

Report on Medicare Compliance Volume 30, Number 1. January 11, 2021

Outlook 2021: COVID-19 Will Shape Compliance Agenda; Other Challenges Also Loom Large

By Nina Youngstrom

The COVID-19 pandemic will continue to set the agenda in compliance and enforcement in 2021 without swallowing it whole. It will be the year of duality, as the virus rages on but vaccines put the nation on the road to recovery, as auditors and enforcers pursue both COVID-19 abuses and more familiar types of overpayments and fraud, and as compliance professionals who are working remotely put one foot back in the office, which may be smaller as some hospitals reduce their real estate footprint. Wherever they are, compliance professionals will have a lot on their plate. New regulations take effect that end the inpatient-only (IPO) list in slow motion and change the Stark Law, and there will be HHS Office of Inspector General (OIG) audits of COVID-19 MS-DRGs, telehealth services and Provider Relief Fund (PRF) money, to name a few risk areas. Compliance officers also should keep an eye on recent directions in False Claims Act enforcement (see story, p. 1).^[1]

“What a long, strange trip it is,” said attorney Andy Ruskin, with K&L Gates in Washington, D.C. “For the next six months, I don’t think there will be any sense of normalcy.” The wild card for hospitals, he said, is how they will fare under the incoming administration of Joseph R. Biden Jr., who will be sworn in as president Jan. 20 and bring new leadership to the Department of Justice, HHS and CMS. Ruskin worries hospitals are in for trouble unless Biden reverses Trump administration payment policies on site neutrality, 340B drug discounts and most-favored nation drug pricing. The first two have been upheld by federal courts, but the U.S. District Court for the District of Maryland on Dec. 23 granted a 14-day restraining order^[2] on CMS’s most-favored nation rule while the court determines whether it’s legal. The rule limits Part B payments for the 50 highest-cost drugs to no more than the lowest prices paid to manufacturers in similar countries. “The policies are totally without any basis,” Ruskin contended.

Another big unknown is whether the U.S. Supreme Court will strike down the Affordable Care Act (ACA) in its entirety. The ACA has a multitude of compliance and enforcement provisions, such as the Medicare 60-day overpayment refund rule and CMS’s Self-Referral Disclosure Protocol for actual or potential Stark violations, said attorney Larry Vernaglia, with Foley & Lardner in Boston. In the eyes of some lawyers, the high court, which is expected to decide the case by June, at most will shoot down the individual mandate and leave the rest of the law intact, he said.

This year also will test the competence of compliance officers, said former federal prosecutor Robert Trusiak, an attorney in Buffalo, New York. With COVID-19-driven budget woes translating into staffing cuts at some facilities, compliance may be shorthanded or asked to help out in other departments. “‘Less is more’ is a management slogan. ‘Less is less’ is the truth,” he said. The board should be made aware if the compliance team is doing less, Trusiak said. “A missed physician contract or lease is often the product of staffing changes,” he noted. “I can’t tell you the exact date and time you will get in an accident, but I can tell you that you will have an accident.”

For fully staffed compliance departments, it will still be “a rock and roll year,” said Kim Danehower, corporate compliance officer of Baptist Memorial Health Care Corp. in Memphis, Tennessee. There are more telehealth

services in the 2021 Medicare Physician Fee Schedule (MPFS)^[3] rule, while 266 musculoskeletal procedures were pushed off the IPO list on Jan. 1. These and other changes must be incorporated and monitored against the backdrop of the pandemic, when fatigue is at an all-time high, which makes her nervous about the potential for mistakes. “I have a good feeling about my organization, but people are tired. There’s a nursing shortage. People are sick and quarantined—the fatigue of the whole pandemic is a compliance nightmare,” Danehower said. “There is room for error just because so much is piled on top of this area.”

Her compliance program, like many others, has been able to operate remotely and that will continue this year, although it’s not always ideal. For example, “I have seen outstanding virtual training and not so outstanding,” Danehower said. Employees must be able to ask questions and reach out to compliance, as emphasized in the Department of Justice’s June 2020 revised guidance on effective compliance programs, *Evaluation of Corporate Compliance Programs*. Whether everything can be incorporated into a hybrid workplace remains to be seen.

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