A report from the Department of Health and Human Services Office of Inspector General (OIG) raises questions about Medicare’s monitoring of hospital preparation of compounded sterile products (CSPs) and hospital purchases of CSPs from outside vendors. Medicare essentially outsources that monitoring to hospital accreditation certification organizations, which have very limited pharmacy expertise. Almost all hospitals compound sterile drugs in-house and, in addition, contract with outside suppliers that may provide CSPs at critical times, particularly during drug shortages. The OIG report raises issues (albeit indirectly) about the care with which in-patient pharmacies prepare CSPs and monitor outside vendors.

Eric Kastango, MBA, RPh, FASHP, President and CEO of Clinical IQ, LLC, believes the OIG report understates hospital compounding shortcomings. Kastango is a leading authority on hospital sterile compounding, having consulted with hospitals hundreds of times. His company has done an annual survey for the past four years on hospital compliance with U.S. Pharmaceutical Convention (USP) General Chapter 797, Pharmaceutical Compounding—Sterile Preparations. The 2014 survey showed that, in aggregate, the 412 self-reporting hospitals complied with 81.9% of USP 797. “My impression, based on hundreds of visits to hospitals, is that people tend to give themselves too much credit,” Kastango says. “So I believe the real aggregate compliance level is 10 or 20 percentage points below 81.9%. Even a score of 82% is not that great. It should be greater than 95%.”

Kastango says Medicare accreditors, mainly The Joint Commission, do not survey based on USP 797 but use their own standards, which may or may not include USP 797. He notes that perhaps 25 states use USP 797 as the basis for state inspections. An article Kastango co-authored in the October 2014 issue of Pharmacy Purchasing & Products stated: “The FDA continues to be uncomfortable with many aspects of pharmacy compounding; in addition, the FDA believes that 797 does not impose sufficient quality standards.”

The report comes as the Food and Drug Administration (FDA) is trying to promote its new inspection and regulatory program—called 503B—of large bulk compounders. They will be labeled “outsourcing facilities” under the 503B program, which Congress established and the FDA is implementing. The FDA’s stamp of approval as a 503B outsourcing facility gives a bulk compounder marketing cachet and presumed legitimacy in the eyes of hospital pharmacies.

However, the FDA list of 48 “outsourcing facilities” that have registered with it includes few that the agency has inspected in the past year. Nearly all the facilities that have been inspected since registering in the 503B program starting in January 2014 have received an FDA Form 483 listing transgressions. The FDA website lists the investigations of those pharmacies as “open.” According to the website, “open” means the FDA has not determined whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include warning letters, seizures, or injunctions.

Allen J. Vaida, PharmD, FASHP, Executive Vice President of the Institute for Safe Medication Practices, gives the 48 503B pharmacies credit “for at least taking the leap to allow the FDA to walk in and inspect them.” He considers the Form 483s to be, in many cases, “a good thing,” giving those pharmacies guidance on what they must do to improve the quality and safety of their manufacturing.

The OIG report depicts accrediting agencies with little on-the-spot pharmacy knowledge, lacking pharmacists as part of the inspection team, and often failing to check important aspects of a hospital’s safety protocols related to CSP formulation. Dr. Vaida agrees. He notes that hospitals can obtain tool kits allowing them to do gap analyses on their own, or they can hire consultants to do an audit.

The OIG report identified 55 recommended practices for the oversight of CSP preparation and use in acute-care hospitals and asked the accrediting organizations whether they checked to see if those 55 practices were in place in every hospital they visited. However, the OIG did not evaluate the validity of hospital surveys conducted by the five oversight entities. Its review relied on self-reported data from the oversight entities.

Only two oversight entities employ pharmacists as hospital surveyors; neither includes a pharmacist on every survey team. Two oversight entities do not provide any compounding-specific training to surveyors. At the other three oversight entities, compounding-specific training ranges from observation of compounding during training surveys to an online training module dedicated to USP 797.

“We didn’t have major issues with this report,” Dr. Vaida says. “But is it the end-all? No, it is not.”

The report has shortcomings. That said, hospital and bulk compounding are undergoing improvements. It would have been nice, however, if the OIG report had measured how far compounding has come since the New England Compounding Center fiasco, and how far it has to go.

REFERENCES