One area that continues to cause concern for the home care industry and respiratory therapists across the country is the use of oximetry technology in the home care setting and its relation to the Joint Commission on Accreditation of Healthcare Organizations survey process. Our need to comply with regulatory requirements, along with the importance of the accreditation process and its potential ramifications, has made this an area that requires additional attention.

The Joint Commission’s mission is to improve the quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations. As a byproduct of that mission, the Joint Commission is sometimes placed in the position of identifying and surveying practices that are at odds with the preferences of various health care providers (a natural predicament of their role). Home oximetry testing is a prime example of this phenomenon.

The issue relates primarily to how the Joint Commission standards apply to a home care provider that performs an oximetry reading in the home. The fol-

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**Take-Home Notes**

- The FDA requires that a physician’s order be obtained before using a pulse oximeter on a patient because it is considered a prescription device.
- The performance of the oximeter makes a provider eligible for the clinical respiratory services and standards compliance.
- There are expectations from both the patient and the ordering physician related to the test’s performance. In short, it becomes part of the patient’s plan of care.
lowing frequently asked questions may help clarify the situations that have arisen over the use of pulse oximetry.

**Does a home care provider need a physician’s order to obtain an oximetry reading from a home care patient?**

Yes. This is true whether you obtain one or 1,000 oximetry values because the U.S. Food and Drug Administration (FDA) requires that a physician’s order be obtained for the use of an oximeter on a patient. This requirement has been verified by the American Association for Respiratory Care and the Joint Commission, and is also included in the Joint Commission Lab Accreditation Program; its position was spelled out in a 1997 clarification that stated:

“There are several factors in home care that support the involvement of a physician in the use of pulse oximetry. For example, the procedure is not without risk to the patient, the indications and contraindications for use need to be clearly related to the assessment and monitoring needs of the patients, staff need to be trained in the use and interpretation of the findings and need to be available (to the physician), and the results of the oximetry need to be validated to overcome any device limitations.”

The FDA has determined that pulse oximeters are prescription devices and should not be utilized without a physician’s order. The FDA cannot extend into the practice of medicine, but a physician does need to make a determination as to how this device is to be used — hence, the need for a physician’s order.

It is also important to note that the order requirement is not limited to the accredited home care organization. The rules apply to all providers of oximetry in the home. The difference is simply that accredited organizations have requested an outside organization to come in and observe their activities related to, among other things, compliance with various rules, regulations, and standards. I have no doubt that there are unaccredited organizations that do not follow the rules and, thus, have a competitive advantage over those that do. This does not, however, relieve the professional health care provider of his or her responsibility to be aware of and follow appropriate practices and laws.

The confusion over the issue can probably be attributed to the fact that since the initiation of the Joint Commission home care accreditation process, there has been a change in the interpretation of the standards as they relate to this issue, and thus a change in onsite survey activities. This means that some organizations and personnel have practical experience that leaves them with the impression that orders are not necessarily required. Remember, the Joint Commission states that clarifications of standards are subject to revision at any time and may be superseded, revised, or rescinded.

Having to obtain a physician’s order is unpopular, as it adds work for both the provider and the physician. In addition, not everyone follows the rules (or is accredited), and thus compliant organizations are sometimes placed at a competitive disadvantage.

On the surface, oximetry appears to be a simple procedure, arguably equitable to other activities (such as blood pressure or diabetic monitoring) with less demanding requirements.

**Does the performance of oximetry automatically subject the accredited organization to survey under the clinical respiratory therapy standards?**

The answer is “maybe,” depending on the circumstances.

For example, the answer is “no” if the request is a one-time event and the person performing the oximetry is not expected to interpret or react to the value obtained.

The answer is also “no” if the person is not expected to perform any function other than the recording/reporting of the patient’s saturation. In this instance, it can be considered a part of the equipment management. However, if the physician were to order a second, independent “one-time” oximetry, it would raise a red flag as to the status of equipment management versus clinical services. If the physician were to order a third, it would be clear that the intent was to perform ongoing monitoring, and the patient would be considered to be in clinical services.
The performance of the test places the organization under the home health or clinical respiratory service standards, if the order:
• Requests multiple, ongoing assessment, or
• Requires the person performing the oximetry to evaluate or somehow assess the values obtained. In this situation, all applicable Joint Commission standards must be met. It was spelled out in the same 1997 clarification on oximetry, which stated: “The performance of the oximetry makes an organization eligible for the clinical respiratory services and standards compliance.”

The rationale behind this position relates to the fact that a professional performs the test, the test is related to the patient’s medical condition, and the goal is to improve and measure the patient’s condition and/or therapy. There are expectations from both the patient and the ordering physician related to the test’s performance. In short, it becomes part of the patient’s plan of care. Recommendations related to noncompliance are addressed in the Joint Commission manual under the standards related to physician’s orders (currently TX.2 and TX.2.1).

**What is the appropriate response to these requirements?**

This should be determined by each organization. However, there are several acceptable ways to handle the situation:
• Elect to remove home oximetry from your list of services. (Not recommended, but it does resolve any confusion.)
• Provide the service and obtain a physician’s order for each oximetry reading performed. In the event that multiple readings are ordered, their frequency or the circumstances requiring their performance should be clearly spelled out. Many providers routinely request this order at the time of the oxygen setup as part of their intake routine.
• A physician could provide an “assessment protocol” that lists the expected activities (including oximetry) associated with your services. In the event that the physician orders your services, he or she could write an order requesting that the protocol be implemented. Note that this assessment protocol should indicate the specific circumstances under which an oximetry would be performed, and it should be understood and followed by all appropriate staff members. PRN orders, without an acceptable protocol, would not be acceptable.
• If the home care company is a Medicare-certified hospice, the medical director could write standing orders for oximetry (as well as other services) that supersedes the patient’s physician’s orders.

**Who is qualified to perform oximetry?**

In the case of equipment management only, a “trained” individual (including nonprofessionals) may perform the test. However, a “see one, do one” mentality would not meet the intent of the standards.

Further, the individual would need to have documented training by a “qualified health care professional.” Finally, remember that surveyors would be acting well within their area of responsibility to question this individual regarding any technical aspects of oximetry.

In the case of clinical services, the expectations increase, as the individual must be a health care “professional.” For the purpose of meeting these standards, this could be defined as “a qualified respiratory therapist or other health care professional who has the documented equivalent in education, training, and/or experience; and who meets current legal requirements of licensure or registration.”

It is important to note that anyone performing an oximetry test must be properly trained in the equipment’s use. There is great opportunity for disservice to the patient and physician in the inappropriate use of the oximeter. Its perceived simplicity works against it, as there is an impression that “anyone” can use it and obtain accurate results. The use of appropriately trained personnel to perform respiratory-related procedures is an ongoing concern of the American Association for Respiratory Care because the AARC has always been a patient advocate. Its members are concerned about quality of care and the competency of those providing respiratory care.

In a related matter, the Joint Commission has witnessed an
increase in the number of incidents where non-qualified personnel (unlicensed or without the proper scope of practice) have performed tasks requiring specific qualifications. An organization may receive a recommendation regarding a non-qualified staff member (HR.3.1 in the Joint Commission’s accreditation manual) if it is determined that an individual was not appropriately trained. If oximetry were specifically limited to a licensed individual, the identification of these activities (even one occurrence) would place an organization in the state of preliminary non-accreditation. The question of qualifications is often determined by individual states, and provider organizations must know the requirements within their own states.

The Joint Commission is available to answer questions related to its standards. Home Care Accreditation Services may be reached by calling: (630) 792-5754.

EDITOR’S NOTE
This article originally appeared in the AARC Home Care Section Bulletin.

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