American Hospital Association

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Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., 314G
Washington, DC 20201

Dear Mr. Weems:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) national coverage analyses of surgery on the wrong patient, wrong surgery on the patient and surgery on the wrong body part.

Every day, America's hospitals strive to provide the best care possible to patients through the use of sophisticated systems, information technology and care protocols. Hospitals continue to implement preventive systems and make changes to keep patients safe from harm. Unfortunately, human error can and does occur. On the rare occasion when a serious, adverse event that could have been prevented occurs, hospitals have undertaken a variety of strategies to support the injured patient and his or her family, including not charging the patient for the costs of care related to the event.

Recently, the AHA adopted a set of principles articulating when hospitals would not expect payment from patients or their insurers or employers for care related to preventable serious, adverse events. The principles can assist hospitals as they refine or develop their own policies for their communities. The principles, which specifically describe the types of errors for which hospitals should forego payment, are:

1. **The error or event must be preventable.** Where there are practices that are effective in preventing a particular harm from occurring, and they could have been implemented by the hospital, the error or event would be considered preventable.

2. **The error or event must be within the control of the hospital.** Errors that may have occurred in the manufacture of drugs, devices or equipment, well before the materials reached a hospital's doors, are examples of events that would be outside of the hospital's control.

3. **The error or event must be the result of a mistake made in the hospital.** These include errors in which a hospital failed to successfully carry out a practice that would have, in all probability, prevented harm to the patient.

4. **The error or event must result in significant harm.** The list of events should be limited to those that yield very serious results.

5. **The error or event must be clearly and precisely defined in advance.** A great level of specificity is required to identify events that could result in a hospital foregoing payment.

As CMS begins deliberations on a national coverage determination for the three surgical conditions, the agency will have to consider several questions, including:

- How are the events defined?
- How will accountability for the event be assigned?
- What costs or services should not be covered?

We urge CMS to reflect on these questions and thoroughly consider the complexities and subtleties that may arise over the issue of serious, adverse events.

CMS must thoughtfully and carefully define the events it includes under the national coverage determination. In those states that have initiated reporting of serious, adverse events, we have seen hospitals dig deeper and report more finely nuanced events as they gain experience with the reporting programs. Hospitals initially reported obvious wrong-site surgeries, such as surgeries on the wrong finger or knee, which are clearly the kind of events most think of when the term "wrong-site surgery" is used. These are the kind of events that would obviously meet our criteria and for which hospitals would not expect payment.

More recently, hospitals have begun to report more nuanced instances of radiation therapy that are off by fractions, removal of a lesion that is on the correct side but is not the correct lesion or procedures in which there are anatomical abnormalities that lead to an incorrect site. Much of the learning about serious, adverse events that has taken place from established reporting programs has come from these more nuanced instances. However, what is valuable for learning and quality improvement purposes may not always be appropriate for payment policy. CMS' coverage decisions should not stifle the reporting of these events.

Further, we urge CMS to develop strategies to address situations in which a potential wrong-site surgery was initiated, but then the procedure was corrected before harm could occur. For example, for a spinal procedure, the surgeon may start the procedure on the wrong level, i.e., with the skin incision, but then realize the error and readjust to the correct site, completing the

procedure successfully. In this instance, the correct procedure was performed. CMS will need to determine the definition of a wrong-site surgery by setting clear boundaries of what is and is not included.

Finally, because of the many nuances surrounding this issue, we recommend that CMS include in the national coverage determinations an appeals process for hospitals to petition any decisions that they believe were made inappropriately.

Thank you for this opportunity to comment. If you have any questions about these remarks, please contact me or Nancy Foster, vice president for quality and patient safety, at (202) 626-2337 or nfoster@aha.org.

Sincerely,

Rick Pollack
Executive Vice President