospital services do not include extended care services provided by hospitals pursuant to swing bed approvals. See Pub. *100-02*, Chapter 8, §*10.3*, "Hospital Providers of Extended Care Services."). However, both inpatient hospital and inpatient SNF benefits are provided under Part A - Hospital Insurance Benefits for the Aged and Disabled, of Title XVIII).

Additional information concerning the following topics can be found in the following chapters *of this manual*:

- Benefit Period is found in Chapter 3
- *Counting Inpatient* Days is found in Chapter *3*
- Lifetime reserve days is found in Chapter 5
- Related payment information is housed in the Provider Reimbursement Manual

What About Private Payers?

- If there's a contract, it controls.
- Absent a contract, industry norms control.

What About Medicare Advantage Plans?

- MA plans are close to private payors, but there are special limits:
  - SSA § 1852 requires MA plans to provide "benefits under the original Medicare fee for service program."
  - 42 CFR 422.101(b) requires the plan to “comply with the general coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in this part or related instructions."

§ 422.101 Requirements relating to basic benefits.

CROSS REFERENCE

Link to an amendment published at 87 FR 27894, May 9, 2022.

Except as specified in § 422.318 (for entitlement that begins or ends during a hospital stay) and § 422.320 (with respect to hospice care), each MA organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with -

(1) CMS's national coverage determinations;

(2) General coverage guidelines included in original Medicare manuals and instructions unless superseded by regulations in this part or related instructions; and

A CMS FAQ

- https://www.cms.gov/files/document/faqs-2-midnight-rule-applicability-ma-plans-6-23-14pdf

1. Do the 2-Midnight Rule provisions and the provisions regarding the order and certification for Part A payment apply to MA plans?

It is at the discretion of MA plans whether or not to adopt the new order and certification requirements for in-patient hospital stays. As consistent with current MA policy, MA plans have the flexibility to enter into contract arrangements with hospitals to provide Medicare benefits in addition to those provided under Original Medicare. Therefore, an MA plan may choose to cover in-patient hospital stays that are shorter than those anticipated by the order and certification requirements. In any event, MA plans must ensure they are providing all Medicare Part A and B benefits without additional restrictions and that the plan's policy for inpatient stays is clear to enrollees.

What About InterQual and MCG?

- For Medicare purposes they are irrelevant.
- For private pay it depends on the contract.

Manual Overboard (Or Overbroad??)

Manuals: We're Missing the Order. We're Toast!

5. Specificity of the Order: The regulations at 42 CFR 412.3 require that, as a condition of payment, an order for inpatient admission must be present in the medical record. The preamble of the FY 2014 IPPS Final Rule at 78 FR 50942 states, "the order must specify the admitting practitioner's recommendation to admit 'to inpatient,' 'as an inpatient,' 'for inpatient services,' or similar language specifying his or her recommendation for inpatient care. While CMS does not require specific language to be used on the inpatient admission order, it is in the interest of the hospital that the ordering practitioner use language that clearly expresses intent to admit the patient as inpatient that will be commonly understood by any individual who could potentially review documentation of the inpatient stay. CMS does not recommend using language that may have specific meaning only to individuals that work in a particular hospital (e.g., "admit to 7W") that will not be commonly understood by others outside of the hospital.

If admission order language used to specify inpatient or outpatient status is ambiguous, the best course of action would be to obtain and document clarification from the ordering practitioner before initial Medicare billing (ideally before the beneficiary is discharged). Under this policy, CMS will continue to treat orders that specify a typically outpatient or other limited service (e.g., admit "to ER," "to Observation," "to Recovery," "to Outpatient Surgery," "to Day Surgery," or "to Short Stay Surgery") as defining a non-inpatient service, and such orders will not be treated as meeting the inpatient admission requirements.

Manuals: We're Missing the Order. We're Toast!

The admission order is evidence of the decision by the ordering practitioner to admit the beneficiary to inpatient status. In extremely rare circumstances, the order to admit may be missing or defective (that is, illegible, or incomplete, for example "inpatient" is not specified), yet the intent, decision, and recommendation of the ordering practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record. In these extremely rare situations, contractors have been provided with discretion to determine that this information constructively satisfies the requirement that the hospital inpatient admission order be present in the medical record. However, in order for the documentation to provide acceptable evidence to support the hospital inpatient admission, thus satisfying the requirement for the order, there can be no uncertainty regarding the intent, decision, and recommendation by the ordering practitioner to admit the beneficiary as an inpatient, and no reasonable possibility that the care could have been adequately provided in an outpatient setting.

This narrow and limited alternative method of satisfying the requirement for documentation of the inpatient admission order in the medical record should be extremely rare, and may only be applied at the discretion of the contractor.

Manuals: We're Missing the Order. We're Toast!

- That language is from Medicare Benefit Policy Manual Chapter 1, Section 10.2.
- While Manuals aren't binding, they should be able to loosen rules, just not tighten them.
- More importantly, the order language was removed from the regulation in 2018. See Slide 14. What is up??

10.2 – Hospital Inpatient Admission Order and Certification

(Rev. 234, Issued: 03-10-17, Effective: 01-01-16, Implementation: 06-12-17)

OOPS!!

The order to admit as an inpatient ("practitioner order") is a critical element in clarifying when an individual is considered an inpatient of a hospital, including a critical access hospital (CAH), and is therefore required for all hospital inpatient cases for hospital inpatient coverage and payment under Part A. As a condition of payment for hospital inpatient services under Medicare Part A, according to section 1814(a) of the Social Security Act, CMS is requiring, only for long-stay cases and outlier cases, separate physician certification of the medical necessity that such services be provided on an inpatient basis. The signed physician certification is considered, along with other documentation in the medical record, as evidence that hospital inpatient service(s) were reasonable and necessary.

LOOKING IN THE MANUALS IS NOT LEGAL RESEARCH!!!!!!

- Manuals can help you understand things and offer insight into CMS' though process.
- Never, ever refund just because you saw it in a manual.

Lin-“Manual” Miranda Warning!!!

The physician wants to keep the patient because they lack transportation to return for follow up. Valid admission?

The physician wants to keep the patient because they lack transportation to return for follow up. Valid admission?

- It is hard to argue the absence of transportation requires an admission.
- There is a safe harbor for some local medical transportation.

The physician wants to keep the patient because they lack transportation to return for follow up. Valid admission?

- This Manual language offers some defense:

admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient;
- The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
- The availability of diagnostic procedures at the time when and at the location where the patient presents.

The physician is worried that if the patient is home alone, they might die. Valid admission?

The physician is worried that if the patient is home alone, they might die. Valid admission?

- This seems entirely appropriate to me.
- What regulation requires people to have care from family?

Two-Midnight Rule 42 CFR § 412.3

d) (1) Except as specified in paragraphs (d)(2) and (3) of this section, an inpatient admission is generally appropriate for payment under Medicare Part A when the admitting physician expects the patient to require hospital care that crosses two midnights.

(i) The **expectation** of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, ***and the risk of an adverse event***. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

Beware of the Phrase “Social Admission”

- It will mean different things to different people.
- “They can’t get the care they need at home” is very different from “they can’t get a ride.”
- “Hospital care” is the key phrase. If they need things you find in a hospital, and are likely to be there over 2 midnights, they should be an inpatient.

1 – Definition of Inpatient Hospital Services

(Rev. 1, 10-01-03)

Inpatient hospital services are defined in Title XVIII of the Social Security Act (the Act) and in the regulations (42 CFR 409.10):

A. Subject to the conditions, limitations, and exceptions set forth in this subpart, the term "inpatient hospital or inpatient CAH services" means the following services furnished to an inpatient of a participating hospital or of a participating CAH or, in the case of emergency services or services in foreign hospitals, to an inpatient of a qualified hospital:

1. Bed and board.
2. Nursing services and other related services.
3. Use of hospital or CAH facilities.
4. Medical social services.
5. Drugs, biologicals, supplies, appliances, and equipment.
6. Certain other diagnostic or therapeutic services.
7. Medical or surgical services provided by certain interns or residents-in-training.

Does the Quality Improvement Organization Manual Offer Insight?

- Never heard of it? You're not alone.
- How much weight should we give it?
- Is it Bush league?

Quality Improvement Organization Manual

4110 - Admission/Discharge Review - (Rev. 2, 07-11-03)

The QIOs must conduct review of admissions and discharges as specified in 42 CFR 476.71(a)(6). Review of the medical record must indicate that inpatient hospital care was medically necessary, reasonable, and appropriate for the diagnosis and condition of the patient at any time during the stay. The patient must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis.

Quality Improvement Organization Manual

Review the medical record and use appropriate criteria to determine if an admission to a PPS or non-PPS hospital should be referred for physician review. Similarly, use criteria to identify, for physician review, cases of potential premature discharge (i.e., the patient was not medically stable and/or discharge was not consistent with the patient's need for continued acute inpatient hospital care) (see §4510 on screening criteria).

The case is referred to a physician reviewer when the non-physician reviewer cannot approve the hospitalization as necessary and/or another level of care would have been appropriate without posing a threat to the safety or health of the patient.

Does the Use of a Physician Reviewer Provide a Defense?

- There is language in the Medicare Claims Processing Manual, Chapter 30, § 100.2 that indicates physician review often indicates that the provider/supplier is “without fault” and any overpayment should be waived.

MCPM Chapter 30, § 100.2

a. The service is for a type of treatment that can be rendered only by a physician, but the contractor has not previously denied payment for the treatment, and it is not unreasonable that a particular physician might consider the treatment appropriate. In order to determine whether the services are reasonable and necessary, the contractor requests its physician consultant or CMS to advise whether the services are covered. This is a case for which there are no general coverage guidelines for the services; the contractor has not advised either the physician or the medical community regarding the coverage of the services; and the contractor is uncertain without expert consultation. In such a case, it may be presumed that neither the beneficiary nor the physician could have known that the services would be noncovered.

Quality Improvement Organization Manual

The physician reviewer must consider, in his/her review of the medical record, any pre-existing medical problems or extenuating circumstances that make admission of the patient medically necessary. Factors that may result in an inconvenience to a patient or family do not, by themselves, justify inpatient admission. When such factors affect the patient's health, consider them in determining whether inpatient hospitalization was appropriate.

Inpatient care rather than outpatient care is required only if the patient's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting. Without accompanying medical conditions, factors that may cause the patient inconvenience in terms of time and money needed to care for the patient at home or for travel to a physician's office, or that may cause the patient to worry, do not justify a continued hospital stay or justify your approval of a higher-than-necessary level of care.

This Should NEVER Appear In Analysis of a Medicare Claim:

- “The patient only required an outpatient level of care.”
- Nevertheless UPICs have denied claims with that rationale.
- There ain’t no inpatient level of care, there ain’t no outpatient level of care.

You're Waiting For A SNF Bed

- What if the patient is ready to go for rehab but there is no SNF bed ready?
- This falls into the "you learn something every day" bucket.

QIO Manual Chapter 7, Section 7005

NOTE: In cases where the beneficiary requires a SNF level of care, the hospital cannot issue a notice of non-coverage if a SNF bed is not available. Medicare pays hospitals for days awaiting placement until a SNF bed is available, and the medical record documentation indicates that SNF placement is actively being sought.

Closing Thoughts

- Some things are much clearer than commonly understood:
  - 2 midnight test is straightforward.
  - There are no “levels of care.
- There is still some grey
  - Awaiting a SNF.
  - Discharge would be “dangerous.”
- Fight MA plans that require more than 2 Midnights.

Closing Thoughts

- For other payors, you need to review their standard.
- Don’t forget the Ilten axiom: payors often fail to follow (or even KNOW) their own standard.
- Don’t make me mention Manuals more.

Presenter

David Glaser
612.492.7143
dglaser@fredlaw.com