A-0457
(Rev. 95, Issued: 12-12-13, Effective: 06-07-13, Implementation: 06-07-13)

§482.24(c) (3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner 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.

Interpretive Guidelines §482.24(c)(3)

What is covered by this regulation?

There is no standard definition of a "standing order" in the hospital community at large (77

FR 29055, May 16, 2012), but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied. For purposes of brevity, in our guidance we generally use the term "standing order(s)" to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols. However, we note that 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 the requirements of §482.24(c)(3), particularly with respect to "order sets."

- Not all pre-printed and electronic order sets are considered a type of "standing order" covered by this regulation. Where the order sets consist solely of menus of treatment or care options designed to facilitate the creation of a patient-specific set of orders by a physician or other qualified practitioner authorized to write orders, and none of the treatment choices and actions can be initiated by non-practitioner clinical staff before the physician or other qualified practitioner actually creates the patient-specific order(s), such menus would not be considered "standing orders" covered by this regulation. We note in such cases the menus provide a convenient and efficient method for the physician/practitioner to create an order, but the availability of such menu options does not create an "order set" that is a "standing order" subject to the requirements of this regulation. The physician/practitioner may, based on his/her professional judgment, choose to: use the available menu options to create an order; not use the menu options and instead create an order from scratch; or modify the available menu options to create the order. In each case the physician/practitioner exercises his privileges to prescribe specific diagnosis and/or treatment activities that are to be implemented for a patient.

- On the other hand, in cases where hospital policy permits treatment to be initiated, by a nurse, for example, without a prior specific order from the treating physician/practitioner, this policy and practice must meet the requirements of this regulation for review of standing orders, regardless of whether it is called a standing order, a protocol, an order set, or something else. Such treatment is typically initiated when a patient's condition meets certain pre-defined clinical criteria. For example, standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order from a physician or other qualified practitioner prior to the provision of care.

- Hybrids, where a component for non-practitioner-initiated treatment is embedded within a menu of options for the physician or other qualified practitioner, still require compliance with the requirements for a standing order for that component. For example, if an order set includes a protocol for nurse-initiated potassium replacement, that protocol must be reviewed under the requirements of this regulation before it may become part of a menu of treatment options from which a physician or other qualified practitioner would select treatments for a particular patient.

Requirements for "Standing Orders"

Hospitals have the flexibility to use standing orders to expedite the delivery of patient care in well-defined clinical scenarios for which there is evidence supporting the application of standardized treatments or interventions.

Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence, when orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practicable for a nurse or other non-practitioner to obtain a verbal or authenticated written order from a physician or other practitioner responsible for the care of the patient prior to the provision of care.

In all cases, implementation of a standing order must be medically appropriate for the patient to whom the order is applied.

Much of the evidence on the effectiveness of standing orders in hospitals has been narrowly focused on aspects of their use by Rapid Response Teams addressing inpatient emergencies. However, standing orders may also be appropriate in other clinical circumstances, including, but not limited to:

- 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. (This does not relieve a hospital of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, stabilizing treatment in a timely manner.)

- Post-operative recovery areas.

- Timely provision of immunizations, such as certain immunizations for newborns, for which there are clearly established and nationally recognized guidelines.

Standing orders may not be used in clinical situations where they are specifically prohibited under Federal or State law. For example, the hospital patient's rights regulation at §482.13(e)(6) specifically prohibits the use of standing orders for restraint or seclusion of hospital patients.

When deciding whether to use standing orders, hospitals should also be aware that, although use of standing orders is permitted under the hospital Conditions of Participation, some insurers, including Medicare, may not pay for the services provided because of the use of standing orders. (77 FR 29056)

Minimum requirements for standing orders. Hospitals may employ standing orders only if the following requirements are met for each standing order for a particular well-defined clinical scenario:

- Each standing order must be reviewed and approved by the hospital's medical staff and nursing and pharmacy leadership before it may be used in the clinical setting. The regulation requires a multi-disciplinary collaborative effort in establishing the protocols associated with each standing order.

    - The hospital's policies and procedures for standing orders must address the process by which a standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by physicians or other practitioners responsible for the care of the patient.

    - For each approved standing order, there must be specific criteria clearly identified in the protocol for the order for a nurse or other authorized personnel to initiate the execution of a particular standing order, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified. 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.

      Since residents are physicians, this regulation does not require specific criteria for a resident to initiate the execution of a particular standing order. However, there may be State laws governing the practice of residents in hospitals that are more restrictive; if so, the hospital is expected to comply with the State law. Likewise,

the hospital may choose through its policies and medical staff bylaws, rules and regulations to restrict the role of residents with respect to standing orders.

- Policies and procedures should also address the instructions that the medical, nursing, and other applicable professional staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders. An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter.

- Likewise, standing order policies and procedures must specify the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders after the fact, with the exception of influenza and pneumococcal vaccines, which do not require such authentication in accordance with § 482.23(c)(2).

  (76 FR 65896, October 24, 2011 & 77 FR 29056, May 16, 2012)

- The hospital must be able to document that the standing order is consistent with nationally recognized and evidence-based guidelines. This does not mean that there must be a template standing order available in national guidelines which the hospital copies, but rather that the content of each standing order in the hospital must be consistent with nationally recognized, evidence-based guidelines for providing care. The burden of proof is on the hospital to show that there is a sound basis for the standing order.

- Each standing order must be subject to periodic and regular review by the medical staff and the hospital's nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols. At a minimum, an annual review of each standing order would satisfy this requirement. However, the hospital's policies and procedures must also address a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions based on changes in nationally recognized, evidence-based guidelines. The review may be prepared by the hospital's QAPI program, so long as the medical staff and nursing and pharmacy leadership read, review, and, as applicable, act upon the final report. Among other things, reviews are expected to consider:

  - Whether the standing order's protocol continues to be consistent with the latest standards of practice reflected in nationally recognized, evidence-based guidelines;

  - Whether there have been any preventable adverse patient events resulting from the use of the standing order, and if so, whether changes in the order would reduce the likelihood of future similar adverse events. Note that the review would not be expected to address adverse events that are a likely outcome of the course of patient's disease or injury, even if the order was applied to that patient, unless there is concern that use of the standing order exacerbated the patient's condition; and

  - Whether a standing order has been 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.

- An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter. The hospital must ensure each standing order that has been executed is dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient. Another practitioner who is responsible for the care of the patient may date, time and authenticate the standing order

instead of the ordering practitioner, but only if the other practitioner is acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules and regulations.

The hospital's standing orders policies and procedures must specify the process whereby the responsible practitioner, or another authorized practitioner, acknowledges and authenticates the initiation of each standing order after the fact, with the exception of standing orders for influenza and pneumococcal vaccines, which do not require such authentication. Further, the responsible practitioner must be able to modify, cancel, void or decline to authenticate orders that were not medically necessary in a particular situation. The medical record must reflect the physician's actions to modify, cancel, void or refusal to authenticate a standing order that the physician determined was not medically necessary. (76 FR 65896, October 24, 2011)

Survey Procedures §482.24(c)(3)

- Ask the hospital's medical staff and its nursing and pharmacy leadership whether standing orders are used. If yes, ask them to describe how a standing order is developed and monitored, and their role in the process.

- Ask to see an example of one or more standing orders, including documentation on the development of the order, including:

    - Reference to the evidence-based national guidelines that support it;

    - Participation of medical staff and nursing and pharmacy leadership in the review and approval of the standing order;

    - Description of the protocol to be followed when initiating the execution of the order, including description of the roles and responsibilities of various types of staff;

    - Description of the process for authenticating the order's initiation by the practitioner responsible for the care of the patient, or another authorized practitioner;

    - Evidence of training of personnel on the order's protocol; and

    - Evidence of periodic evaluation and, if needed, modification of the standing order, including whether the order remains consistent with current evidence-based national guidelines, staff adherence to the protocol for initiation and execution, and whether there have been any preventable adverse events associated with the order.

- Ask staff providing clinical services in areas of the hospital where standing orders might be typically used, including but not limited to, the emergency department, labor and delivery units, and inpatient units, whether standing orders are used. If they say yes, ask them:

    - To describe a typical scenario where a standing order would be used, and what they would do in that case.

    - For a copy of the protocol for that standing order. Does their description conform to the protocol?

- Review a sample of medical records of patients where a nurse-initiated standing order was used and verify that the order was documented and authenticated by a

practitioner responsible for the care of the patient.