FF. Standing Orders, Ordered Protocols, and Standardized Order Sets

Timothy P. Blanchard
Blanchard Manning LLP
Orcas, WA

Joan C. Ragsdale
CEO
MedManagement LLC
Birmingham, AL
Standing Orders and Ordered Protocols

Timothy P. Blanchard, MHA, JD
Joan C. Ragsdale, JD

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Plan for Discussion

- Terminology Issues
- Policy Evolution
- Fundamental Concepts
- Current Medicare COP and related policy
- Types of Standing Orders – Case Studies
- EHR Solutions and Confusions
- Questions
Terminology Issues

- “the lack of a standard definition for these terms and their interchangeable and indistinct use by hospitals and health care professionals may result in confusion regarding what is or is not subject to [Medicare COPs].” (SOM at A-0457)

Joint Commission Policy

- See MM.04.01.01, EP 15
- Revised effective September 1, 2012 for consistency with revised CMS policy
Historical OIG Concerns

“Although standing orders are not prohibited in connection with an extended course of treatment, too often they have led to abusive practices. Standing orders in and of themselves are not usually acceptable documentation that tests are reasonable and necessary... As a result of the potential problems standing orders may cause, the use of standing orders is discouraged.”


Medical Necessity Concerns & Confusions

- Physician-ordered patient-specific insulin adjustment treatment protocol in SNFs
- Physicians orders directed nurses to:
  - (1) take reading of the patient's blood glucose via the finger-stick method
  - (2) administer a specific dose of insulin based the specific glucose level, as specified in the order
  - (3) report any "aberrant" result below or above the sliding scale set forth in the order.
Medical Necessity Concerns (cont.)

- Glucose testing claims denied – physicians allegedly “not using the results” (citing § 410.32(a))
- ALJs, however, thoughtfully disagreed:

  “[l]t makes every sense for the doctor to be able to monitor blood sugar after a series of blood tests over a period of a week or so, in order to assess any fluctuations. . . . Expecting a physician to check every day on the results and make changes based on each report in isolation is neither cost-effective nor warranted for good health.” (Extendicare Health Services, Inc. (Aug. 12, 2004))

- But Willowood of Great Barrington v. Sebelius
- CMS specific rule on glucose testing in SNFs
  - See 42 CFR § 424.24(f); CPM, Ch. 7, § 90.1; NCDM § 190.20

Orders for Diagnostic Services

- “All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.”
- 42 CFR § 410.32(a) (emphasis added).
- Hospital rules (§§ 410.28, 440.10) do not include this requirement, but it is commonly applied as evidence of medical necessity (necessary, but not sufficient).
What Are Physicians Orders?

- No general statutory or regulatory definition
- Communication from a physician directing that a service be provided
  - in writing, by telephone, by electronic mail
  - electronic medical record entries
  - physician order entry (POE)
  - may be relayed by the physician’s staff
  - a prescription for medicine or device

Purposes of Orders

- Three functions for Medicare purposes
  - Communicating directives regarding the medical care of the patient
  - Demonstrating “under the care of a physician” and active involvement of physician in the care of the patient
  - Evidence of medical necessity
- Conditions of Participation and/or Payment
- Medical practice rules, scope of practice
Authentication of Physician’s Orders

- Prompt authentication of medical record entries important to establish accuracy and assure necessary corrections based on fresh recollection.
- “All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations.” 42 CFR § 482.24(c)(2)

Authentication: Condition of Payment

- “For medical review purposes, Medicare requires that services provided/ordered be authenticated by the author. . . . Stamped signatures are not acceptable.” Program Integrity Manual § 3.3.2.4
- If specific signature is required
  - “If the signature is missing from an order, MACs and CERT shall disregard the order during the review of the claim (e.g., the reviewer will proceed as if the order was not received).”
- If no specific signature is required
  - Unsubstantiated medical necessity
Evolving CMS Policy 42 CFR 482.24(c)(3)

- Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if: . . .
- State Operations Manual Instructions:
  - A-0457 – Use of pre-Printed and Electronic Standing Orders, Order Sets and Protocols
  - A-0405, A-0406 – Prep. & Admin. of Drugs/Biologicals
  - A-0450 – Medical Record Entries
  - See also A-0454 – Verbal Orders
- Note that these are Hospital COPs

Medicare COP: § 482.24(c)(3)(i), (iii)

- such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership
- periodic and regular review ... is conducted . . . to determine the continuing usefulness and safety
  - Latest standard of practice. Preventable adverse events
  - “initiated and executed in a manner consistent with the order’s protocol, and if not, whether the protocol needs revision and/or staff need more training in the correct procedures.”
Medicare COP: § 482.24(c)(3)(ii)

- Orders and protocols are consistent with nationally recognized and evidence-based guidelines;
- Specific Clinical Criteria
  - “Under no circumstances may a hospital use standing orders in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders.”

Medicare COP: § 482.24(c)(3)(iv)

- Orders and protocols are dated, timed, and authenticated promptly in the patient’s medical record by the ordering practitioner or by another practitioner responsible for the care of the patient … Not all pre-printed and electronic order sets are a type of “standing order” covered by the regulation
  - “The medical record is expected to include the standing order that was used for the patient, in order to fully and accurately document the care provided.”
COP Policies and Procedures

- **Initiation of Services under Standing Orders**
  - Not really “orders,” but linguistic confusion likely.

- **Authentication Subsequent to Initiation**
  - “Responsible practitioner must be able to modify, cancel, void or decline to authenticate orders that were not medically necessary in a particular situation.”

- **Acknowledgment of Initiation of Services**
  - “Acknowldg[e] and authenticat[e] the initiation of each standing order after the fact.”

Types of “Standing Orders”

- **Individual Physician’s Established Patient, PRN Orders**
- **Hospital-Wide PRN/Emergency Orders**
- **Individual Physician’s Established Patient, Treatment Protocol Orders**
- **Individual Physician’s Standard Procedure/Admission Orders**
- **Hospital Triage Patient Orders**
Standard Admission/Procedure Orders

- Standard set of orders entered by a physician for every patient scheduled to receive a particular procedure/treatment or to be admitted for a particular condition.
- Standardized, but not truly “standing”
- Not subject to the “standing orders” conditions, unless they include elements triggering applicability.
- But Subject to Special Authentication Rules

Authentication Standardized Order Sets

- Standardized order sets include, but are not limited to, “standing orders”
- Ordering practitioners must:
  - Sign, date, and time the last page of the orders, last page must identify the total number of pages in the order set, AND
  - Sign or initial any internal pages where selections or changes have been made
    - Except in integrated EHR documents
PRN Orders Individual/Facility/Department

- Directing a specific intervention in the event specified circumstances/clinical criteria
- Nursing is not called to exercise discretion outside scope of practice or to exercise medical judgment
- “Where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order prior to the provision of care.”

Conditional or “Reflex Testing” Orders

- An order may conditionally request an additional diagnostic test if the result of the initial test yields to a certain value determined by the treating physician
  - BPM, Ch. 15, § 80.6.1
- OIG Compliance Guidance for Clinical Labs advises that:
  - “the condition under which the reflex test will be performed should be clearly indicated on the requisition form.”
Hospital Rapid Response Team/Triage

- Hospital policies authorizing specified testing/treatment w/o a specific order.
- Appropriate for well-defined clinical scenarios such as “protocols for triaging and initiating required screening examinations and stabilizing treatment for emergency department patients presenting with symptoms suggestive of acute asthma, myocardial infarction, stroke, etc.”

Established Patient Treatment Protocols

- Specific treatment regimen for a specific patient with specified dosage adjustments based on a protocol or algorithm.
- Nursing adjusts dosage administered based on laboratory test results and protocol without additional discrete orders.
- Nurses are implementing, not changing, physician's orders.
- Beware of medical necessity concerns.
Looking Forward, Proceeding Cautiously

- Possible Applications
  - Follow-up Diagnostic Orders
  - Post Discharge Follow-up Orders
- Probable Challenges
- Non-Hospital Settings
- Remember Fundamental Principles

Some Useful References

- Ehringer & Duffy, “Promoting Best Practice and Safety Through Preprinted Physician Orders”


- National Guideline Clearinghouse (AHRQ)
  - www.guideline.gov