Compliance and ethics program (§483.85). Facilities will be required to have a compliance and ethics program with written standards, and policies and procedures that can reduce the prospect of criminal, civil and administrative violations.

Training requirements (§483.95). A section on training will require facilities to develop, implement, and maintain an effective training program for new and existing staff, contracted individuals, and volunteers.

CMS estimated that the projected estimated cost of the final rule will be $831 million in the first year, and $736 million annually thereafter. The average facility costs are estimated to be $62,900 the first year, and $55,000 per year for subsequent years.

The Society and many other stakeholders submitted comments to the proposed rule last summer, and CMS clearly responded to these by removing some of the original regulations, including a requirement that every resident be evaluated by a physician or non-physician practitioner before any transfer to the emergency department.

Caring will provide more information on the final rule in future issues. The Society also will post a webinar on this topic sometime in November. For more information, go to https://federalregister.gov/d/2016-23503.

Carey Cowles is the managing editor of *Caring for the Ages*.

FDA: New Boxed Warning on Combining Opioids, Benzodiazepines

Sharon Worcester

Labeling for prescription opioid pain or cough medicines and benzodiazepines will now carry the strongest available warning regarding serious side effects and death associated with their combined use, according to the Food and Drug Administration.

The new boxed warnings urge health care professionals to limit prescribing opioid pain medicines with benzodiazepines or other central nervous system depressants only to patients for whom alternative treatment options are inadequate, and to limit dosages and treatment duration to the minimum possible while achieving the desired clinical effect.

Opioids will include a warning regarding prescribing with benzodiazepines and other central nervous system depressants, including alcohol. Benzodiazepines will include a warning regarding prescribing with opioids.

The action comes amid ongoing efforts to address an epidemic of opioid addiction across the United States, and in response to a first-of-its-kind "citizen petition" calling for the boxed warnings.

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EDITOR'S NOTE

Most of us should know the potentiation of respiratory depression with concomitant administration of benzodiazepines and opioids. Although the risk of clinically significant respiratory depression with pure opioids (e.g., morphine) has been overblown and is rare in clinical practice, mixing opioids with benzos is known to increase the risk of serious respiratory compromise. The new boxed warning won't mean we can't use them together, but we can expect to get the usual communications from our consultant pharmacists when we do. Benzodiazepines —- although most of us still prescribe them at times — are pretty risky and not that effective for many conditions they're commonly used for, most notably dementia-related agitation. They disinhibit behavior and increase the risk of falls, among other adverse effects. The FDA is taking an appropriate step to remind us not to combine opioids and benzos indiscriminately. As always, let's keep our individual patients' situations always at the forefront of decision making.

—Karl Steinberg, MD, CMD, HMDC
Editor in Chief