December 12, 2016

Q: We have a number of facilities that surveyors have been asking to see black box warning information on both care plans and consents. Checking to see how specific this information needs to be on both, as am not able to locate this information in the regulations.

A: The regulations do not specifically state how detailed the information must be on the care plans and the consents. Interpretive guidance under F329 indicates that “the FDA may require manufacturers to place statements about serious problems in a prominently displayed box (so-called boxed or “black box” warnings), which indicates a need to **closely evaluate and monitor the potential benefits and risks of that medication.**”

F155 addresses the resident’s right to refuse treatment and the facility’s obligation to inform the resident of this right. Interpretive guidance under F155 indicates that: “the facility is required to **establish, maintain, and implement written policies and procedures** regarding residents’ rights to formulate an advance directive, refuse medical or surgical treatment and right to refuse to participate in experimental research. In addition, the facility is responsible for ensuring that **staff follows policies and procedures.**”

The facility’s policies and procedures delineate the various steps necessary to promote and implement these rights, including, for example:

- Defining and clarifying medical issues and presenting the information regarding relevant health care issues to the resident or his/her legal representative, as appropriate;
- Identifying, clarifying, and periodically reviewing, as part of the comprehensive care planning process, the existing care instructions and whether the resident wishes to change or continue these instructions; …”

Having said this, the facility should establish and follow their own policies/procedures for ensuring that the resident is informed and that all staff is aware of the resident’s choices, and that the informed consent and/or care plan is as detailed as required for that particular resident.