## **PULSE OXIMETRY** IN THE HOME





Q: Is a physician's order required for pulse oximetry in the home?



## CMS RESPONSE PER NAHC:

"Thank you for your recent question relating to the need for physician's orders for pulse oximetry in the home. I have researched the issue, including consultation with many clinical practitioners (physicians, nurse practitioners, registered nurses and therapists) at CMS. The consensus agrees that a physician's order for pulse oximetry should be required for home health clinicians in home health. Our primary concern in survey and certification is the health and safety of the patient."

"While we agree that pulse oximetry is not invasive, we recognize that not all clinicians have the same level of training and understanding about the procedure. When the home health clinician is required to obtain orders for pulse oximetry, the clinician should also obtain parameters to be reported to the physician. Failure to report changes in the patient's condition that might require a change in the plan of care continues to be of the most frequent deficiencies on HHA surveys."

Centers for Medicare & Medicaid Services Survey and Certification Group | March, 2013



## FDA PERSPECTIVE:

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 oximetry makes a provider eligible for the clinical respiratory services and standards of 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. As it can drive additional orders etc...

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.

Guidance for Industry and Food and Drug Administration staff Pulse Oximeters- Premarker- Notification Submissions [510(K)S] | March, 2013



NOTE: Home Health and Hospice agencies should also obtain a physician's order for pulse oximetry along with parameters to be reported to the physician.